

**Competition Act 1998 and**

**Treaty on the Functioning of the European Union**

**Decision of the Office of Fair Trading:**

**Abuse of a dominant position by Reckitt Benckiser Healthcare (UK)  
Limited and Reckitt Benckiser Group plc**

**Decision No. CA98/02/2011**

**Case CE/8931/08**

**12 April 2011**

**OFT1368**

Please note that [...] indicates figures or text which have been deleted or replaced in ranges for reasons of commercial confidentiality.

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# **1 EXECUTIVE SUMMARY**

## **A. Introduction**

- 1.1. By this decision, of which Annexes A to C form an integral part, (this Decision), the Office of Fair Trading (the OFT) has concluded that Reckitt Benckiser Healthcare (UK) Limited and Reckitt Benckiser Group plc (together 'RB') have infringed the prohibition imposed by section 18(1) (the Chapter II prohibition) of the Competition Act 1998 (the Act) and Article 102 of the Treaty on the Functioning of the European Union (Article 102 TFEU). The Chapter II prohibition provides that any conduct on the part of one or more undertakings that amounts to the abuse of a dominant position in a market is prohibited if it may affect trade within the United Kingdom. Article 102 TFEU provides that any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States.

## **B. Summary of the infringement and action by the OFT**

- 1.2. In this Decision, the OFT sets out the evidence which it relies on to come to the finding that by withdrawing and de-listing NHS presentation packs of Gaviscon Original Liquid (GL) in June 2005 (the Withdrawal), RB abused a dominant position in the market for the supply of alginates and antacids by prescription in the UK. A summary of the OFT's finding is provided below.
- 1.3. Gaviscon products are alginate based compounds that are used to treat acid reflux, gastro-oesophageal reflux disease (GORD) and dyspepsia by forming a raft over the contents of the stomach and preventing acid reflux into the oesophagus. RB supplies Gaviscon products in packs for prescription and over the counter (OTC) sales channels. The OFT considers the relevant market to be no wider

than the supply of alginates and antacids in the prescription channel. RB retained a market share of over 80 per cent between 2004 and 2008 and the OFT considers that RB held a dominant position in the relevant market (whether or not antacids are included in any relevant market definition) at least between 2004 and 2008.

- 1.4. GL was launched in 1977 and its patent expired in 1997. Gaviscon Advance Liquid (GA) was launched in 1997 and remains patent protected until 2016.
- 1.5. Between 1997 and 2005, both GL and GA were available in the OTC and prescription channels. However, since the Withdrawal, only GA and OTC packs of GL have been available in the prescription channel.
- 1.6. The Withdrawal took place in June 2005, in advance of the publication of a generic name relevant to GL. Before the Withdrawal, GL was RB's leading Gaviscon product in the prescription channel and accounted for 49 per cent (by value) of its Gaviscon sales to the NHS. RB's second most popular product, GA, accounted for 35 per cent of its Gaviscon sales in the prescription channel.
- 1.7. The publication of a generic name is necessary to facilitate full generic competition in relation to prescription medicines. Where no generic name exists, GPs write prescriptions that refer to the brand name of their chosen product (a 'closed' script). On receipt of a closed script, pharmacies are obliged to dispense the branded product prescribed. As pharmacies are unable to choose between products when presented with a closed script, pharmaceutical manufacturers are unable to use price as a means of persuading pharmacies to purchase their products, and their incentive to offer attractive prices to pharmacists is therefore limited. To generate sales of their products, pharmaceutical manufacturers must instead invest in marketing ('detailing') activities that are designed to encourage GPs to prescribe their medicines.

- 1.8. Where a generic name exists, GPs can write prescriptions that refer to that name (an 'open' script), and on receipt of an open script pharmacies may choose to dispense any product that is described by that generic name. This choice fosters price competition between pharmaceutical manufacturers, which have a strong incentive to compete on price to persuade pharmacies to choose to dispense their products. Where a pharmaceutical manufacturer can generate sales in this way, it has less need or incentive to invest in detailing activities.
- 1.9. In advance of the Withdrawal, RB was anticipating that a generic name relevant to GL would be published towards the end of 2005 or early in 2006.
- 1.10. The OFT finds that RB's decision to withdraw and de-list NHS packs of GL was motivated by a desire to hinder the development of full generic competition following the publication of a generic name relevant to GL. RB's internal documents indicate that RB was seeking to ensure that GPs would be unable to identify prescription packs of Gaviscon products against which open scripts could be issued and against which pharmacies could choose to dispense a Gaviscon product or an equivalent alternative. RB's internal documents reveal that it considered that it would be able to persuade many GPs and patients to switch to its patent protected product, GA, which would not be covered by the generic name corresponding to GL and therefore not subject to full generic competition.
- 1.11. RB's internal documents also reveal that its view was that, were it not for the prospect of using the Withdrawal to hinder the development of full generic competition to its Gaviscon portfolio, the Withdrawal would have been loss-making and not therefore a commercially rational strategy. On carrying out the Withdrawal, RB expected to suffer decreases in its Gaviscon revenues and profitability in the prescription channel as a result of having withdrawn its leading product. However, RB considered that carrying out the Withdrawal was nevertheless desirable as it

anticipated that, by hindering the development of full generic competition, it could maintain much higher prices and retain a higher market share than would have been possible had NHS packs of GL been retained.

- 1.12. The Withdrawal took place in the context of a long term intention to delay the onset of full generic competition.<sup>1</sup> RB's internal documents indicate that, over a number of years, RB had been considering actions that may delay or inhibit the publication of a generic name corresponding to GL.
- 1.13. The OFT therefore considers that RB's Withdrawal was motivated by a desire to hinder the development of full generic competition, and cannot be regarded as 'competition on the merits' or as 'normal competition'.
- 1.14. The OFT has assessed the effect on competition that it was reasonable to expect at the time of the Withdrawal. The OFT finds that RB foresaw that the effect of the Withdrawal would be to hinder the development of full generic competition in the relevant market by ensuring that pharmacists were denied a choice of product on receipt of prescriptions relevant to Gaviscon products. RB's internal documents indicate that, had GL NHS packs remained available, RB anticipated that it would have lost significant market share and would have needed to offer significant discounts to pharmacies in order to preserve some sales in respect of a significant volume of open scripts. The OFT also finds that the forecasts of RB's primary competitor, Pinewood Healthcare Limited, broadly support RB's analysis.
- 1.15. The OFT finds that, at the time of the Withdrawal, it was reasonable to expect that the Withdrawal would restrict competition, hindering the development of the full generic competition that would have been expected to emerge had NHS

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<sup>1</sup> See paragraphs 2.17 to 2.18 below.

packs of GL been retained following the publication of the generic name for GL.

- 1.16. The OFT therefore finds that the Withdrawal tended to restrict competition or was capable of having that effect.
- 1.17. The OFT considers that the market developments observed since the Withdrawal are not inconsistent with its finding that the Withdrawal tended to restrict competition or was capable of having that effect.
- 1.18. The OFT therefore finds that RB held a dominant position in the market for the supply of alginates and antacids in the NHS prescription channel and that by withdrawing and de-listing NHS packs of GL in June 2005, RB abused its dominant position.
- 1.19. The Act provides that the OFT may impose on an undertaking which has intentionally or negligently committed an infringement of the Chapter II prohibition and/or Article 102 TFEU, a financial penalty and/or directions to bring the infringement to an end.<sup>2</sup> The OFT is imposing a financial penalty of £10.2 million, reduced from £12 million to reflect RB's admission and decision to co-operate as part of an early resolution agreement with the OFT.<sup>3</sup> RB has agreed to pay this penalty as part of that agreement.

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<sup>2</sup> Sections 33 and 36 of the Act relate to directions and penalties respectively.

<sup>3</sup> The early resolution agreement was signed on 14 October 2010. The text of the ERA is provided at Annexe A of this Decision.

## 2 THE FACTS

### A. Introduction

- 2.1. On 7 March 2008, the OFT was made aware of allegations that RB had abused a dominant market position by seeking to delay and hinder the development of full generic competition to its Gaviscon portfolio in the prescription channel. These allegations were the subject of a BBC Newsnight television programme, based largely on evidence provided by a 'whistleblower'.
- 2.2. Following a preliminary investigation, on 20 November 2008 the OFT launched a formal investigation into these allegations. The OFT considered there to be reasonable grounds to suspect that:
  - RB held a dominant position in relation to the market for the UK supply of alginates and antacids by prescription, and
  - RB abused that dominant position through its conduct, including:
    - actions taken between 2000 and 2006 that delayed the regulatory processes relevant to the introduction of a generic name for GL and equivalent products (the Delay Allegation) and
    - withdrawing and de-listing NHS presentation packs of GL in 2005.
- 2.3. The investigation has subsequently focused on the Withdrawal.
- 2.4. This Part sets out the following:
  - Section B describes the relevant undertaking and the other parties that are relevant to the OFT's investigation.
  - Section C describes the OFT's investigation, including its key stages and the approach to information gathering.

- Section D describes the products that are the subject of this investigation, namely the Gaviscon portfolio including GA and GL, as well as alginate products produced by other manufacturers, such as Acidex, Peptac, Gastracote and Algicon.
- Section E provides an outline of the different treatments for dyspepsia, acid reflux and GORD. Relevant treatments include alginates such as Gaviscon, antacids, proton pump inhibitors and H2 receptor antagonists. The modes of action and therapeutic uses of these treatments are outlined.
- Section F provides an outline of the sales and price trends that have been observed in relation to the different treatments for dyspepsia, acid reflux and GORD.
- Section G describes the process and benefits of generic competition. In particular, the Section provides an overview of the lifecycle of a medicine, highlighting the stage at which generic competition would typically emerge. The different forms of generic competition are then outlined, followed by a description of the potential benefits of full generic competition.
- Section H describes the various aspects of the regulatory framework that are relevant to competition in the sector, in particular those relating to the publication of generic names, GP prescribing, pharmacy dispensing, medicines pricing and product withdrawals.
- Section I presents an overview of the events relevant to the publication of a generic name for GL, including extracts from certain of RB's internal documents that are relevant to the intentions behind some of its actions between 2000 and 2006 in relation to the process for developing and publishing a generic name relevant to GL.
- Section J describes the events and discussions that were relevant to RB's decision to withdraw and de-list GL NHS

packs. It also describes the processes that RB undertook and the representations it made to stakeholders around the time of the Withdrawal.

## **B. The parties**

### **i) The undertaking**

2.5. The legal entity directly engaged in the alleged conduct that is the subject of this Decision was Reckitt Benckiser Healthcare (UK) Limited.<sup>4</sup> Reckitt Benckiser Healthcare (UK) Limited is a wholly owned subsidiary of Reckitt Benckiser Group plc. As set out at Part 3D below, the OFT is addressing this Decision to Reckitt Benckiser Group plc and Reckitt Benckiser Healthcare (UK) Limited as it attributes liability, on a joint and several basis, to both the parent and the subsidiary for the infringement attributed to Reckitt Benckiser Healthcare (UK) Limited and for the resulting financial penalty that the OFT imposes. The registered address of both entities is 103-105 Bath Road, Slough, Berkshire, SL1 3UH, UK.

2.6. RB is a global producer of branded products in the health and personal care, surface care, fabric care, dishwashing, homecare, pest control and food sectors. RB's key brands in the healthcare sector include Gaviscon, Nurofen, Strepsils, Suboxone, Durex and Scholl.<sup>5</sup> Major household product brands produced by RB include Cillit Bang, Lysol, Harpic, Calgon, Vanish, Finish and Airwick.

2.7. Reckitt Benckiser Group plc's turnover (operating profit) in the year ending 31 December 2009 was £7,753 million (£1,891 million) and in the year ending 31 December 2008 was £6,563 million

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<sup>4</sup> The respondent to the OFT's initial Notice under section 26 of the Competition Act 1998 ('OFT section 26 Notice'), addressed to 'Reckitt Benckiser' was Reckitt Benckiser Healthcare (UK) Limited. (Covering letter to RB submission dated 12 December 2008 in response to OFT section 26 Notice dated 28 November 2008 (OFT File 2, document 9)).

<sup>5</sup> RB obtained the latter two brands when it acquired SSL International in July 2010.



(£1,505 million).<sup>6</sup> Reckitt Benckiser Healthcare (UK) Limited's turnover (operating profit) was £600.5 million (£328.8 million) in the year ending 31 December 2009 and £476.4 million (£246.2 million) in the year ending 31 December 2008.<sup>7</sup> Reckitt Benckiser Healthcare (UK) Limited's UK turnover was £253.2 million in the year ending 31 December 2009 and £245.7 million in the year ending 31 December 2008.<sup>8</sup>

**ii) Other relevant parties**

2.8. This sub-section describes the parties relevant to the conduct considered in this Decision. The relevant parties are described in alphabetical order.

2.9. **Britannia Pharmaceuticals Limited (Britannia)** was a division of Forum Bioscience Holdings Limited (Forum) and was the distributor of RB's prescription medicine portfolio, including Gaviscon, to the NHS from 1 September 2000 until 1 February 2009 (see paragraph 2.10 below). Britannia also provided expert advisory services to RB on the operation of the PPRS (see paragraphs 2.116 to 2.120 below).<sup>9</sup>

2.10. On 21 September 2007, Forum was acquired by Stada Arzneimittel AG (Stada), which is the parent company of Genus Pharmaceuticals Limited (Genus). Genus informed the OFT that, on

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<sup>6</sup> Reckitt Benckiser Group plc annual report and financial statements for the year ended 31 December 2009.

<sup>7</sup> Reckitt Benckiser Healthcare (UK) Limited Annual report and financial statements for the year ended 31 December 2009.

<sup>8</sup> Reckitt Benckiser Healthcare (UK) Limited Annual report and financial statements for the year ended 31 December 2009.

<sup>9</sup> Appendix 1 of letter dated 6 February 2009 from RB in response to OFT section 26 Notice dated 14 January 2009. (OFT file part 2, document 44.01)

28 September 2008 Stada sold much of Forum's business to the management of Forum, though it retained contracts relating to RB, including that which related to the distribution of Gaviscon. Genus also told the OFT that, on 1 February 2009 Britannia transferred all of its RB contracts (including that which relates to the distribution of Gaviscon) to Forum Healthcare Products Limited.<sup>10</sup>

2.11. **Pinewood Healthcare Limited (Pinewood)** is an Irish company which is active in the development and manufacture of generic medicines, with particular emphasis on liquids and creams. Pinewood manufactures Acidex, a generic equivalent of GL, which is marketed under the brand name 'Peptac'.<sup>11</sup>

2.12. **Teva UK Ltd (Teva)** is part of Teva Pharmaceutical Industries group which is a leading international manufacturer and distributor of generic medicines.<sup>12</sup> Teva has distributed Peptac for Pinewood since January 2006, when it acquired Ivax Corporation.<sup>13</sup>

## **C. The OFT's investigation**

### **i) The preliminary investigation**

2.13. As outlined above, the allegations which form the subject matter of this Decision were brought to the OFT's attention after they were featured on the BBC Newsnight programme on 7 March

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<sup>10</sup> Letter dated 3 July 2009 from Genus Pharmaceuticals in response to OFT section 26 Notice dated 4 June 2009. (OFT file part 4, document 1).

<sup>11</sup> Attachment to letter dated 9 March 2009 from Pinewood to OFT (OFT file part 2, document 67.02).

<sup>12</sup> [www.tevauk.com](http://www.tevauk.com)

<sup>13</sup> Peptac was previously distributed by Norton Healthcare Ltd, which had been owned by Ivax Corporation since 1990. Ivax Corporation was acquired by Teva on 6 January 2006. (Chronology enclosed with letter dated 9 March 2009 from Pinewood to OFT (OFT file part 2, document 67.02)).

2008. The OFT understands that this coverage was prompted by, and largely based on, materials supplied to it by a 'whistleblower'.

- 2.14. Following this, the OFT obtained from the BBC copies of some of the documents provided to it by the whistleblower. These constituted a collection of internal RB emails, memos and presentation slides. The BBC withheld some documents from the OFT in order to protect the identity of the whistleblower. The OFT then carried out a preliminary investigation into the relevant allegations during which it received voluntary, informal submissions and information from RB, Pinewood and the British Pharmacopoeia Commission (BPC).<sup>14</sup>
- 2.15. On 24 June 2008, the OFT met with RB to discuss issues regarding market definition in this case. On 3 July 2008, and in response to questions raised by the OFT at the meeting, RB provided a written submission to the OFT.
- 2.16. During July 2008, the OFT conducted short, informal telephone interviews with several GPs in order to ascertain some basic, general background information about prescribing practices.

**ii) The formal investigation**

- 2.17. Following the OFT's preliminary enquiries, on 20 November 2008 the OFT launched a formal investigation, under section 25 of the Act,<sup>15</sup> having established reasonable grounds for suspecting that:
- RB held a dominant position in relation to the market for the supply of alginates and antacids by prescription, and

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<sup>14</sup> The BPC is described at paragraphs 2.92 to 2.96 below.

<sup>15</sup> Sections 25(4) and 25(5) of the Act provide that the OFT may conduct an investigation where there are reasonable grounds for suspecting that the Chapter II prohibition and the prohibition in Article 102 TFEU respectively have been infringed.

- RB had abused that dominant position through its conduct, including:
  - actions taken between 1999 and 2006 that delayed the regulatory processes relevant to the introduction of a generic name for GL and equivalent products and
  - withdrawing and de-listing NHS packs of GL in 2005.

2.18. In September 2009, the OFT wrote to RB and other interested parties to inform them that it was focusing its investigation on the Withdrawal. Following consultation with interested parties, the OFT has decided to close its investigation into the Delay Allegation on the grounds of administrative priorities, and a closure letter was sent to the relevant parties on 12 April 2011, having made no finding as to the conduct's legality or otherwise.

2.19. During the course of the investigation the OFT sent formal Notices requiring documents and information under section 26<sup>16</sup> of the Act (section 26 Notices) to RB and to third parties.<sup>17</sup>

2.20. The OFT also received information and documents voluntarily submitted by the British National Formulary (BNF), the BBC, the BPC, the Department of Health (DH), and the whistleblower. The

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<sup>16</sup> Section 26 of the Act empowers the OFT, for the purposes of an investigation under section 25 of the Act, to require any person to produce to it a specified document, or to provide it with specified information, which it considers relates to any matter relevant to the investigation.

<sup>17</sup> Section 26 Notices were sent to RB in November 2008, and in January, February (supplementary Notice), May, July and November 2009. In May 2009 the OFT also sent a section 26 Notice to Pinewood. The OFT sent a section 26 Notice to Genus in June 2009.

OFT also held meetings with representatives of RB and third parties.<sup>18</sup>

- 2.21. In March 2009 the OFT commissioned the research company medeConnect, part of the Doctors.net.uk group, to carry out a survey of a representative sample of 700 GPs in the UK in order to understand further GPs prescribing practices in relation to GORD and dyspepsia.
- 2.22. The OFT issued a Statement of Objections (SO) to RB on 23 February 2010. RB provided a written response<sup>19</sup> on 7 June 2010 and attended an oral representations hearing at the OFT on 13 July 2010.
- 2.23. Following their requests, the OFT provided Pinewood, Teva and Mr M Carmody<sup>20</sup> with a non-confidential version of the SO on 14 July 2010. The OFT received Pinewood's representations on the OFT's proposed Directions on 30 July 2010 and on the remainder of the non-confidential SO on 25 August 2010 and 31 August 2010. Representations on the entire non-confidential version of the SO were received from Teva on 20 August 2010. Mr Carmody did not provide any representations to the OFT.

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<sup>18</sup> The OFT held meetings during the information gathering phase of the formal investigation with RB, the whistleblower and the BNF in January 2009 then with the BPC in April 2009, DH in June 2009 and Teva in October 2009. (The OFT was contacted by the whistleblower at the OFT's request. The OFT sent a letter to the whistleblower via a third party that was aware of the whistleblower's identity).

<sup>19</sup> As set out at paragraph 2.26 to 2.27 below, RB subsequently withdrew its written response and replaced it with a Statement of Material Factual Inaccuracies under the terms of an Early Resolution Agreement.

<sup>20</sup> Mr Carmody is an ex-member of the board of Pinewood. He was supplied with a non-confidential copy of the SO on the same basis as for the other applicants who were granted access: that they were able to materially assist the OFT in its investigation by testing the factual, legal or economic arguments set out in the SO.

- 2.24. On 10 August 2010 the OFT met with officials from DH to discuss the proposed Directions as set out in the SO.
- 2.25. On 24 August 2010 the OFT met with representatives of ScriptSwitch<sup>21</sup> to discuss issues raised by RB in its initial response to the Statement of Objections.
- 2.26. RB approached the OFT in relation to early resolution in July 2010, and discussions were subsequently held, culminating in the signing of an Early Resolution Agreement (ERA) on 14 October 2010.<sup>22</sup>
- 2.27. RB withdrew its original response to the Statement of Objections and on 28 October 2010 RB submitted a Statement of Material Factual Inaccuracies in the Statement of Objections dated 28 October 2010 (SMFI).
- 2.28. During the early resolution discussions, RB asked the OFT to confirm its position in relation to certain points that were relevant to the future progress of its investigation. In this regard, on 14 October 2010 the OFT wrote to RB to confirm that, having not sought to do so in the SO, the OFT was not minded to quantify the extent of any actual effects on competition (either when analysing the infringement or when calculating the penalty) in any Decision. The OFT took the view that it was unnecessary and disproportionate to do so given that there is no legal requirement to demonstrate or quantify actual effects<sup>23</sup> and because significant further data and analysis would have been required to do so in this case.

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<sup>21</sup> OFT File Part 10, document 12A. See paragraphs 2.108 to 2.110 below.

<sup>22</sup> The terms of the ERA are set out in Annexe A to this Decision.

<sup>23</sup> As set out in Part 3 below, to find an infringement, the OFT is not required to demonstrate that the conduct had actual effects on competition, or to quantify such effects.

2.29. In reaching this Decision, the OFT has carried out a detailed review of the submissions made by RB and third parties.

## **D. The Products**

### **i) Introduction**

2.30. This Section describes RB's Gaviscon portfolio, as well as the products of other suppliers.

### **ii) The Gaviscon Portfolio**

2.31. Gaviscon products are formulations for the symptomatic treatment of acid reflux, dyspepsia and GORD (see Section E below).

2.32. One of the active ingredients of Gaviscon products is a foaming agent called sodium alginate (derived from seaweed) that reacts with the other active ingredients to form a 'raft' which floats on top of stomach contents and stops the reflux of stomach acid into the oesophagus. Gaviscon products are commonly referred to as 'alginates'.

2.33. Gaviscon products are sold in the prescription channel and as OTC medicines. This Decision concerns products supplied in the prescription channel.

2.34. The conduct considered in this Decision relates most particularly to the leading products, GL and GA.

2.35. **GL** is an alginate formulation that entered the market in 1977. Its active ingredients are sodium alginate, calcium carbonate and sodium bicarbonate. The patent for GL expired in April 1997.<sup>24</sup>

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<sup>24</sup> Annexe 1 of RB submission dated 7 December 2009 in response to question 2 of the OFT section 26 request dated 24 November 2010.

- 2.36. GL was available in 500ml NHS presentation packs from September 1977 until June 2005. OTC presentation packs of GL became available in September 1977. They are available in 150ml, 300ml and 600ml packs.
- 2.37. OTC presentation packs have always been listed and available in the prescription channel in addition to NHS packs.<sup>25</sup> GL has continued to be prescribed, albeit far less frequently, since the Withdrawal. In these circumstances OTC packs are dispensed against NHS prescriptions.<sup>26</sup> For example, an internal RB email dated 4 April 2006 notes that:

'6.4% of scripts are still being written for Gaviscon original, 32% of these scripts are being filled with 500ml according to the IMS data, and the remainder are being filled with OTC packs, mainly 600ml, which is used to fill 47% of the scripts...'<sup>27</sup>

with the result that:

'On a MAT [Moving Annual Total] basis there has been a £1.2m increase in the value of OTC packs that are being dispensed against Gaviscon prescriptions [sic].'<sup>28</sup>

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<sup>25</sup> In the 12 months to June 2005 approximately five per cent of units of all Gaviscon dispensed on prescription were OTC packs. See letter dated 3 July 2008 from RB to OFT (OFT File Part 1, document 46.01).

<sup>26</sup> From 1 July 2005, DH added the 600ml OTC pack of GL to the Drug Tariff at Part VII. This allows for proportional reimbursement by reference to that pack size in accordance with clause 8C of the Tariff, at the manufacturer's list price for the pack (RB SMFI, paragraph 2.3). See section H below for further background on pharmacy reimbursement.

<sup>27</sup> RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 413.

<sup>28</sup> Ibid.



2.38. **GA** is an alginate product which entered the UK market in 1997. Its active ingredients are sodium alginate and potassium bicarbonate. GA has the same mode of action as GL. Since 1997, GA has been available in 500ml NHS presentation packs and since June 2005 it has also been available in the NHS prescription channel in 250ml packs. GA is also available in OTC presentation packs, in 150ml, and 300ml pack sizes.

2.39. GA retains patent protection until February 2016. The basis of its patent was described by RB as follows:

'The patent is directed to a new liquid formulation, with double the concentration of alginate. A change in one of its components allows for a smaller volume to be consumed but achieves the same effect as the Original product'.<sup>29</sup>

2.40. In a letter responding to an OFT section 26 Notice RB defined the main differences between GL and GA as follows:<sup>30</sup>

'The concentration of sodium alginate per dose in Gaviscon Advance is twice that in Gaviscon Liquid. The sodium content is 63 percent less in Gaviscon Advance than in Gaviscon Liquid and Gaviscon Advance contains potassium whereas Gaviscon Liquid does not.'

2.41. In that letter RB listed a number of differences in the formulation properties of GA and GL in relation to dosage, indications,<sup>31</sup> in

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<sup>29</sup> Annexe 1 of RB submission dated 7 December 2009 in response to question 2 of the OFT section 26 request dated 24 November 2010.

<sup>30</sup> Appendix 2 to letter dated 6 February 2009 from RB to OFT, in response to OFT section 26 Notice dated 14 January 2009 (OFT file part 2, document 44.01).

<sup>31</sup> Symptoms for which the formulation may be prescribed.

vitro<sup>32</sup> raft strength and resilience, and in vivo<sup>33</sup> raft residence time which were said to result from the formulation difference described above. RB explained that some of these differences are of clinical relevance and offer some advantage of one Gaviscon formulation over the other, making it more suitable for one patient group or another.<sup>34</sup> However, in its letter to the OFT dated 6 February 2009 RB notes that in some of these cases the greater suitability of GA is based only on the fact that supporting clinical data exists in respect of GA whereas it does not in the case of GL. RB stated that the only patient group where either GA or GL would be more suitable than the other, which is not a result of the presence or absence of data but is a simple consequence of the different formulation, is in those patients who must restrict their sodium or potassium intake respectively.<sup>35</sup>

2.4.2. Immediately prior to the Withdrawal (in the first quarter of 2005), GL and GA were RB's leading products in the prescription channel as set out in Table 2.1 below. Table 2.1 also refers to the following formulations within the Gaviscon portfolio:

- **Gaviscon Advance Tablets:** a tablet version of GA. The active ingredients are sodium alginate 500mg and potassium bicarbonate 100mg.

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<sup>32</sup> Taking place in a test-tube or other laboratory environment (Concise Oxford Dictionary).

<sup>33</sup> Taking place in a living organism (Concise Oxford Dictionary).

<sup>34</sup> In summary: GA has lower sodium content, is indicated for use alongside acid suppressants such as PPIs, can protect the oesophagus from damage caused by bile and pepsin, is indicated for treatment of laryngopharyngeal reflux (LPR); GL contains no potassium.

<sup>35</sup> Appendix 2 to letter dated 6 February 2009 from RB to OFT, in response to OFT section 26 Notice dated 14 January 2009 (OFT file part 2, document 44.01).

- **Gaviscon Extra Strength Tablets:** contain double the quantity of alginate to Gaviscon Original tablets. The active ingredients of Extra Strength Tablets are alginic acid 500mg, sodium bicarbonate 170mg, dried aluminium hydroxide gel 100mg and magnesium trisilicate 25mg.
- **Gaviscon Infant Sachets:** Gaviscon formulated for children. The active ingredients are sodium alginate 225mg and magnesium alginate 87.5mg.
- **Gaviscon Tablets Chewable 500mg:** A chewable version of Gaviscon tablets with double the quantity of alginate to Gaviscon Original.

**Table 2.1: Sales of Gaviscon products in the NHS prescription channel in England in Q1 2005**

| <b>Product</b>                  | <b>Net Ingredient Cost (in £ thousands)</b> | <b>As a percentage of total Net Ingredient Cost</b> |
|---------------------------------|---------------------------------------------|-----------------------------------------------------|
| Gaviscon Liquid                 | 2,210                                       | 49.0%                                               |
| Gaviscon Advance Liquid         | 1,587                                       | 35.2%                                               |
| Gaviscon Tablets Chewable 500mg | 372                                         | 8.3%                                                |
| Gaviscon Infant Sachets         | 314                                         | 7.0%                                                |
| Gaviscon Advance Tablets        | 14                                          | 0.3%                                                |
| Gaviscon Extra Strength Tablets | 13                                          | 0.3%                                                |
| All formulations                | 4,514                                       | 100.0%                                              |

Source: OFT analysis of NHS data

**iii) Acidex/Peptac**

2.43. **Acidex** is a generic product manufactured by Pinewood. Acidex contains the same active ingredients as GL in the same proportions and is regarded as therapeutically equivalent<sup>36</sup> to GL. Acidex holds

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<sup>36</sup> The term 'therapeutically equivalent' indicates that the generic product is prescribed for the same symptoms as the original branded product and is 'essentially similar' in formulation such that it is able to obtain Marketing Authorisation on the basis of the trials of the original branded product. The meaning of the concept of 'essential similarity' was established by the European Court of Justice (recently renamed: Court of Justice of the European Union) in the *Generics* case (Case C-368/96 *R v Licensing Authority established by the Medicines Act 1968 ex parte Generics UK Ltd and others* [1998] ECR

a marketing authorisation as a generic version of GL, and is included within the same British Pharmacopoeia monograph<sup>37</sup> as GL.<sup>38</sup>

2.44. Pinewood obtained its first generic licence corresponding to GL in March 1998 and began manufacturing Acidex in April 1998. In July 1998 Pinewood varied its licence to add Peptac as an own-label which enabled Pinewood to supply product to Norton Healthcare Ltd under the brand name 'Peptac' from September 1998.<sup>39</sup> Pinewood now supplies Peptac to Teva.<sup>40</sup>

**iv) Other alginate products**

2.45. **Gastrocote** is a formulation with the active ingredients sodium alginate, dried aluminium hydroxide gel, magnesium trisilicate and sodium bicarbonate. It is manufactured by Thornton & Ross Limited and the marketing authorisation is held by the Icelandic company Actavis Group PCT ehf.

2.46. **Algicon** suspension has the active ingredients aluminium hydroxide-magnesium carbonate co dried gel, calcium carbonate,

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I-7967) and is enshrined in Article 10(2)(b) of Directive 2004/27/EC 'Amending Directive 2001/83/EC on the Community code relating to medicinal products for human use'.

<sup>37</sup> See paragraph 2.93 below.

<sup>38</sup> In its SMFI RB observes that, although it is correct that Acidex/Peptac is therapeutically equivalent to GL and essentially similar in formulation, there are material differences between GL and Peptac in terms of: (i) raft strength and resilience (although both products meet the performance criteria for the BP monograph); and (ii) organoleptic profile (taste and texture) (RB SMFI, paragraph 2.1).

<sup>39</sup> Chronology enclosed with letter dated 9 March 2009 from Pinewood to OFT (OFT file part 2, document 67.02).

<sup>40</sup> Teva acquired Ivax in 2006. Ivax had owned Norton Healthcare Limited since 1990. See paragraphs 2.9 to 2.10 above.

magnesium alginates, magnesium carbonate and potassium carbonate. It is manufactured by Sanofi-Aventis.

- 2.47. Gastrocote and Algicon contain different ingredients to GA and GL and are not regarded as being therapeutically equivalent to either GA or GL.

## **E. The treatment of dyspepsia, acid reflux and GORD**

### **i) Introduction**

- 2.48. As outlined above at paragraphs 2.31 to 2.47 above, GL, GA, Peptac, Acidex, Gastracote and Algicon are alginate products used in the treatment of dyspepsia, acid reflux and/or GORD.

### **ii) Dyspepsia, acid reflux and GORD**

- 2.49. The National Institute for Health and Clinical Excellence (NICE)<sup>41</sup> defines dyspepsia as 'any symptom of the upper gastrointestinal tract, present for four weeks or more, including upper abdominal pain or discomfort, heartburn, acid reflux, nausea, or vomiting'.<sup>42</sup> Dyspepsia is therefore not itself a disease but a term to describe the symptoms caused by a range of conditions, including:

- irritation of the stomach lining (mucosa) by certain medicines including non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin and ibuprofen

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<sup>41</sup> NICE is an independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.

<sup>42</sup> See NICE, *Dyspepsia: Managing dyspepsia in adults in primary care – Evidence-based clinical practice guideline*, August 2004, p. 42, available at <http://guidance.nice.org.uk/CG17>.

- damage to the mucosa and the top of the small intestine (duodenum) by excess stomach acid resulting from helicobacter pylori (H. pylori) infection
- acid reflux and GORD (see below)
- peptic ulcers, which appear as a result of damage to the mucosa (gastric ulcers) or the wall of the duodenum (duodenal ulcers), often caused by H. pylori infection and
- stomach cancer, which causes damage to the mucosa and exposes the stomach wall to acid.

2.50. Dyspepsia is also typically aggravated by factors such as alcohol, stress, pregnancy and eating rich, spicy and fatty foods.

2.51. Acid reflux, also known as 'heartburn', is a common condition in which the valve at the top of the stomach (oesophageal sphincter) fails to prevent stomach acid from leaking back up into the food pipe (oesophagus). Acid reflux can occur as a result of various factors such as pregnancy, obesity, hiatus hernia, smoking and eating before bed.<sup>43</sup>

2.52. GORD occurs when the mucosa of the oesophagus is damaged by repeated irritation from stomach acid due to acid reflux. A related condition is oesophagitis, which is an inflammation of the mucosa as a result of acid reflux.

### iii) **Treatments for dyspepsia, acid reflux and GORD**

2.53. There are four principal treatments for dyspepsia, acid-reflux and/or GORD: antacids,<sup>44</sup> alginates,<sup>45</sup> Histamine-2 receptor

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<sup>43</sup> [www.nhsdirect.nhs.uk](http://www.nhsdirect.nhs.uk)

<sup>44</sup> For example, Rennie.

<sup>45</sup> For example, Gaviscon and Peptac.

antagonists (H2RAs)<sup>46</sup> and proton pump inhibitors (PPIs).<sup>47</sup> Below the OFT sets out the modes of action and therapeutic uses of each of these treatments.

2.54. The modes of action of the treatments for dyspepsia, acid reflux and GORD can be summarised as follows:

- **Antacids** neutralise the acid in the stomach. In general, antacids should not be taken at the same time as other medicines because they can stop these other medicines from being properly absorbed into the body.
- **Alginates** contain a foaming agent called sodium alginate (derived from seaweed) that reacts with the other active ingredients such as calcium carbonate and sodium bicarbonate to form a 'raft' which floats on top of stomach contents and stops the reflux of stomach acid into the oesophagus. Some alginates are combined with antacids.
- **H2RAs** reduce the amount of acid pumped into the stomach by an enzyme, called the 'proton pump', inside 'gastric parietal cells' in the stomach wall. H2RAs bind to histamine-2 receptors, which are one of the stimulants of the proton pump. In this sense, they are considered to act indirectly on the source of acid secretion.<sup>48</sup>
- **PPIs** stop acid secretion directly at the source of acid production (the proton pump). They are generally considered to be more effective and present fewer adverse effects than H2RAs.

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<sup>46</sup> For example, Tagamet and Zantac.

<sup>47</sup> For example, Losec and Zoton.

<sup>48</sup> Case COMP/A.37.507/F3 – *AstraZeneca*; paragraph 34.



2.55. The BNF describes the side effects of the products in the treatment area as follows:

- **Antacids** may be laxative (if containing magnesium) or constipating (if containing aluminium). Calcium-containing antacids can induce rebound acid secretion.<sup>49</sup>
- **Alginates** are not associated with any side-effects. In addition alginates are known to be suitable during pregnancy.<sup>50</sup>
- **H2RAs** can cause side-effects such as diarrhoea and other gastro-intestinal disturbances, altered liver function tests, headache, dizziness, rash and tiredness. Rare side-effects include acute pancreatitis, bradycardia, AV block, confusion and depression. The BNF advises that H2RAs should 'be used with caution in renal impairment, pregnancy, and in breast-feeding'.<sup>51</sup>
- **PPIs** can cause side-effects such as gastro-intestinal disturbances (including nausea, vomiting, abdominal pain, flatulence, diarrhoea, constipation), and headache. Less frequent side-effects include dry mouth, dizziness, sleep disturbances and fatigue. Rare side-effects include taste disturbance, stomatitis, hepatitis and jaundice. The BNF advises

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<sup>49</sup> With modest doses the clinical significance is doubtful, but prolonged high doses also cause hypercalcaemia and alkalosis, and can precipitate the milk-alkali syndrome (BNF No. 60, paragraph 1.1.1).

<sup>50</sup> British National Formulary No. 58 (and previous editions throughout the 2000s) – Section 1.1.2. 'Compound alginates and proprietary indigestion preparations'. See also Summaries of Product Characteristics (SPCs) from the electronic Medicines Compendium (eMC), at [www.emc.medicines.org.uk](http://www.emc.medicines.org.uk).

<sup>51</sup> British National Formulary No. 58 (and previous editions throughout the 2000s) – Section 1.3.1 'Histamine H2-receptor antagonists'. See also the letter dated 11 July 2008 from Pinewood, paragraphs 4.23 to 4.25.

that PPIs should be 'used with caution in patients with liver disease, in pregnancy and in breast feeding.'<sup>52</sup>

- 2.56. Tables 1 to 4 in Annexe B list the main therapeutic indications for the most frequently prescribed PPIs, H2RAs, alginates and antacids. While alginates are only used to treat symptoms of GORD and dyspepsia, H2RAs and PPIs have a wider range of indications (in addition to the symptomatic treatment of GORD and dyspepsia) including gastric, duodenal, and NSAID<sup>53</sup>-associated ulcers;<sup>54</sup> eradication of the *H. pylori* infection (in the case of PPIs only); and Zollinger-Ellison syndrome, which is a very rare condition associated with tumours.<sup>55</sup> Antacids also have a wider range of indications: in addition to providing relief from heartburn and dyspepsia, they also provide relief from or treatment of flatulence, gastritis, hyperacidity, indigestion and gastric/duodenal ulcers.
- 2.57. The therapeutic uses of the above treatments are explained in prescribing guidelines produced by NICE. The NICE guidelines contain recommendations for pharmacists and for GPs. The primary NICE guideline in relation to GORD/dyspepsia is Clinical Guideline 17: 'Dyspepsia: management of dyspepsia in adults in primary care' (NICE CG17), which was published in 2004.<sup>56</sup>

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<sup>52</sup> British National Formulary No. 58 (and previous editions throughout the 2000s) – Section 1.3.5 'Proton-pump inhibitors'. See also the letter dated 11 July 2008 from Pinewood, paragraphs 4.19 to 4.22.

<sup>53</sup> Non-steroidal anti-inflammatory drugs.

<sup>54</sup> In what follows PPIs and H2RAs are sometimes jointly referred to as 'anti-ulcerants'.

<sup>55</sup> Case COMP/A.37.507/F3 – *AstraZeneca*; paragraph 25.

<sup>56</sup> <http://guidance.nice.org.uk/CG17/NICEGuidance/pdf/English>. Prior to this, NICE published *Guidance on the Use of Proton Pump Inhibitors in the Treatment of Dyspepsia* in July 2000. The NICE guidance represents the view of the Institute, and is arrived at after careful consideration of the evidence available. NICE notes that 'health

- 2.58. NICE considers that in the absence of the patient reporting alarm signs and symptoms (for example, difficulty swallowing, unintentional weight loss and persistent vomiting), pharmacists are able to provide adequate treatments for dyspepsia to patients. This includes advice on life-style interventions (for example, healthy eating, weight reduction, and smoking cessation) and on the use of medicines that are available OTC such as antacids and alginates. However, if symptoms have persisted for several weeks and/or self-medication has not been effective in adequately relieving symptoms, NICE recommends that pharmacists advise patients to see a GP.<sup>57</sup>
- 2.59. For GPs, the NICE guideline distinguishes cases of dyspepsia which are not accompanied by alarm signs and symptoms from cases when these are present. Where alarm signs and symptoms are present, the underlying cause is investigated (for example, through an endoscopy). Where alarm signs and symptoms are not present, treatment is provided 'empirically' (without a proven diagnosis).
- 2.60. In cases of 'uninvestigated dyspepsia' the NICE guideline recommends as a first step that GPs review the 'common elements of care for managing dyspepsia'.<sup>58</sup> The 'common elements of care' include primarily self-treatment with antacids or alginates and life-

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professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.' See NICE CG17 page 2. The current guidelines are due for revision in 2011.

<sup>57</sup> According to data reported by NICE, when broadly defined, dyspepsia occurs in 40 per cent of the population annually but only leads to GP consultation and referral for endoscopy (see below in the text) in 5 per cent and 1 per cent, respectively, of the population.

<sup>58</sup> NICE CG17, paragraph 1.4.1

style changes. They also note that patients requiring long-term management of dyspepsia symptoms should be encouraged to reduce their use of prescribed medication stepwise: by using the effective lowest dose, by trying as-required use when appropriate, and by returning to self treatment with antacid and/or alginate therapy.<sup>59</sup>

- 2.61. After reviewing the 'common elements of care', the guidance recommends that initial therapeutic strategies for dyspepsia are empirical treatment with a PPI (full dose for one month)<sup>60</sup> or testing for and treating H. Pylori.<sup>61</sup> If symptoms return after initial care strategies, the guidelines recommend stepping down PPI therapy to the lowest effective dose or use on an as-required basis.<sup>62</sup> If there is an inadequate response to PPIs, NICE recommends offering an H2RA or prokinetic therapy.<sup>63</sup>
- 2.62. An annual review of treatment is recommended for patients requiring long-term management of dyspepsia symptoms, in which the patient should be encouraged to step down or stop treatment and to return to self-treatment with antacid and/or alginate therapy

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<sup>59</sup> NICE CG17, paragraph 1.3.7

<sup>60</sup> NICE notes that PPIs are more effective than antacids, alginates and H2RAs at reducing symptoms in trials of patients with un-investigated dyspepsia.

<sup>61</sup> NICE CG17, paragraph 1.4.2. NICE notes that there is currently insufficient evidence to guide which treatment – such as PPI therapy or H. pylori 'test and treat' – should be offered first. H. pylori eradication therapy consists of a one-week triple-therapy regime comprising PPIs and two different anti-bacterial drugs.

<sup>62</sup> NICE CG17, paragraph 1.4.5

<sup>63</sup> NICE CG17, paragraph 1.4.6. Prokinetic therapy involves the use of medicines which make food pass more quickly through the duodenum.

(either prescribed or bought over the counter). NICE also recommends that GPs offer advice on lifestyle changes.<sup>64</sup>

2.63. Cases of 'uninvestigated reflux-like symptoms' should be treated in the same way as above for 'uninvestigated dyspepsia'.<sup>65</sup> GPs should refer patients presenting alarm signs and symptoms to a specialist urgently (within two weeks) so that they can undergo an endoscopy. The results of this test will then indicate whether the dyspepsia is caused by 'endoscopically determined oesophagitis' or 'endoscopically-negative reflux disease' (GORD), peptic ulcer disease (PUD), or it is a functional, or non-ulcer, dyspepsia (NUD).<sup>66</sup>

2.64. The recommended course of action in each case is as follows:

- in the case of GORD: a therapy consisting of a full dose of PPIs for one or two months<sup>67</sup>
- in the case of PUD: a test for the presence of *H. pylori*, followed by:
  - a full-dose PPI therapy for one or two months, if *H. pylori* is absent or

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<sup>64</sup> NICE CG17, section 1.5

<sup>65</sup> NICE CG17; paragraph 1.6.1

<sup>66</sup> NICE reports that, in patients with signs or symptoms severe enough to merit endoscopy, 40 per cent have NUD, another 40 per cent have GORD, and 13 per cent are diagnosed with PUD (with the remainder being diagnosed with gastric and oesophageal cancer – three per cent – and other diseases).

<sup>67</sup> The NICE guideline suggests that PPIs can also be used (at the lowest dose possible) on an 'as required' basis if symptoms recur following the initial treatment. NICE recommends H2RAs or prokinetic therapy if there is an inadequate response to PPIs. Surgery is not recommended for the routine management of persistent GORD.

- an H. pylori eradication therapy (for H. pylori positive patients), which may be preceded by a full-dose PPI therapy for two months if the ulcer is associated with the use of non-steroidal anti-inflammatory drugs (NSAIDs)
- in the case of NUD: an H. pylori test, followed by:
  - a low dose of PPIs or H2RAs for one month, if the test is negative or
  - an H. pylori eradication therapy, if the test is positive.

2.65. NICE also notes, however, that apart from H. pylori eradication therapy and surgery,<sup>68</sup> no other treatments address the underlying reasons for dyspepsia, and once treatment stops symptoms tend to recur within a year in about half of patients. In these cases, in the short-term, if symptoms return after the initial care strategies, a 'step-down' of the PPI therapy to the lowest dose of PPIs required to control symptoms or on an 'as required' basis is recommended.

2.66. In addition to the guidelines published by NICE, another principal source for prescribers is the National Prescribing Centre (NPC), which is an NHS organisation whose aim is to promote and support high quality, cost-effective prescribing and medicine management across the NHS and to help improve patient care and service delivery. The NPC's prescribing guidelines have been published by MeReC since 1990. MeReC provides evidence-based information about current medicines and prescribing-related issues, whilst taking into account ongoing NHS developments and is used by a wide range of healthcare professionals.<sup>69</sup> MeReC supports the

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<sup>68</sup> Surgery is not recommended by NICE for the routine management of persistent GORD, although NICE notes that individual patients whose quality of life remains significantly impaired may value this form of treatment (CG17, paragraph 1.1.6).

<sup>69</sup> [www.npc.co.uk/ebt/about\\_merec.htm](http://www.npc.co.uk/ebt/about_merec.htm)

NICE clinical guidance programme and implementation strategy. In addition to publishing NPC briefings,<sup>70</sup> MeReC has also published a summary of the key recommendations in the NICE guideline on dyspepsia.<sup>71</sup>

## **F. Sales and price trends within the treatment area**

### **i) Introduction**

2.67. This Section provides an overview of the trends that have characterised the treatment area between 1991 and 2008. These trends are considered in detail in Part 4E on the relevant market.

### **ii) General developments in the treatment area**

2.68. Between 1991 and 2008 the GORD and dyspepsia treatment area has been characterised by significant change. The overall value<sup>72</sup> of medicines sold in the treatment area in the NHS prescription channel rose from £79 million in 1991 to over £136 million in 1997. By 2004 sales values had declined slightly to £132 million, before decreasing significantly to £56 million in 2008.

2.69. Much of this change was driven by an initial growth and subsequent decline in the sales value of PPIs. Quarterly sales of

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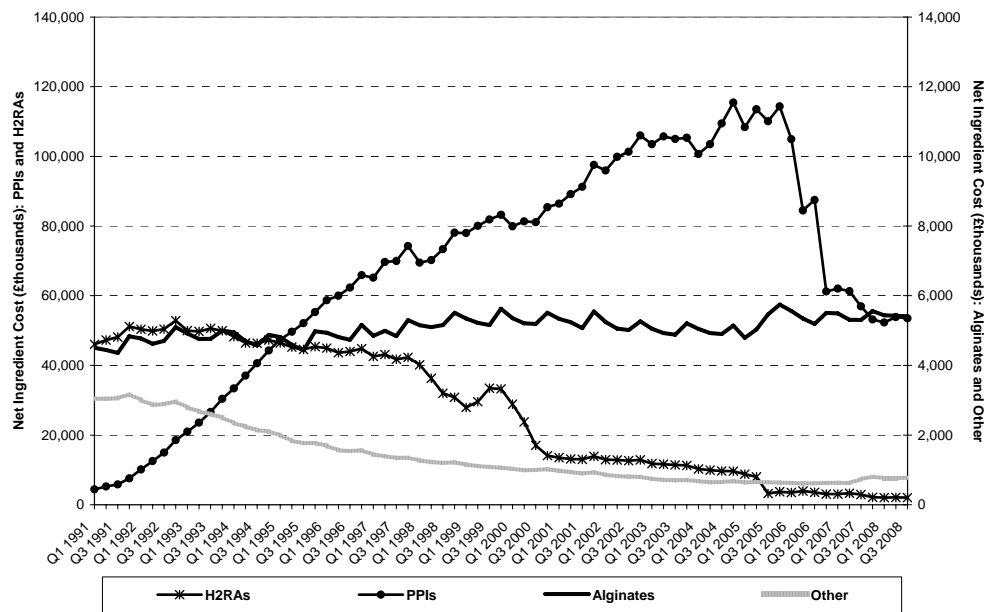
<sup>70</sup> See, for example, MeReC Bulletin No.16 2006: *Dyspepsia: The initial management of dyspepsia in primary care*; MeReC Briefing No.32 2005/2006: *Dyspepsia: The management of dyspepsia in primary care*; and MeReC Bulletin Volume 9, No.11, 1998: *Proton pump inhibitors: their role in dyspepsia*.

<sup>71</sup> [www.npc.co.uk/MeReC\\_Briefings/2006/summary\\_of\\_NICE.pdf](http://www.npc.co.uk/MeReC_Briefings/2006/summary_of_NICE.pdf)

<sup>72</sup> The value of sales is expressed in terms of 'Net Ingredient Cost' (NIC), which is the amount that the NHS pays to dispensers for each medicine before discounts and excluding any dispensing costs or fees. The value of sales is reported in nominal terms given that, under the terms of the PPRS, prices are not adjusted for inflation and list prices will only vary as a result of agreed portfolio-wide price cuts and a manufacturer's response to them.

PPIs grew from approximately £4m in Q1 1991 to almost £120m in 2005, before falling to £53m in Q3 2008. Quarterly sales of H2RAs declined significantly over the same period, from over £46m in Q1 1991 to only £2m in Q3 2008. Alginates sales increased very slightly, from just over £4m in Q1 1991 to just over £5m in Q3 2008. These trends are illustrated in Figure 2.1 below.

**Figure 2.1: Value of sales (in nominal terms) of PPIs, H2RAs, alginates and other treatments for dyspepsia prescribed by GPs in England, Q1 1991 – Q3 2008**



Source: OFT analysis of data provided by the NHS Information Centre

2.70. A key factor in these sales trends has been the launch of new branded products and the emergence of generic competition in respect of leading formulations whose patents have expired. For example, a number of major branded PPIs were launched between 1991 and 2000 and contributed to the rapid growth of sales of PPIs in that period. In 2002 and 2005 respectively, generic competitors to the major PPIs, Losec and Zoton, were launched. No major branded H2RAs were launched between 1991 and 2008, though generic substitutes to Zantax, Pepcid and Axid



were launched between 1997 and 2002. In the alginate product category, GA and Peptac were launched in 1997 and 1998 respectively. A summary of the key product launches is provided in Table 2.2 below.

**Table 2.2: Summary of major product launches relating to H2RAs, PPIs, and alginates**

| <b>Product category</b> | <b>Date</b> | <b>Event</b>                                     |
|-------------------------|-------------|--------------------------------------------------|
| H2RAs                   | Q3 1997     | Entry of generic version of Zantac (Ranitidine)  |
|                         | Q3 2000     | Entry of generic version of Pepcid (Famotidine)  |
|                         | Q3 2002     | Entry of generic version of Axid (Nizatidine)    |
| PPIs                    | Q2 1994     | Launch of Zoton (Lansoprazole)                   |
|                         | Q4 1996     | Launch of Protium (Pantoprazole)                 |
|                         | Q3 1998     | Launch of Pariet (Rabeprazole Sodium)            |
|                         | Q3 1999     | Launch of Losec MUPS (Omeprazole)                |
|                         | Q3 2000     | Launch of Nexium (Esomeprazole)                  |
|                         | Q2 2002     | Entry of generic version of Losec (Omeprazole)   |
| Alginates               | Q4 2005     | Entry of generic version of Zoton (Lansoprazole) |
|                         | Q1 1997     | Launch of Gaviscon Advance                       |
|                         | Q3 1998     | Launch of Peptac Liquid                          |

Source: OFT analysis of data provided by the NHS Information Centre. Note: The first generation of H2RAs (for instance cimetidine, for which branded names include Tagamet) was already off-patent in Q1 1991.

2.71. The remaining key product change that affected the leading formulations in the treatment area was the Withdrawal in June 2005.

**iii) Pricing trends in the treatment area**

2.72. Given the different formulations and pack sizes that characterise the different product types, it is helpful to consider price changes by reference to average treatment costs.

2.73. The average treatment costs for PPIs, H2RAs and alginates – calculated using a representative sample of products in each type<sup>73</sup> – are shown (in nominal terms) in Figure 2.2 below.

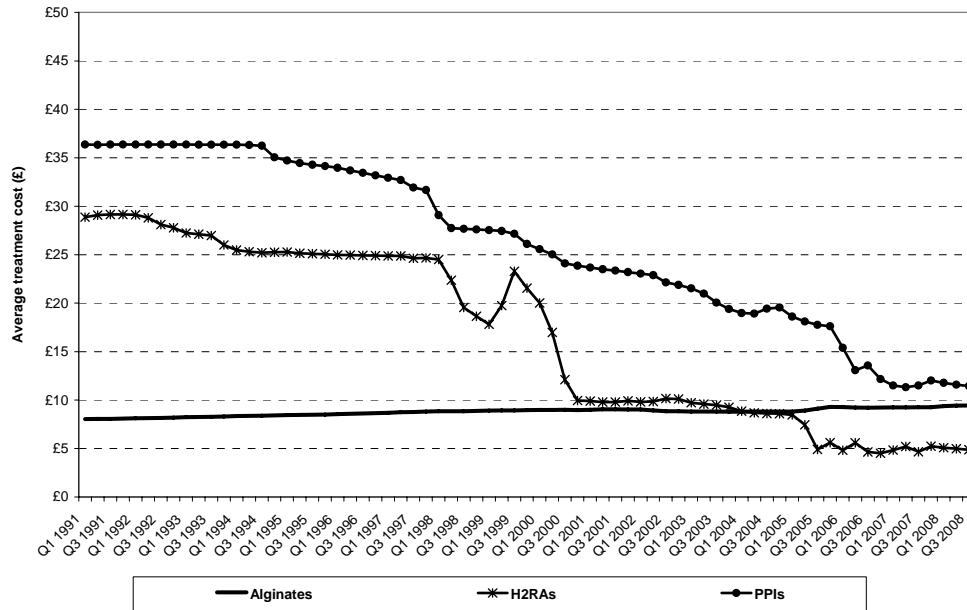
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<sup>73</sup> The sample includes any branded or generic product which reported a share of total Net Ingredient Cost (NIC) equal to five per cent or more in at least one year between 1991 and 2008 in the NHS dataset. The products included were:

- Alginates: Gastrocote tablets; Gaviscon Advance Liquid; Gaviscon Advance tablets; Gaviscon Original Liquid; Gaviscon Original tablets; and Peptac Liquid
- H2RAs: Axid and nizatidine capsules 150mg; Tagamet and cimetidine tablets 400mg; Zantac and ranitidine tablets 150mg; Zantac and ranitidine tablets 300mg
- PPIs: Losec and omeprazole capsules 10mg; Losec and omeprazole capsules 20mg; Losec MUPS tablets 20mg; Nexium tablets 20mg and 40mg; Pariet tablets 20mg; Zoton and lansoprazole capsules 15mg; Zoton and lansoprazole capsules 30mg.

The duration of the treatment was set at 28 days, which is the duration of a typical treatment with PPIs and H2RAs as per product literature (retrieved from the specialist website Medicines Compendium <http://emc.medicines.or.uk>) and BNF indications. Together, the products included in the sample account on average for at least 87 per cent of total sales value (as expressed by NIC) in each category. For each product type, the average treatment costs shown in the chart above are weighted averages, calculated using the share of sales value of each product as weights.

**Figure 2.2: Average cost (in nominal terms) of treating dyspepsia during 28 days using H2RAs, PPIs, and alginates in England, Q1 1991 – Q3 2008**



Source: OFT analysis of data provided by the NHS Information Centre

2.74. As shown in Figure 2.2 above, between Q1 1991 and Q3 2008 average treatment costs for both H2RAs and PPIs decreased considerably whereas average treatment costs for alginates increased slightly. The average cost of a four-week treatment with H2RAs decreased from almost £30 in Q1 1991 to about £5 in Q3 2008, and for PPIs the corresponding decrease was from around £35 to £10. The average treatment cost for alginates increased from £8 to £9.40 in the same period.

## G. The process and benefits of generic competition

### i) Introduction

2.75. Following the expiry of a branded medicine's patent, there is the possibility of generic competition. This Section begins with an overview of the lifecycle of a medicine, and goes on to consider

different forms of generic competition and the potential benefits they have.

**ii) The lifecycle of a medicine**

2.76. The *EC Pharmaceutical Sector Inquiry Report*<sup>74</sup> described the lifecycle of a product as being constituted of three main phases: (i) the Research & Development (R&D) phase up to market launch; (ii) the period between launch and loss of exclusivity (patent expiry); and (iii) the period following the loss of exclusivity, when generic products can enter the market. The second and third periods are particularly relevant to this investigation.

2.77. During the second period, following the launch of the product, the manufacturer looks to generate sufficient revenue from the medicine to cover its R&D costs and to earn a profit, before the medicine becomes subject to competitive pressure from generic equivalents. It is in the interests of manufacturers to prolong and maximise this phase, and to carry out strategies known as 'life-cycle management' to extend either the period of market exclusivity or to expand the market that the product has during its period of exclusivity. An example of the former would be to carry out further R&D, known as 'incremental innovation', with a view to improving the medicine or finding new uses for it and filing resulting associated 'secondary patent' applications. An example of the latter is to introduce related OTC products.<sup>75</sup>

2.78. In the third period, after the patent on a branded medicine has expired, manufacturers of generic medicines will, subject to

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<sup>74</sup> *EC Pharmaceutical Sector Inquiry Report*, 8 July 2009, section 1.2 (see <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>).

<sup>75</sup> *EC Pharmaceutical Sector Inquiry Report*, 8 July 2009, Annexe to Chapter B.1.2. paragraphs 72 to 75.

restrictions around data exclusivity,<sup>76</sup> have the opportunity to produce and obtain marketing authorisation<sup>77</sup> for generic equivalents of the branded medicine.

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<sup>76</sup> Data exclusivity refers to the period during which the data of the original marketing authorisation holder relating to (pre-) clinical testing is protected. Rules on data exclusivity (Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use) prevent Marketing Authorisation (MA) bodies from processing abridged applications for generic medicines for a certain number of years after the first MA. Where the initial national authorisation application for a reference medicinal product was made in the UK before 30 October 2005, or a central authorisation application was made before 20 November 2005, the product benefits from 10 years' protection. Where the initial national authorisation application for a reference medicinal product was made in the UK after 30 October 2005, or a central authorisation application made was after 20 November 2005, new rules harmonised at EU level apply (Regulation (EC) No. 726/2004). Under the harmonised rules an abridged application for a generic product is possible eight years after the initial MA although it is not possible to actually place that product on the market until 10 years after the original MA. In addition, if a new therapeutic indication with a significant clinical benefit has been approved for the reference product during the first eight years following the MA, the reference product will benefit from an additional year of marketing exclusivity.

<sup>77</sup> In the EU, medicinal products may only be launched on the market after they have obtained a National or Community MA. The MA process verifies the safety, quality and efficacy of the proposed medicine. (Regulation (EC) No. 726/2004 'Laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency' and Directive 2004/27/EC amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use). The national MA process in the UK is carried out by the MHRA and lasts for approximately two years. Producers of generic medicines are able to make an 'abridged application' for a MA without providing results of pre-clinical tests and clinical trials if it can be demonstrated that the generic product is 'essentially similar' to the original product. The meaning of the concept of 'essential similarity' was established by the European Court of Justice (recently renamed: Court of Justice of the European Union) in Case C-368/96 and is enshrined in Article 10(2)(b) of Directive 2004/27/EC 'Amending Directive 2001/83/EC on the Community code relating to medicinal products for human use').

### iii) **Competition between branded and generic medicines**

- 2.79. The existence of a generic name can materially impact upon the choices afforded to GPs and pharmacies. After patent expiry, the effectiveness of generic competition will therefore depend on whether or not a generic name has been issued that applies to both the generic medicine and the branded originator medicine.
- 2.80. As outlined below, GPs are encouraged to prescribe generically where possible (see paragraphs 2.100 to 2.102 below), and pharmacies are typically incentivised (through higher margins) to dispense the cheapest applicable medicine.<sup>78</sup> Where GPs provide an open prescription, pharmacies are free to choose to dispense any product that is described by the generic name. Under this scenario manufacturers have an incentive to engage in strong price competition in order to encourage pharmacies to dispense their products and full generic competition is said to exist.
- 2.81. In its internal documents RB describes this scenario as the 'full generic threat' (as distinct from the 'branded generic threat', see below) and in this context states that 'if a generic name should be granted, it is envisaged that we would begin to lose a significant market share as generic prescribing eroded [sic] Gaviscon script share'.<sup>79</sup>
- 2.82. Where no generic name exists, a GP will prescribe using a brand name and on receipt of such a closed script pharmacies are obliged to dispense the named product (see paragraph 2.115 below).  
Where no generic name exists, generic pharmaceutical

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<sup>78</sup> For each product dispensed against a generic prescription, pharmacies would be reimbursed at the Drug Tariff price rather than the PPRS price (see paragraphs 2.116 to 2.125 for further details).

<sup>79</sup> RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 35.

manufacturers must therefore convince GPs to prescribe their medicines by specific product name (rather than generic name).

2.83. Under this scenario, it is necessary for generic manufacturers to assign brand names to their products (such that they become known as 'branded generics') and to invest in marketing spend to convince GPs to prescribe their product rather than the product of the branded originator product of the incumbent supplier. Where a GP's awareness of the originator brand is high, generic manufacturers would typically be required to invest significant sums in convincing GPs to prescribe their product such that their costs are inflated. Given that, by virtue of its therapeutic equivalence to the branded originator product the generic product will offer no material clinical advantages over it, it may not be commercially viable for generic manufacturers to generate significant sales through marketing. As a consequence, under this scenario the effectiveness of generic competition is significantly limited.

2.84. RB describes this scenario as the 'branded generic threat' (as opposed to the 'full generic threat', see above). In this regard, RB notes that Pinewood 'have only managed to get 5% of the Gaviscon business because of the strong brand loyalty to Gaviscon amongst GPs, even though Peptac are offering a 20% discount'.<sup>80</sup>

#### **iv) The benefits of full generic competition**

2.85. The EC Pharma Sector Inquiry reports that the average time to generic entry after patent expiry is about 13 months.<sup>81</sup> It takes less

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<sup>80</sup> Ibid.

<sup>81</sup> When this analysis is adjusted to weight the drugs in relation to their sales levels in the year before loss of exclusivity, the average drops to just under eight months (EC Pharma Sector Inquiry Report, paragraph 192).

time for high value products to be faced with generic entry<sup>82</sup> and the time taken in the UK is relatively short in comparison with other EU Member States.<sup>83</sup>

- 2.86. On average in the EU, about four to five generic entrants are typically present in the market one year after the loss of exclusivity. Within three years of the loss of exclusivity the ratio of generic companies to originators is about 6:1. The ratio is likely to be higher in the case of high value products than it is with other products.<sup>84</sup>
- 2.87. When generic companies enter a market in the EU they enter with, on average, two to 2.5 formulations for each drug. This is usually a lower number of formulations than are produced by the originator company due to factors such as remaining patent protection on some formulations, or generics companies focusing on the highest selling formulations.<sup>85</sup>
- 2.88. In the EU generic medicines typically come onto the market at prices that are about 25 per cent lower than the price of the originator product immediately prior to the loss of exclusivity. Generic entry also has the effect of decreasing the price of the originator product. In markets where generic entry occurs, average prices drop by almost 20 per cent after one year after the loss of exclusivity and about 25 per cent after two years. In some cases the decrease can be as much as 80-90 per cent.<sup>86</sup> In the period

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<sup>82</sup> EC Pharma Sector Inquiry Report, paragraph 193.

<sup>83</sup> EC Pharma Sector Inquiry Report, paragraph 194. The average time in the UK is just under four months whereas it exceeds six months for many Member States.

<sup>84</sup> EC Pharma Sector Inquiry Report, paragraphs 201-202.

<sup>85</sup> EC Pharma Sector Inquiry Report, paragraph 208.

<sup>86</sup> EC Pharma Sector Inquiry Report, paragraph 212.



2004 – 2006 the average (weighted by sales) price reduction for a drug in the UK one year after generic entry was 42 per cent.<sup>87</sup> Much of this may be attributed to the encouragement and incentives given by PCOs to GPs to prescribe generically, and also to greater profitability for pharmacies in sourcing and dispensing generic rather than branded medicines.

2.89. In its SMFI, RB commented that a joint DH/ABPI study<sup>88</sup> published in 2002 identified some reasons why generic entry may not occur or may be slow in some markets. RB asserted<sup>89</sup> that the following factors are present in the alginates sector such that the typical features and benefits of generic competition do not apply to the same extent:

- 'Size of market: in most cases, generic companies are not interested in small and/or rapidly declining markets and
- Nature of product: apart from a few companies, which specialise in the manufacture of oral liquids, generic companies concentrate on oral solid dosage forms, in particular tablets and generally avoid other presentations; complexity of the manufacturing process...'.<sup>90</sup>

2.90. The OFT recognises that as alginates are typically delivered in liquid form, they will differ from markets that are characterised by

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<sup>87</sup> Report entitled *Competition in the off-patent market post generic entry*, prepared by CRA International for Baker & McKenzie CVBA/SCRL, September 2008. Page 40, Figure 16: 'The impact of generic entry 2000-2003 vs. 2004-2007 in UK' (cited data source: IMS and CRA analysis).

<sup>88</sup> Report prepared jointly by DH and ABPI entitled *PPRS: The Study into the Extent of Competition in the Supply of Branded Medicines to the NHS*, December 2002 (hereafter 'joint DH/ABPI study').

<sup>89</sup> RB SMFI, Annex 4, paragraph 9

<sup>90</sup> Joint DH/ABPI study, pp134, as quoted by RB in its SMFI, paragraph 2.2

tablets or capsules. However, the OFT observes that one liquid alginate producer (Pinewood) had entered the market. The OFT does not consider that the alginates sector was either small or rapidly declining at the time of the Withdrawal. The UK market for GL and Peptac in 2004 (the year prior to the Withdrawal) had a NIC of £13 million and was not experiencing declining sales. Therefore these products would not fall into the DH/ABPI report's definition of a small or declining market and, in fact, would fall into the DH/ABPI report's top category of market size (more than £10m per year, measured by NIC).

## **H. The regulatory framework relevant to generic competition**

### **i) Introduction**

2.91. This Section considers the regulatory processes relevant to generic competition. It sets out (i) the roles of the BNF and BPC in generating generic names and monographs; (ii) the rules, guidelines and processes relevant to GP prescribing; (iii) the rules, guidelines and processes relevant to pharmacy dispensing; (iv) the regulatory pricing mechanisms relevant to branded medicines (such as GL and GA) and generic medicines (such as Peptac/Acidex); and (v) the processes relevant to withdrawing NHS packs of a pharmaceutical product.

### **ii) BPC and BNF roles in generating generic names**

2.92. The **British Pharmacopoeia Commission** (BPC) is a committee of the Medicines and Healthcare products Regulatory Agency (MHRA)<sup>91</sup> and is an independent, advisory, non-departmental public body.

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<sup>91</sup> The MHRA is the Government agency which is responsible for ensuring that medicines and medical devices work and are acceptably safe (see [www.mhra.gov.uk](http://www.mhra.gov.uk)). It also carries out the process for granting national Marketing Authorisation for new drugs in the UK (see footnote 77 above).

- 2.93. The BPC is responsible for producing new editions of the British Pharmacopoeia (BP).<sup>92</sup> The BP currently contains over 3,000 monographs for substances and articles used in the practice of medicine.<sup>93</sup> Monographs are objective, public standards of quality for medicines and formulated preparations. They are also compliance requirements in that they provide the means for an independent judgement as to the overall quality of an article.<sup>94</sup> The legal basis for the BP is the Medicines Act 1968 (MA68) (as amended). It is published annually in August and comes into effect in January of the following year.
- 2.94. The BPC states on its website that it welcomes participation from manufacturers in the development of monographs. Guidelines for manufacturers in relation to monograph development are published by the BPC in BP Supplementary Chapter III C. Monograph Development: Guidance to Manufacturers. Manufacturers may also propose revisions to published monographs by submitting draft proposals, supporting validation data and samples.
- 2.95. All members of the BPC are required to comply with the BPC Code of Practice on Declaring Interests in the Pharmaceutical Industry and to complete an annual Declaration of Interests form. The BPC appoints members of Expert Advisory Groups, Panels of Experts and Working Parties in order to assist in carrying out its role. The BPC usually holds three scheduled meetings per year. These are held at the MHRA offices in London. Summary Minutes of these meetings are publicly available on the BPC website, in addition to

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<sup>92</sup> The BPC also produces the BP(Vet), which is a pharmacopoeia for veterinary medicines.

<sup>93</sup> The BPC will consider production of a monograph in the BP if doing so would meet the criteria in BP Supplementary Chapter III B. Monograph Development Mechanism.

<sup>94</sup> See [www.pharmacopoeia.gov.uk](http://www.pharmacopoeia.gov.uk).

annual reports of its activities which are reported as part of the MA68 Advisory Bodies Annual Reports.

- 2.96. The BPC is also responsible for the selection and publication of British Approved Names (BANs) which are used as the headings of monographs in the BP, where a monograph exists. The BAN is the official non-proprietary name (also known as a generic name) given to a pharmaceutical substance for use in the UK. BANs are short, distinctive names for substances where the systematic chemical or other scientific names are too complex for convenient use. BANs are devised or selected by the BPC and published by the Health Minister on the recommendation of the Commission on Human Medicines in accordance with section 100 of the MA68. Where possible the BAN is harmonised with the recommended International Nonproprietary Name (INN). Where an INN cannot be assigned to a medicinal product a BAN may be assigned for use in the UK.<sup>95</sup>
- 2.97. The **British National Formulary** (BNF) is a public body based at the Royal Pharmaceutical Society of Great Britain (RPSGB) which aims to provide prescribers, pharmacists and other healthcare professionals with authoritative and practical information on the selection and clinical use of medicines. The BNF publishes its formulary (also named 'BNF') biannually under the authority of the Joint Formulary Committee (JFC) which is comprised of representatives of The British Medical Association (BMA), the RPSGB and UK Health Departments, alongside a Dental Advisory Group and Nurse Prescribers' Advisory Group.<sup>96</sup>
- 2.98. In the BNF, information on drugs is drawn from the manufacturers' product literature, medical and pharmaceutical literature, UK health departments, regulatory authorities and professional bodies.

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<sup>95</sup> [www.pharmacopoeia.gov.uk/publications/british-approved-names.php](http://www.pharmacopoeia.gov.uk/publications/british-approved-names.php)

<sup>96</sup> [www.bnf.org](http://www.bnf.org)

Advice is constructed from clinical literature and reflects, as far as possible, an evaluation of the evidence from diverse sources. The BNF also takes account of authoritative national guidelines and emerging safety concerns. In addition, the editorial team receives advice on all therapeutic areas from expert clinicians. The BNF is designed as a digest for rapid reference and it may not always include all the information necessary for prescribing and dispensing.<sup>97</sup>

2.99. Since 31 March 2003 the BNF has published on its website a procedure for constructing names for non-proprietary medicinal products.<sup>98</sup> That procedure will be used only when the BPC is not minded to publish a name.

**iii) GP prescribing**

**a) Generic prescribing**

2.100. GPs are encouraged to write open prescriptions using the drug's generic name (where one exists),<sup>99</sup> whether or not the product in question is out of patent, unless there are specific clinical reasons not to.<sup>100</sup> For example, the BNF states that 'Where non-proprietary [generic] titles are given they should be used in prescribing'.<sup>101</sup>

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<sup>97</sup> [www.bnf.org/bnf/extra/current/450002.htm](http://www.bnf.org/bnf/extra/current/450002.htm)

<sup>98</sup> [www.bnf.org/bnf/extra/current/popup/NonProprietaryNamesForMedicinalProducts.pdf](http://www.bnf.org/bnf/extra/current/popup/NonProprietaryNamesForMedicinalProducts.pdf)

<sup>99</sup> It is in theory possible for GPs to write prescriptions that list a given compound's ingredients and the required proportions of each. On receipt of such a prescription, a pharmacy could choose whether to dispense any available product that contained the relevant ingredients in the relevant proportions. However, such an approach is generally considered to be impractical and would be inconsistent with the practice of determining and adopting generic names. The OFT understands that prescribing in this way is extremely rare and does not understand it to have occurred with any frequency in relation to any alginates (or antacids).

<sup>100</sup> See paragraph 2.34 of the OFT report *The Pharmaceutical Price Regulation Scheme*, February 2007.

2.101. This policy is motivated by both safety and cost concerns. There are sometimes many brand names for one medicine and possible confusion or mistakes are reduced if all doctors use the same names when discussing and prescribing drugs. Also when a branded medicine's patent expires, generic equivalents that appear in the market are usually cheaper for the NHS (see paragraph 2.88 above) but, for a pharmacist to be able to dispense a generic, a prescription must be written using the drug's generic name.<sup>102</sup>

2.102. In total, prescribing by generic name accounted for about 70 per cent of primary care expenditure in England in 2005, up from just over 40 per cent in 1995.<sup>103</sup> The overall generic prescribing rate was similar in Scotland and Wales, whilst in Northern Ireland it was 45 per cent.<sup>104</sup>

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<sup>101</sup> See, for example, the 'General Guidance' section of the chapter 'Guidance on Prescribing' in the British National Formulary No. 58 (September 2008).

<sup>102</sup> See paragraph 2.35 of the OFT report *The Pharmaceutical Price Regulation Scheme*, February 2007.

<sup>103</sup> Paragraph 2.36 of the OFT report *The Pharmaceutical Price Regulation Scheme*, February 2007. In addition, in an internal paper entitled 'Project White Tiger – Review', circulated in an internal RB email dated 16 May 2006, RB noted that: 'The rate of generic prescribing is 69 per cent and this is one of the measures used to assess performance in primary care. GP prescribing is monitored by Primary Care Organisations (PCO) which also hold the medicines budget. Primary Care Organisations would look at ways by which they could increase generic prescribing by GPs, and there are varied actions taken which include limiting GP systems to prescribe medicines by their generic name, unless specifically over-ridden. They may also provide incentives to GPs for meeting targets in expenditure' (RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 428).

<sup>104</sup> Paragraph 2.36 of the OFT report *The Pharmaceutical Price Regulation Scheme*, February 2007.

**b) GPs' prescribing software**

2.103. To facilitate generic prescribing GPs' prescribing software is able to identify if a generic product is available. Having identified a suitable branded product, GPs may then use their 'Ctrl G' function to identify the applicable generic name, and to provide patients with an open script that lists the applicable generic name against which a recipient pharmacist can then choose to dispense any applicable product.<sup>105</sup> If a generic name does not exist the prescribing software would not be able to identify a generic name against which open scripts could then be issued.

2.104. In 2005, RB estimated that the key prescribing software companies had the following market shares:<sup>106</sup>

- EMIS: 50 per cent of practices in England, Wales and Northern Ireland, and 15 per cent of practices in Scotland
- Vision, Torex and System One: 20 per cent, five per cent and five per cent respectively of practices in England, Wales and Northern Ireland<sup>107</sup> and
- GPass: 85 per cent of Scottish practices.

2.105. The prescribing software operated by the companies works in slightly different ways. In 2005, RB set out in an internal presentation a summary of some of the basic mechanisms:<sup>108</sup>

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<sup>105</sup> RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 425.

<sup>106</sup> RB internal presentation entitled 'White Tiger 2', dated 5 May 2006 (RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 418).

<sup>107</sup> Supplied by the Multilex drug database (see letter from RB to OFT dated 10 December 2009, in response to OFT s26 Notice dated 24 November 2009, (OFT File Part 6, document 105A)). EMIS and GPass have their own drug databases.

- The Vision programme allowed the GP to select a drug from either the full drug dictionary or from the pre-selected practice formulary by typing the first few letters of the drug name (for example, 'Gav'). These were displayed either alphabetically or by BNF hierarchy. The GP could then click a 'branded to generic' icon or press Ctrl + G to replace the selected drug with its generic name.
- As with the Vision programme, the EMIS programme enables the GP to press their 'G' button to identify the generic name for a particular branded product. The EMIS programme differed from Vision in that it could be set up by the practice to list drugs on the screen in a number of ways. RB identified that the most usual way was by frequency of prescribing.
- The GPass programme differed from Vision in that, when the drug name was typed in, 'SKUs'<sup>109</sup> of that drug only were listed alphabetically. The GP then selected the required format (for example, tablets/liquid) and pack size. The selection displayed whether it was a branded or generic drug and the generic name (where available) was printed automatically on the script unless the brand was selected.

2.106. EMIS and GPass have stated that certain OTC medicines are listed on GP prescribing's software. However, a note is raised in respect of these products to alert the GP to the fact that the medicine is available only in OTC presentation packs.<sup>110</sup>

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<sup>108</sup> RB internal presentation entitled 'White Tiger 2', dated 5 May 2006 (RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 418).

<sup>109</sup> Stock-keeping units.

<sup>110</sup> See note of telephone conversation between OFT and EMIS dated 7 January 2010 (OFT File Part 7, document 2A), and note of telephone conversation between OFT and GPass dated 11 January 2010 (OFT File Part 7, document 7.01).



- 2.107. Some prescribing software used by GPs allows PCOs or individual GP practices to set up 'local formularies'. These essentially pre-determine the order in which products appear in the 'pick-list' from which a GP selects an item to prescribe. They may also set a preference for a generic name or specific product; or provide a list of equivalent products when one is selected.<sup>111</sup>
- 2.108. ScriptSwitch is a software package which supplements the GP's normal prescribing software.<sup>112</sup> ScriptSwitch is described as primarily a medicines management tool, with a secondary benefit of improving the cost effectiveness of prescribing.<sup>113</sup> Its stated aim is to deliver consistency and conformity in prescribing, whilst quantifying and reporting on cost savings.<sup>114</sup>
- 2.109. ScriptSwitch sources information from the Multilex database and from publications of bodies such as the National Prescribing Centre and NICE. Part of its purpose is to facilitate customers' timely

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<sup>111</sup> RB SMFI, paragraphs 2.5 – 2.9.

<sup>112</sup> RB SMFI, paragraphs 2.10 – 2.13. ScriptSwitch entered into its first customer contracts in 2005 and received investment from ISIS Equity Partners in 2007. In November 2009 ScriptSwitch was acquired by UnitedHealth UK (see [www.unitedhealthuk.co.uk](http://www.unitedhealthuk.co.uk) and [www.isisep.com/default.asp?docId=14821](http://www.isisep.com/default.asp?docId=14821)). ScriptSwitch is triggered automatically without the need for a GP to proactively launch it. The software provides a number of details of prescription drugs, including their dosage and cost and the prescriber can quickly accept or decline the software's recommendations and so retain clinical freedom (Note of meeting between OFT and ScriptSwitch held on 24 August 2010; OFT File Part 10, document 12A). It is not supported by the GPass system in Scotland (RB SMFI, Appendix 5).

<sup>113</sup> Martyn Carroll, Head of Medicines Management, ScriptSwitch. Quoted in Western Mail article: 'System's hi-tech prescription will help to cut health costs', published by MGN Ltd, 17 December 2007.

<sup>114</sup> Birmingham Post article: 'Isis rises to snap up ScriptSwitch in £9.9m deal', published by MGN Ltd, 29 May 2007

access to information provided by these bodies in order to inform their prescribing strategies.<sup>115</sup>

2.110. The primary users of ScriptSwitch are PCOs, which purchase the software package in order to assist them in executing their prescribing strategies.<sup>116</sup> As at August 2010, ScriptSwitch was used by 73 per cent of PCOs in England, Wales and Scotland, and by 58 per cent of GP practices.<sup>117</sup> ScriptSwitch is independent of direct influence from the pharmaceutical industry and its information content, such as drug switch recommendations, is directed solely by the customer (either PCOs or GP practices where they are using the software independently of PCOs).<sup>118</sup>

**c) Restrictions on prescribing**

2.111. In order, in part, to manage the NHS budget, prescribers do not have total freedom to prescribe as they wish. The majority of prescribers in England act under General Medical Services (GMS) contracts.<sup>119</sup> They are constrained by those contracts<sup>120</sup> and,

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<sup>115</sup> Note of meeting between OFT and ScriptSwitch held on 24 August 2010; OFT File Part 10, document 12A

<sup>116</sup> Note of meeting between OFT and ScriptSwitch held on 24 August 2010; OFT File Part 10, document 12A

<sup>117</sup> See [www.scriptswitch.co.uk](http://www.scriptswitch.co.uk). ScriptSwitch also informed the OFT that it rarely has direct contracts with individual GPs although it has recently become more common for practice-based commissioning groups of GPs to directly contract with ScriptSwitch (Note of meeting between OFT and ScriptSwitch held on 24 August 2010; OFT File Part 10, document 12A).

<sup>118</sup> Note of meeting between OFT and ScriptSwitch held on 24 August 2010; OFT File Part 10, document 12A

<sup>119</sup> Under Section 28Q National Health Service Act 1977 and subsequently by Section 84 National Health Service Act 2006, which came into force on 1 March 2007.

through them by reference to The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004, Regulation 2, Schedule 1,<sup>121</sup> from prescribing at all certain drugs, medicines or other substances.<sup>122</sup> This list originated as 'the Limited List' in 1985 and is now referred to as the Medicines Selected List Scheme (MSLS). The list includes a number of OTC products and brands such as the antacids Rennie, Tums and Andrews Antacid Tablets. It also includes some Gaviscon preparations, in particular Gaviscon Granules and Gaviscon 250 tablets.<sup>123</sup>

2.112. The power to include a product in the list (referred to as 'blacklisting') is exercisable by DH, with the decision being made by the Secretary of State.<sup>124</sup> The relevant criterion applied by DH in deciding whether to blacklist a product, is set out in the Drug Tariff as being:

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<sup>120</sup> Paragraph 42 of Schedule 6 to The National Health Service (General Medical Services Contracts) Regulations 2004 (SI 2004/291, amended by SI 2004/2694, SI2005/893, SI2005/3315 and SI 2007/3491), which came into force on 1 March 2004.

<sup>121</sup> SI 2004/629. These regulations came into force on 1 April 2004 and replaced The National Health Service (General Medical Services) Regulations 1992 (Schedule 10). Similar provision is made in respect of Wales, Scotland and Northern Ireland (National Health Service (general Medical Services Contracts)(Prescription of Drugs Etc.)(Wales) Regulations 2004; National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004; and Health and Personal Social Services (General Medical Services Contracts) (Prescription of Drugs Etc) Regulations (Northern Ireland) 2004)

<sup>122</sup> Schedule 2 of the same Regulation and constrains GPs from prescribing certain other drugs save in specified clinical circumstances.

<sup>123</sup> RB SMFI, Annex 3 paragraph 3

<sup>124</sup> RB SMFI, Annex 3 paragraph 3

'on expert advice, they had no clinical or therapeutic advantage over other, cheaper, drugs.'<sup>125</sup>

2.113. It is by virtue of those restrictions on what may be prescribed (at all or in certain circumstances) that control is exercised by the Department of Health (DH) over NHS drug costs: if a drug cannot be prescribed (or can only be prescribed in certain cases), it cannot be dispensed (or can be dispensed only in those limited cases) and so no claim for reimbursement can be made (or claims for reimbursement can be made only in respect of those limited cases).<sup>126</sup>

**iv) Pharmacy dispensing**

2.114. The activities of pharmacists are governed, in England, by Schedule 1 of the National Health Service (Pharmaceutical Services) Regulations 2005<sup>127</sup> and across the whole of Great Britain by the Code of Ethics for Pharmacists and Pharmacy Technicians, produced by the Royal Pharmaceutical Society of Great Britain (RPSGB).<sup>128</sup> The RPSGB is the professional and

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<sup>125</sup> Drug Tariff, Part XVIIIIC – Criteria notified under the Transparency Directive.

<sup>126</sup> This is subject to a certain freedom granted to pharmacists to supply a drug which appears on Schedule 1 or 2 of The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 in order to satisfy a generic or formula prescription.

<sup>127</sup> SI 2005/641. The corresponding provisions for Wales and Scotland are found in The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulation 2009 (SI 2009/1491); and The National Health Service (Pharmaceutical Services) (Scotland) Regulation 2009 (SI 2009/183) respectively. Similar provision is made for Northern Ireland under the Pharmacy Order (Northern Ireland) 1976 (No.1213 (N.I. 22)), as amended.

<sup>128</sup> [www.rpsgb.org.uk/protectingthepublic/ethics](http://www.rpsgb.org.uk/protectingthepublic/ethics). Also the Code of Ethics for Pharmacists in Northern Ireland, produced by the Pharmaceutical Society for Northern Ireland.

regulatory body for pharmacists in England, Scotland and Wales. Its primary objectives are to lead, regulate, develop and represent the profession of pharmacy.

2.115. Currently, if a branded drug is prescribed (a closed script), that branded drug must be dispensed.<sup>129</sup> If a generic drug or formula is prescribed (an open script), it is permissible to dispense any branded or generic drug that falls within the relevant descriptor. If, in satisfying an open prescription the pharmacist dispenses a branded drug where a cheaper generic could have been dispensed, the pharmacist will only be reimbursed at the Drug Tariff price (minus clawback, see paragraphs 2.121 to 2.125 below) of the generic drug. Where available, pharmacies therefore generally have an incentive to dispense the cheaper generic medicine.

**v) Medicine pricing**

**a) The Pharmaceutical Price Regulation Scheme**

2.116. The PPRS is not a formal regulatory system or binding contract, nor does it control prices directly. Rather, it is a voluntary arrangement between UK health bodies, as represented by the DH, and the pharmaceutical industry, as represented by the Association of the British Pharmaceutical Industry (ABPI).<sup>130</sup> The first of the PPRS schemes came into effect in 1999 under section 33 of the

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<sup>129</sup> In relation to pharmacists, paragraph 8 of Schedule 1 of The National Health Service (Pharmaceutical Services) Regulations 2005 (SI 2005/641), which came into force on 1 April 2005 and replaced The National Health Service (Pharmaceutical Services) Regulations 1992 (S.I. 1992/662 as amended by 1993/2451, 1994/2402, 1995/644, 1996/698, 1998/681, 1998/2224, 1999/696, 1999/2563, 2000/121, 2000/593, 2001/2888, 2002/551, 2002/888, 2002/2016, 2002/2469, 2002/2861, 2003/699, 2003/1084, 2004/922, and 2005/28). Similar provision is made in respect of dispensing doctors.

<sup>130</sup> In the event that agreement cannot be reached voluntarily between the ABPI and DH, a statutory scheme may be imposed. See email from Luisa Stuart (DH) to Geoff Steadman (OFT) dated 11 January 2010 (OFT file part 7 document 5).

Health Act 1999 and since that time the PPRS has been periodically re-negotiated.<sup>131</sup> Between 1957 and 1999, a similar role was performed by the Voluntary Price Regulation Scheme.

2.117. The aims of the PPRS have remained broadly constant throughout the consecutive schemes and are illustrated here by the terms of the 2009 PPRS.<sup>132</sup>

2.118. The principal aim of the PPRS is to strike a balance to ensure that the interests of patients, the NHS, industry and the taxpayer are promoted for each other's mutual benefit.<sup>133</sup> Its objectives are to:<sup>134</sup>

- deliver value for money for the NHS by securing the provision of safe and effective medicines at reasonable prices, and encouraging the efficient development and competitive supply of medicines
- promote a strong and profitable pharmaceutical industry that is both capable of and willing to invest in sustained research and development to encourage the future availability of new and improved medicines for the benefit of patients and industry in this and other countries

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<sup>131</sup> The re-negotiated PPRS schemes came into effect in 2005, 2008 and 2009.

<sup>132</sup> The 2009 PPRS became effective on 1 January 2009 and has a duration of not less than five years (See [www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH\\_091825](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH_091825)). At the time of publication of this Decision the Government is consulting on a proposal that the current scheme be replaced on expiry by a new type of scheme based on the principle of Value-based Pricing.

<sup>133</sup> *The Pharmaceutical Price Regulation Scheme 2009*, paragraph 2.1 [www.dh.gov.uk/dr\\_consum\\_dh/groups/dh\\_digitalassets/documents/digitalasset/dh\\_098498.pdf](http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_098498.pdf)

<sup>134</sup> *Ibid*, paragraphs 2.1.1 to 2.1.4.

- increase uptake and patient access for new clinically and cost-effective medicines in the NHS in a sustainable manner and
- help the NHS and industry develop sustainable financial and investment strategies.

2.119. The scheme comprises two key components which relate to the entire portfolio of branded, licensed medicines (both in- and out-of-patent) sold by a medicines manufacturer to the NHS:<sup>135</sup>

- A profit cap: This is based on a target rate of return<sup>136</sup> and applies to all the branded products sold by a company to the NHS. There are allowances for R&D, marketing and information costs.
- A range of price controls: There is freedom to set the initial price of new active substances (NAS). However, where a new product has not been subject to a NAS marketing authorisation, a company must seek the DH's agreement to the price of the new product. This can include new products regarded by a company as innovative but which are not classified by the MHRA or the EMEA as NASs; combination products containing active substances that have been marketed separately; active substances with new indications; 'complex' branded generics; and variations in formulation, presentation or pack size to

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<sup>135</sup> Further details on the operation of the PPRS can be found in the OFT report on *The Pharmaceutical Price Regulation Scheme*, see in particular Annexes G, H and J ([www.offt.gov.uk/advice\\_and\\_resources/resource\\_base/market-studies/completed/price-regulation](http://www.offt.gov.uk/advice_and_resources/resource_base/market-studies/completed/price-regulation)).

<sup>136</sup> In the 1999 PPRS this was a maximum of 21 per cent return on capital (ROC) and six per cent return on sales (ROS) to the NHS and a minimum of 17 per cent ROC and 4.9 per cent ROS, with a margin of tolerance (MOT) of 50 per cent to 140 per cent of the target level. In the 2005 PPRS it was 21 per cent ROC and six per cent ROS with a MOT of 40 per cent to 140 per cent of target. In the 2009 PPRS it is 21 per cent ROC per year with a MOT of 40 per cent to 140 per cent of that target.

existing products. There are also restrictions on subsequent increases to the list price.

2.120. In respect of non-NAS products, one-off price cuts are periodically agreed at the time of scheme renegotiations. In the 1999 and 2005 PPRS, the cuts were 4.5 per cent and seven per cent respectively. There was no price cut in 2008. The 2009 PPRS provides for two separate price cuts (a price cut of 3.9 per cent in February 2009 and a further price cut of 1.9 per cent in January 2010). Price adjustments apply to all companies with NHS home sales above £5 million in the company's financial year ending in 2007. For companies with NHS home sales of £25 million or less in that year, the first £5 million sales are exempt from the price adjustments. As an alternative to an across the board reduction, it has been an option for scheme members to deliver the price cuts by modulating the prices of some or all of their products covered by the PPRS.<sup>137</sup>

**b) The Drug Tariff**

2.121. The Drug Tariff is produced monthly by the NHS Prescription Services department of the NHS Business Services Authority.<sup>138</sup> It outlines, inter alia, what will be paid to contractors (for example, pharmacists) for reimbursement for the cost of drugs which they have supplied against NHS prescriptions.

2.122. The Drug Tariff provides that reimbursement of drugs supplied under the NHS is calculated on the basis of a 'basic price'. Generic

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<sup>137</sup> However, in the 2009 PPRS this is subject to a number of exceptions, for example: using price reductions that may be necessary as a result of patent or supplementary protection certificate expiry to justify a price increase on other NHS products; and including volumes of sales where the NHS list price of the brand is reduced below the reimbursement price of the equivalent generic, or where additional discounts are offered that result in branded products being dispensed against prescriptions written generically (commonly known as brand equalisation deals).

<sup>138</sup> [www.nhsbsa.nhs.uk/PrescriptionServices.aspx](http://www.nhsbsa.nhs.uk/PrescriptionServices.aspx)



drugs are listed in Part VIII of the Tariff,<sup>139</sup> which is divided into five categories:

- Category A – Drugs which are readily available where the reimbursement price is calculated from a list of its suppliers
- Category B – Drugs for which usage has declined over time
- Category C – Drugs for which the price is based on a particular brand or supplier
- Category E – Extemporaneously prepared items and
- Category M – Drugs which are readily available where the reimbursement price is calculated by DH based on information submitted by manufacturers.<sup>140</sup>

2.123. In respect of drugs not listed in Part VIII (namely branded drugs), the 'basic price' is the PPRS list price.<sup>141</sup>

2.124. The Drug Tariff (notably the Part VIII basic prices (in particular Category M) for England and Wales) is amended periodically (Category M typically quarterly) by DH. These adjustments are made in order that an overall 'retained buying profit' for

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<sup>139</sup> The list of items and pack sizes specified in Part VIII is agreed between DH and the Pharmaceutical Services Negotiating Committee (PSNC).

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[www.nhsbsa.nhs.uk/PrescriptionServices/documents/Drug\\_Tariff\\_Guidance\\_Notes.doc](http://www.nhsbsa.nhs.uk/PrescriptionServices/documents/Drug_Tariff_Guidance_Notes.doc)

<sup>141</sup> This includes 'branded generic' drugs such as Peptac. One of the recommendations of the OFT Market Study report on the PPRS was that 'standard' branded generics be removed from the PPRS and added to Category M. The Government did not implement that recommendation in the 2009 PPRS. It did consult stakeholders on alternative provisions, namely the Generic Substitution initiative which was due for introduction in 2010, but following that consultation it decided in October 2010 not to implement that scheme.

contractors (pharmacists), agreed between DH and the pharmacy sector, represented by the Pharmaceutical Services Negotiating Committee (PSNC), can be achieved.

2.125. Separate tariffs exist for England/Wales, Scotland and Northern Ireland, however the prices set out by DH in Category M of Part VIII of the Drug Tariff are mirrored in Scotland and Northern Ireland.<sup>142</sup>

**c) Brand equalisation deals**

2.126. Brand equalisation deals are a common feature of competition between branded and generic medicines. They are agreements between manufacturers of branded medicines and pharmacies whereby the manufacturer offers the pharmacy a single 'blended' or average price for the supply of an off-patent branded medicine on the condition that that medicine be dispensed against both branded and generic prescriptions. The blended or average price would typically be higher than the price of the competing generic (as listed in the Drug Tariff) but lower than that of the branded product (as constrained by the PPRS). To secure the 'blended' price, pharmacies must purchase an assigned volume of the branded product. Such deals are constructed to provide

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<sup>142</sup> Section 164 of the National Health Service Act 2006 makes provision for the remuneration of those providing pharmaceutical services. Regulation 56 of the National Health Service (Pharmaceutical Services) Regulations 2005 provides for the creation of the Drug Tariff for the determination of payments to pharmacists. In respect of Wales, power to compile the Drug Tariff comes from regulation 18 of the National Health Service (Pharmaceutical Services) Regulations 1992, which makes similar provision to regulation 56 of the 2005 Regulations quoted above. The 1992 Regulations have been repealed in respect of England but remain in force for Wales. In Scotland, Regulation 9 of the National Health Service (Pharmaceutical Services) (Scotland) Regulations 1995, made under section 27 of the National Health Service (Scotland) Act 1978, makes similar provision in respect of Scotland. In respect of Northern Ireland, regulation 9 of the Pharmaceutical Services Regulations (Northern Ireland) provides for the creation and updating of the Drug Tariff. This is done by the Department of Health, Social Services and Public Safety.

pharmacists with an incentive to dispense the branded medicine against a given volume of the generically written open prescriptions that it receives.

**vi) The withdrawal of medicines**

2.127. A manufacturer may wish to withdraw a product from the market for a number of reasons such as changes in medical practice, commercial decisions or problems in obtaining active ingredients. Under Best Practice Guidelines agreed between DH and the ABPI, companies should provide DH with advance notification of such a discontinuation for the purpose of enabling the NHS to begin contingency planning to ensure security of supply and to minimise the impact of the withdrawal on patients.

2.128. The role of DH in the circumstances at issue in this Decision is limited and it has no power to prevent product discontinuations or to take punitive action in the event that it disapproves of a product withdrawal.<sup>143</sup> DH has confirmed to the OFT that its examination of the Withdrawal would have been 'minimal', and that its role 'was essentially to ensure that the pricing of the products (GA and GL) was such that the dosage price would not increase for the NHS'.<sup>144</sup>

2.129. Whilst it is correct that DH may have the power to bring products within the MSLS<sup>145</sup> in some circumstances, it is rare for DH to do this and the circumstances in which it is able to do so are very

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<sup>143</sup> See letter from DH to OFT dated 3 July 2009 (OFT File Part 3, document 47.01). Also, letter from OFT to DH dated 26 June 2009 (OFT File Part 3, document 45.01); email from DH to OFT dated 15 May 2009 (OFT File Part 3, document 14); note of meeting between OFT and DH held on 9 June 2009 (OFT File Part 3, document 33A).

<sup>144</sup> Note of meeting between OFT and DH on 9 June 2009 (OFT file part 3, document 33A).

<sup>145</sup> See paragraph 2.111 above.

specific and are not applicable to the Withdrawal.<sup>146</sup> The criterion used by DH for adding products to the MSLS demonstrates that it could not 'blacklist' any product for non-clinical reasons such as disapproval about a product withdrawal. As set out at paragraph 2.112 above, that criterion is:

'... on expert advice, they had no clinical or therapeutic advantage over other, cheaper, drugs'<sup>147</sup>

## **I. The publication of a generic name for GL**

2.130. This Section presents an overview of the events relevant to the Delay Allegation including extracts of certain documents that are relevant to the intentions behind some of its actions between 2000 and 2006 in relation to the process for developing and publishing a generic name corresponding to GL. The OFT considers that the intentions behind RB's actions in this period represent relevant background and context to the Withdrawal.

2.131. Having received a generic licence for GL in March 1998, Pinewood began production of a therapeutically equivalent product, Acidex/Peptac, for commercial sale in April 1998.<sup>148</sup>

2.132. Following the expiry of the GL patent in 1997, the BPC informed the BNF that it considered it inappropriate to produce a product

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<sup>146</sup> In its SMFI, RB states that Gaviscon Granules and Gaviscon 250 tablets have been blacklisted in the past (see RB SMFI, Annex 3 paragraph 3). However, the inference to be drawn from the source cited by RB (The National Health Service (General Medical Services) Amendment (No 2) Regulations 1993 (SI 1993 No.2421)) is that this occurred at least as long ago as 1993. In addition, RB does not provide any further information or evidence relating to the reasons why these products were blacklisted and in what way those events are analogous to the Withdrawal.

<sup>147</sup> Drug Tariff, Part XVIIIIC – Criteria notified under the Transparency Directive.

<sup>148</sup> Acidex is marketed under the brand name 'Peptac'.

monograph relevant to GL given the perceived need to specify performance measures such as raft performance. In 2000, following lobbying from Pinewood and support from DH,<sup>149</sup> the BNF announced its intention to publish a generic name for GL and equivalent products.

2.133. Between 2000 and 2003, RB made several representations to the BNF, the BPC, the DH and the Medicines Control Agency<sup>150</sup> challenging the right of the BNF to publish a generic name for GL in the absence of a published monograph compiled by the BPC.<sup>151</sup> RB expressed concerns that the BNF's actions constituted the introduction of a new procedure for devising and issuing non-proprietary names but was not accompanied by the appropriate consultation mechanisms. RB also expressed concerns about the possibility of prescriber, dispenser and patient confusion resulting from differences in the various formulations that may be described by the BNF's proposed non-proprietary name.<sup>152</sup>

2.134. The BPC responded to RB by explaining that it had previously considered the feasibility of preparing a monograph applicable to alginate-containing antacid preparations but that it had decided that this was not possible in view of the widely differing compositions and the associated analytical problems. The BPC

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<sup>149</sup> Chronology enclosed with letter dated 9 March 2009 from Pinewood to OFT (OFT file part 2, document 67.02).

<sup>150</sup> Now the MHRA

<sup>151</sup> RB states in its SMFI (Annex 1, paragraph 2) that it became aware of the BNF's intention by chance. See letter from RB to BNF dated 19 January 2000. RB submission of 12 December 2008 in response to the OFT's section 26 notice dated 28 November 2008 (OFT File Part 2, document 9.01).

<sup>152</sup> Letter from RB to BNF dated 23 February 2000. RB submission of 12 December 2008 in response to the OFT's section 26 notice dated 28 November 2008 (OFT File Part 2, document 9.12)

informed RB that the BPC had advised the BNF that it was content for the BNF to adopt generic titles of the style 'Compound Alginate Oral Suspension' in line with the established practices for describing non-pharmacopoeial preparations in the BNF. The BPC noted that although it was no longer seeking to establish a generic name for alginate-based preparations, it did not have jurisdiction over any decisions made by the BNF.<sup>153</sup>

2.135. During that time, RB discussed internally how it should engage with the BNF and other bodies. It determined that its key objective should be that the BNF publication of a generic name be delayed.<sup>154</sup> For example, RB considered whether this could be achieved by initiating legal action shortly before the BNF print deadline.<sup>155</sup>

2.136. Similarly, an internal RB email of 20 January 2000 stated that RB's objective was delaying, for as long as possible, the introduction of a generic name:

'We should remind ourselves what our objective is here ... to delay for as long as possible, the introduction of a generic name and subsequent black listing for Gaviscon while we cannibalise our NHS franchise with Gaviscon Advance.'

2.137. In response to the concerns raised by RB, the BNF took legal advice on whether it had followed suitable procedures prior to announcing its intention to publish a generic name for GL. The BNF

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<sup>153</sup> Fax from BPC to RB dated 25 January 2000. RB submission of 12 December 2008 in response to the OFT's section 26 notice dated 28 November 2008 (OFT File Part 2, document 9.06)

<sup>154</sup> RB submission of 6 March 2009 in response to Q1(i) of OFT section 26 notice dated 14 January 2009, document 15. See also documents 16, 17 and 30.

<sup>155</sup> RB submission of 6 March 2009 in response to Q1(i) of the OFT's section 26 notice dated 14 January 2009, document 11. See also Q1(i) documents 9 and 10.

opted not to publish a generic name pending a review of its process and its right to publish a generic name for GL.<sup>156</sup> The BNF wrote to RB on 2 March 2000 to inform it that 'in view of the concerns that [RB] raised, a title to cover antacid-alginate products will not be introduced into BNF No. 30 (March 2000).' In addition, the BNF informed RB of its decision that titles constructed by the BNF should relate to specific formulae, with active ingredients and amounts being clearly specified, and that it had resolved to take further advice on devising a procedure for the construction of titles which would take into account the need for consultation.<sup>157</sup>

2.138. The plan to delay the publication of a generic name continued to be expanded upon and taken forward by RB staff. Internal RB emails dated 19 March 2001 noted that RB should write to the BPC and discuss RB's intention to work with them on producing a product monograph for GL. The purpose of this was said to be to delay the production of a generic name corresponding to GL by the BNF or subsequently by the BPC. RB set itself the challenge of delaying the granting of a generic name for a further year and it considered making a monograph application to the BPC as a means of achieving this.<sup>158</sup>

2.139. On 28 March 2003, the BNF wrote to the BPC and stated that the 'procedure [for publishing generic names] has now been finalised,

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<sup>156</sup> Chronology enclosed with letter dated 9 March 2009 from Pinewood to OFT (OFT file part 2, document 67.02).

<sup>157</sup> Letter from BNF to RB dated 2 March 2000. RB submission of 12 December 2008 in response to the OFT's section 26 notice dated 28 November 2008 (OFT File Part 2, document 9.15).

<sup>158</sup> RB submission of 6 March 2009 in response to Q1 (ii) of the OFT's section 26 notice dated 14 January 2009, document 22.

having taken into account advice from the BPC, the DH, and most recently, from Counsel.<sup>159</sup>

2.140. On 10 April 2003<sup>160</sup> the BNF wrote to RB (and other interested parties) outlining its new procedures for publishing a generic name, and its intention to publish a generic name applicable to GL and Peptac. RB responded by expressing concerns about the ramifications of this for RB in commercial terms and for the patient in terms of quality, efficacy and safety due to the complex nature of the product.<sup>161</sup> RB also submitted a response to the BNF's consultation, in line with the BNF's deadline, in which RB described its concerns in more detail.<sup>162</sup> Primarily, RB's concerns were that the BNF was undermining the statutory authority of the BPC and of NICE; that the BNF's process was unfair because RB had not been provided with access to the application for a generic name; and that the proposed name presented the potential for clinical confusion.<sup>163</sup> RB again also alerted DH,<sup>164</sup> the MHRA<sup>165</sup> and

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<sup>159</sup> Chronology enclosed with letter dated 9 March 2009 from Pinewood to OFT (OFT file part 2, document 67.02).

<sup>160</sup> RB submission of 6 March 2009 in response to Q1 (i) of OFT section 26 notice dated 14 January 2009, document 150.

<sup>161</sup> Letter from RB to BNF dated 25 April 2003. RB submission of 12 December 2008 in response to the OFT's section 26 notice dated 28 November 2008 (OFT File Part 2, document 9.26).

<sup>162</sup> Letter plus attached submission dated 22 May 2003 from RB to the BNF. RB submission of 12 December 2008 in response to the OFT's section 26 notice dated 28 November 2008 (OFT File Part 2, document 9.35. This document includes a copy of Counsel's advice indicating that RB had grounds for a legal challenge).

<sup>163</sup> Letter plus attached submission dated 22 May 2003 from RB to the BNF. RB submission of 12 December 2008 in response to the OFT's section 26 notice dated 28 November 2008, document 9.35.



the BPC<sup>166</sup> to its concerns and appears to have sought to persuade the BPC to resist the BNF's initiative to produce a generic name.<sup>167</sup>

2.141. By 2003, under the name 'Project Eric', RB had developed its strategic thinking with regard to potential genericisation across several RB healthcare brands, including Gaviscon. Part of the Project Eric strategy was to engage with the BPC and the BNF processes to produce a monograph and a generic name corresponding to GL.<sup>168</sup>

2.142. As set out in an internal RB email dated 17 April 2003 which expanded on the possible options open to RB at that time, the nature of that engagement was stated as being to find ways to 'muddy the waters' in relation to the process:

'We are currently reviewing ERIC which is our Gaviscon generic strategy.

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<sup>164</sup> Letter plus attached submission dated 7 May 2003 from RB to DH. RB submission of 12 December 2008 in response to the OFT's section 26 notice dated 28 November 2008, document 9.29.

<sup>165</sup> RB submission of 12 December 2008 in response to the OFT's section 26 notice dated 28 November 2008 (OFT File Part 2, document 9.32)

<sup>166</sup> Letter plus attached submission dated 9 May 2003 from RB to the BPC. RB submission of 12 December 2008 in response to the OFT's section 26 notice dated 28 November 2008, document 9.30.

<sup>167</sup> Letter plus attached submission dated 9 May 2003 from RB to the BPC. RB submission of 12 December 2008 in response to the OFT's section 26 notice dated 28 November 2008. (OFT File Part 2, document 9.30. See also documents 9.37 and 9.40).

<sup>168</sup> Cover letter to RB submission of 6 March 2009, in response to the OFT's section 26 notice dated 14 January 2009, page 7.

over ½ of our total NHS Gaviscon business is still in constant threat from the potential introduction of a Generic.

...

there is a threat of a generic name as there is a product on the market – Peptac – which is essentially the same as Gaviscon liquid and therefore the BNF are within their rights to consider awarding a generic name for a 'compound alginate oral suspension'. If we were to change the formulation of our current Gaviscon liquid (as above) with the rationale that we were doing so for health and safety reasons ... we could withdraw Gaviscon liquid from sale within the NHS and replace it with the new formulation ... We could potentially apply for a patent on this new formulation and effectively protect all of our Gaviscon liquid business within the NHS for another 20 years.

...

The other, more immediate, option would be to review any formulation changes we have done over the past 20 years to see if there is anything we could do in the short term to muddy the waters in the face of the threat of the BNF proposing that a generic name be granted at anytime.<sup>169</sup>

2.143. On 5 June 2003 Pinewood wrote to the BNF sending copies of letters from companies such as Teva, Lagap<sup>170</sup> and Mawdsleys<sup>171</sup> which each supported the proposed introduction of a non-

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<sup>169</sup> RB submission of 6 March 2009 in response to Q1 (i) of OFT section 26 notice dated 14 January 2009, document 163.

<sup>170</sup> Lagap Pharmaceuticals was a generic pharmaceutical manufacturer. It was acquired by Novartis in 2001.

<sup>171</sup> Mawdsleys is a pharmaceutical wholesaler.

proprietary name for 'Compound Alginate Oral Suspension'.<sup>172</sup>  
Lagap noted that the associated 'saving potential to the UK government ... could be very significant.'<sup>173</sup>

2.144. On 10 June 2003<sup>174</sup> Ged Lee of the BPC wrote to RB to inform it that he had taken note of RB's concerns and would ask the BPC to review its decision on the development of a monograph for alginate suspensions. Dr Lee informed the OFT during its investigation that the BPC was concerned that the proposed BNF name did not adequately define the necessary quality standard.<sup>175</sup>

2.145. On the 18 June 2003 the BNF informed RB<sup>176</sup> (and others) that as a result of the BPC reconsidering its position not to produce a monograph corresponding to Gaviscon it would take no further action on this matter until the BPC had come to a decision. This was expected to be at the meeting of the Commission of 22 September 2003.

2.146. RB's internal documents set out the internal discussions that were then held about what approach RB should take going forward. For example, an internal RB email dated 7 July 2003 acknowledged that RB had achieved its aim of stopping the BNF process by persuading the BPC to agree to re-assess its previous decision not

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<sup>172</sup> Chronology enclosed with letter dated 9 March 2009 from Pinewood to OFT (OFT file part 2, document 67.02).

<sup>173</sup> Chronology enclosed with letter dated 9 March 2009 from Pinewood to OFT (OFT file part 2, document 67.02).

<sup>174</sup> RB submission of 12 December 2008 in response to the OFT's section 26 notice dated 28 November 2008, document 9.37.

<sup>175</sup> Note of meeting between OFT and BPC on 7 April 2009 (OFT File Part 3, document 6).

<sup>176</sup> RB submission of 12 December 2008 in response to the OFT's section 26 notice dated 28 November 2008, document 9.39.

to produce a monograph. It then described a plan to extend the development of a BP name relevant to GL for as long as possible before then withdrawing GL and replacing it with another formulation that is not described by the new generic name:

'what this means for RB is that we are driving for the inevitable granting of a generic name but within a set timetable that we will try and control as far as possible. With this in mind, we need to develop a plan to protect our £9m of Gav liquid NR for when this happens - we are not going to do this by upgrading into GA as we know we have almost come to a grinding halt with upgrades. We need a new plan.

The plan is this – withdraw Gav Liquid from sale within the NHS before the monograph is completed and a BP name is granted and replace it with a new Gav Liquid that has a real consumer/patient benefit (i.e. lower sodium). ... The sooner we do this, the sooner we can ensure that all GL repeat patients are switched and therefore protected.<sup>177</sup>

2.147. In July 2003, as part of Project Eric, RB launched 'Project Atlas', which was a research project aimed at developing a replacement formulation for GL which could be patent protected and which would fall outside the monograph which was being developed for GL.<sup>178</sup>

2.148. In September 2003 the BPC agreed at an internal meeting that it should develop a monograph relevant to Gaviscon and that all relevant manufacturers would be consulted. In October 2003, the BPC confirmed to RB its intention to develop a product monograph

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<sup>177</sup> RB submission of 6 March 2009 in response to Q1(i) of the OFT's section 26 notice dated 14 January 2009, document 218. See also RB submission of 6 March 2009 in response to Q1(vi) of OFT section 26 notice dated 14 January 2009, document 8.

<sup>178</sup> Cover letter to RB submission of 6 March 2009, in response to the OFT's section 26 notice dated 14 January 2009, page 7 (OFT File Part 2a, document 1).

and invited RB to assist the BPC in the development of the monograph.<sup>179</sup>

2.149. The BPC had decided that it was necessary for a monograph for Gaviscon-type alginate products to specify the performance of the 'raft' rather than be defined only according to the specific contents. While such an approach is very rare and had not been considered possible when the BPC had previously contemplated producing a monograph in 1997, the BPC now considered that it had the necessary expertise.<sup>180</sup>

2.150. In response to the BPC's invitation to comment, RB made its initial submission to the BPC in February 2004.<sup>181</sup> In that submission, RB argued for the production of two separate monographs, one that related to the product specification and one that would specify the grade of alginate that could be used in those products.

2.151. In October 2004, the BPC wrote to the relevant manufacturers setting out a draft product monograph.<sup>182</sup> The BPC clarified that it had not been practical to include quantitative test procedures for all the active components in the formulations due to the wide range of products currently available. It stated that the range of different active components used by the various manufacturers would lead to an overly lengthy and cumbersome monograph if tests were included for all of them. The proposed monograph

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<sup>179</sup> RB submission of 12 December 2008 in response to the OFT's section 26 notice dated 28 November 2008 (OFT File Part 2, document 9.41)

<sup>180</sup> Note of meeting between OFT and the BPC of 7 April 2009 (OFT file part 3, document 6).

<sup>181</sup> RB submission of 12 December 2008 in response to the OFT's section 26 notice dated 28 November 2008, document 43.

<sup>182</sup> RB submission of 12 December 2008 in response to the OFT's section 26 notice dated 28 November 2008 (OFT file part 2, document 9.47).

included both alginate compounds (such as Peptac and Gaviscon) and alginate/antacid compounds (such as Rennie Duo). The BPC requested comments from manufacturers on the raft test procedure, the applicability of the proposed limits to their products, and the degree of intra- and inter-batch variability observed for their products.

2.152. At this time RB continued to hold internal discussions relating to its objectives of delaying the publication of the monograph for as long as possible and ensuring that the monograph be as specific as possible, in particular that it excluded GA. Following an internal RB meeting 'to brainstorm the BPC monograph issue', an internal RB email dated 22 November 2004 sets out RB's plan to delay the publication of the monograph and to ensure that GA is excluded from the monograph applicable to GL:

'Our objectives are:

to delay the publication of the monograph for as long as possible.

make the monograph as specific as possible, but at least to have separate monographs for Advance and Liquid'.

2.153. On 6 January 2005, RB submitted its comments on the draft monograph in which it made a number of points.<sup>183</sup> In summary these were:

- there was no BP monograph for a comparably complex area
- the monograph was too broad as it covered drugs with different characteristics, dose regimes and side effects. It could therefore have led to inappropriate prescribing and dispensing.

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<sup>183</sup> RB submission of 12 December 2008 in response to the OFT's section 26 notice dated 28 November 2008, OFT file part 2, document 9.49.

RB said that it was taking legal advice in relation to liability on this issue

- the type and quality of alginate was not specified tightly enough and could lead to safety and efficacy problems. RB recommended that a separate monograph for this active ingredient be published prior to the monograph for 'Alginate Raft Forming Oral Suspension'
- RB strongly recommended that the monograph be limited to the three active ingredients in Gaviscon and its generic equivalents and refer back to the Sodium Alginate BP monograph. RB suggested a meeting to discuss this further
- RB proposed a separate monograph to cover GA as GA does not perform well in a 'raft volume' test (as it has a thinner but stronger raft) and so would weaken the standard required for other alginates. Also, GA contains potassium which is not suitable for some patients. RB also suggested a third monograph to cover other alginate products such as Rennie Duo and
- the raft-forming test was not stringent enough and the key criterion should be raft strength not raft volume. RB recommended a meeting to discuss this further.

2.154. Pinewood also submitted comments to the BPC on 17 January 2005<sup>184</sup> which included points in relation to the raft test procedure and other aspects, some of which were consistent with the arguments submitted by RB to the BPC. In summary:

- the proposed monograph did not define the product in terms of active ingredients

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<sup>184</sup> Letter dated 17 January 2005 from Elizabeth Sullivan (Pinewood) to Stephen Young and Warner Payne (BPC). (OFT File Part 3, document 35.65)

- the proposed monograph would have allowed generic substitution of products that are not 'essentially similar'
- the proposed monograph was not consistent with the BNF's declaration that alginate products are not freely interchangeable
- there were safety concerns in relation to the wide variation of sodium levels in the products included in the monograph
- pinewood suggested tightening the specifications to allow inclusion of only liquid products that are equivalent.

2.155. On 23 June 2005, the BPC wrote to RB setting out the latest draft monograph.<sup>185</sup> The BPC now proposed two monographs,<sup>186</sup> one which related to antacid/alginate compounds (the 'CAAOS' monograph), and another which was relevant only to alginate products, such as Peptac and GL (the 'ARFOS' monograph). By this point, RB had already withdrawn NHS packs of GL (see below), and its primary interest was in ensuring that GA did not fall within the ARFOS monograph (the same monograph as Peptac).<sup>187</sup> This is illustrated by an internal RB email stating the following:

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<sup>185</sup> RB submission of 12 December 2008 in response to the OFT section 26 notice dated 28 November 2008, OFT file part 2, document 9.64.

<sup>186</sup> The BPC reported, at a meeting with OFT during its investigation, that it had become apparent from the comments of all affected manufacturers that the first, all-encompassing, draft monograph was not suitable. The BPC considered that this was because it had rushed the process. See note of meeting between OFT and BPC on 7 April 2009 (OFT File Part 3, document 6)

<sup>187</sup> RB submission of 6 March 2009 in response to Q1(ii) of OFT section 26 Notice dated 14 January 2009, document 288. The BNF has also informed the OFT that RB requested the removal of GL from the BNF in 2005 (see note of meeting between OFT and BNF on 14 January 2009, OFT File Part 2, document 32, paragraph 23).



'We must now do everything in our power to slow down the [Gaviscon] liquid monograph and speed up the [Gaviscon] advance monograph. It is essential to the business that the liquid monograph does not come out before the advance monograph. The best outcome would be to have a generic name for advance before liquid. This would mean that all prescriptions entered in the prescribing databases as Gav, or Gaviscon would default to the advance generic name and only Advance would be dispensable.'

2.156. RB met with the BPC in September 2005 to discuss proposed changes to the draft monograph and to volunteer to produce a third, separate monograph for GA. The BPC then sent a further and 'final' draft ARFOS monograph to RB in May 2006. RB considered that the BPC had made material changes to the draft monograph since its meeting with RB in September 2005 without further consultation with RB. RB's response to this was to threaten judicial review. RB's main arguments were as follows:

- the BPC had failed to adhere to its own processes and to consult RB on material revisions to the draft monograph and
- the proposed monograph could be interpreted as including GA as it was focused on raft performance and did not specify the required ingredients and their quantities. This was inappropriate given the differing safety implications of GA and GL, with the former containing potassium carbonate and the latter containing sodium bicarbonate.

2.157. In response, the BPC agreed to list ingredients in the ARFOS monograph. However, it refused to specify quantities as it considered that to do so may stifle innovative ways of producing the same raft strength with different quantities of the same ingredients. Having obtained the BPC's agreement to list ingredients in the ARFOS monograph, RB did not pursue a judicial review claim, though RB continued to express the view that the finalised monograph was in fact unlawful.

2.158. The final ARFOS monograph was published by the BPC in August 2006.<sup>188</sup> The monograph came into effect on 1 January 2007. The generic name corresponding to ARFOS was subsequently published in the BNF in September 2008.

2.159. Following the publication of the BNF generic name in September 2008, the generic name 'ARFOS Sugar-free' was published on EMIS prescribing software on 30 January 2009 following receipt of confirmation from the Dictionary of Medicines and Devices that this description is valid for prescribing.<sup>189</sup> The name was also added to the Vision software in January 2009. The name has not been added to the eVadis database which supplies the GPass prescribing software.<sup>190</sup>

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<sup>188</sup> The BPC has informed the OFT that it does not consider that the time that it took to publish the ARFOS monograph was atypical. The BPC considers that, to the extent that the monograph was delayed, this was largely the consequence of the BPC itself having initially drafted a monograph that it later thought to be too 'wide' in that it encompassed products that were not sufficiently similar. In this regard, the BPC has stated that it agreed with RB's representations in response to its first draft monograph in relation to the need to define the minimum raft strength as a performance/functionality test in the monograph. (See note of meeting between OFT and BPC on 7 April 2009 (OFT File Part 3, document 6.)

<sup>189</sup> Letter from EMIS to OFT dated 15 January 2010 (OFT file part 7, document 12.01).

<sup>190</sup> Email from the National Information Systems Group (NISG) to OFT dated 4 February 2010 (OFT file part 7, document 33.01). NISG told the OFT that this was because 'a number of issues arose with the generic description to cover the products already on file'. The parent name Compound Alginic Acid Preparations (corresponding to BNF Chapter 1.1.2) continued to be used by eVadis and the term Compound Alginates covers all salts of alginic acid and bicarbonates used with antacids for alginate raft formation.

## **J. The Withdrawal**

### **i) Introduction**

2.160. This Section sets out the discussion and events that are relevant to the Withdrawal.

### **ii) The decision to withdraw GL NHS packs**

2.161. As outlined above, between 2000 and 2004, RB anticipated that a generic name would eventually be published for GL, and therefore considered its best response to that event. RB considered a number of options as strategies that could be implemented to best protect its prescription channel Gaviscon portfolio following the publication of a generic name. Two broad options were:<sup>191</sup>

- to withdraw GL in the hope of forcing GPs to instead prescribe GA
- to replace the existing GL formulation with a new version of GL that would incorporate a patentable patient benefit or, failing that, to at least develop a formulation that would be outside of the monograph (and therefore not described by the associated generic name) that would be developed for the existing GL formulation and therapeutically equivalent medicines such as Peptac.

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<sup>191</sup> Other options included ensuring that a new product monograph for GL included an alginate specification that only RB could match (see, for example, the Slide presentation dated August 2000 – RB submission dated 6 March 2009 in response to Q1(i) of OFT section 26 Notice dated 14 January 2009, document 51 and internal RB email dated 4 September 2000 – RB submission dated 6 March 2009 in response to Q1(i) of OFT section 26 Notice dated 14 January 2009, document 57) and [...] (internal RB email dated 13 May 2004 – RB submission of 6 March 2009 in response to Q1(iii) of OFT section 26 Notice of 14 January 2009, document 28).

2.162. As outlined above, GA was launched in 1997. RB hoped that GA would replace GL as its leading prescription channel alginate product. However, following its launch the growth in sales of GA was slower than RB had hoped.<sup>192</sup> In 2003 RB noted that there was resistance on the part of GPs to using GA and a significant loyalty to GL among GPs.<sup>193</sup> In 2004 GA accounted for around 33 per cent of RB's Gaviscon sales in the prescription channel and GL remained RB's leading prescription channel product, accounting for around 51 per cent of Gaviscon sales.

2.163. In July 2003 RB's internal documents refer to a conclusion that it was not going to be possible to protect the £9 million of GL revenue from the threat of a generic name by 'upgrading into GA' as to do so would risk sales losses to products that were equivalent to the preferred GL formulation, such as Peptac/Acidex.<sup>194</sup>

2.164. RB therefore took the decision to launch Project Atlas. The aims of Project Atlas are set out in detail in RB internal documents such as the New Product Development (NPD) Brief for Project Atlas dated March 2004.<sup>195</sup> First, the NPD sets out the objective, which is to

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<sup>192</sup> Page 5, letter from RB to OFT dated 6 March 2009 (OFT file part 2a, document 1).

<sup>193</sup> See internal RB email dated 10 July 2003 (RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 14, and see also RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 233. In addition, the New Product Development Brief for Project Atlas (RB submission dated 6 March 2009 in response to Q1(vi) of OFT section 26 Notice dated 14 January 2009, document 91) refers to a number of 'blockers' which had to date slowed RB's strategy of 'cannabilsing' GL to GA. These include: '...2) Patients will [...] re Gaviscon Advance.'

<sup>194</sup> Internal RB email dated 7 July 2003 – RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 14.

<sup>195</sup> RB submission dated 6 March 2009 in response to Q1(vi) of OFT section 26 Notice dated 14 January 2009, document 91.

withdraw GL and to 'force' the switching of business to a new product which is not covered by the proposed generic name:

'Project Description: The development of a patented Gaviscon Liquid variant that is essentially similar to current Gaviscon Liquid but differs somehow from the monograph that is currently being developed by the BPC for current Gaviscon Liquid.

The objective of the NPD is to replace/cannibalise all current 500ml Gaviscon Liquid sales (Peppermint and Aniseed) in the NHS with the new patent protected variant. RB will drive this cannibalisation through the withdrawal of the current Gaviscon Liquid SKUs from sale in parallel to the launch of the new SKUs.

In the face of the guaranteed granting of a generic name for the current Gaviscon Liquid formulation through the BPC, our ultimate objective is to force cannibalisation of our exposed NHS business into a protected variant more efficiently than has been achieved since the launch of Gaviscon Advance.'

2.165. The NPD then lists the requirements for success, which are that the replacement is perceived as being an improvement on GL; the timing of publication of the BP monograph is controlled by RB as far as possible to ensure that the new product is introduced before the proposed BP monograph is published; and the new product is excluded from the proposed BP monograph so that no generic name is applicable to it.

'It is ... essential that the new formulation offers both the patient and prescriber a (perceived) benefit over the current formulation. This will (a) ensure that we have a robust rebuttal should the PPRS/DoH question our actions and (b) ensure that we have a positive/flawless promotional message to communicate to prescribers, pharmacists and PCTs.

Other critical dimensions to the project include:

(1) Ensuring that the new formulation is launched a minimum of 6 months prior to the publication of the BP generic name for the original formulation to avoid confusion and ensure a smooth change over on [prescribing] databases and reference publications (for example, BNF/Mims).

(2) Ensuring that this project is aligned with the development of the Monograph to ensure that the new formulation will be completely excluded from the Monograph formulation criteria. ... RB's objectives are to (a) ensure that the barriers to entry/conformity are high to not only exclude Atlas but also all other potential generic competitors who could enter the market and (b) to also work to control the timescales to ensure that it is published at the earliest September 2005.

In summary the Critical Success Factors for the project are:

1. The new formulation complies with the mandatory criteria.
2. The new formulation is patent protected.
3. The communication programme is flawlessly implemented.
4. The timings and entry criteria for the monograph are controlled by RB in line with Atlas'

2.166. By February 2005 RB had abandoned project Atlas having failed to successfully develop a suitable new formulation of GL.<sup>196</sup> At that time, RB expected the generic name to be published in the relatively near future and considered that its 'Generics Defence' included two options. The first of these was to 'fight generic competition using [...]'.<sup>197</sup> The second option was to 'withdraw

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<sup>196</sup> See RB submission of 6 March 2009, in response to Q1(vi) of the OFT's section 26 notice dated 14 January 2009, document 158.

<sup>197</sup> RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 454. See also Q1 (iii) document 77.

Gaviscon Liquid and force a choice between GA and competitors' and to 'implement BEFORE a generic name is granted'.<sup>198</sup>

2.167. Having determined that it was not possible to develop a new formulation of GL that was in accordance with the project Atlas brief, RB chose to pursue the withdrawal of NHS packs of GL and their replacement with GA. The name given to this strategy was project 'White Tiger' and it was carried out in parallel with efforts to ensure that GA was not included within the ARFOS monograph<sup>199</sup> and corresponding BNF descriptor. RB defined the first phase of project White Tiger, implemented in May-June 2005, as 'the proactive withdrawal of GL from the NHS in advance of the anticipated publication of a generic monograph and hence the creation of a generic name'.<sup>200</sup>

2.168. RB's internal presentations summarise the rationale for the Withdrawal as including to prompt switching to the patented GA and to thereby enable RB to 'protect' the GL revenues that would otherwise be exposed to full generic competition following the anticipated publication of a generic name for GL.<sup>201</sup> For example, in a presentation<sup>202</sup> that was provided to RB directors, the background to project White Tiger was presented in two slides as

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<sup>198</sup> RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 454. See also Q1 (iii) document 77.

<sup>199</sup> See paragraph 2.152 above.

<sup>200</sup> RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 55. See also documents 425 and 454.

<sup>201</sup> RB also acknowledged other benefits of Project White Tiger as being to provide a 'viable base to invest for future growth' through related research and development projects, and to preserve much of its specialised workforce for the future growth and development of GA (RB SMFI, paragraphs 2.18 to 2.18(b)).

<sup>202</sup> RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 100.

follows:

'Why are we here?

- BPC are in process of developing Alginate monograph
- Once monograph is issued, generic name is created
- VERY HIGH LIKELIHOOD OF GENERIC NAME BY END 2005
- £10.4m NR [Net Revenue] at risk
- No Generic impact built into 2005 plan
- Business remains highly focused on delaying generic name by all means. Longer the lack of generic name the better for all options

Options to respond to generic name

- Fight generic competition via [...] ...

OR

- Implement Project White Tiger – RECOMMENDED
  - Withdraw Gaviscon Liquid and force a choice between other options ...
  - Must be implemented BEFORE a generic name is granted

(once generic name is granted all Gaviscon scripts become converted to generic name (computer G button and healthcare prescribing targets). Gaviscon Advance scripts would also be converted to generic but only Gav Advance could be dispensed against this until 2016)

2.169. Similarly, a presentation entitled 'Project White Tiger' included the following four slides as part of the agenda item entitled 'What is



Project White Tiger and why are we doing it?':

'The Generic Monograph

- Monographs developed by the British Pharmacopoeia Committee (the BPC)
- They are currently developing a series of Alginate monographs
- Publication of a monograph automatically creates a generic name

The Significance of a Generic name

- Gaviscon Liquid is out of patent
- 'Essentially similar' equivalents exist (Peptac)
- Once a generic name is issued, the GP can write a script for 'Raft Forming Alginates Suspension'
- It is then up to the Pharmacist to dispense whatever he chooses
- Peptac have been waiting for the generic name for eight years

Gaviscon Advance

- Gaviscon Advance is patent-protected until 2016
- Even if a GP writes a GA script generically, only GA can be used to fill it
- Business in GA is therefore protected from Generic competition until patent expiry

Project White Tiger

- In ADVANCE OF the granting of a generic name ....
- Withdraw Gaviscon Liquid 500ml from NHS sales
- Do everything possible to encourage GPs and Pharmacists to upgrade patients to Gaviscon Advance instead.'

2.170. After the Withdrawal had taken place, in a document entitled 'Project White Tiger – Review' dated 16 May 2006, the 'Rationale for Project White Tiger' was described as having been as follows:

'The rationale for Project White Tiger was based on the premise that:

a) The publication of a generic name for Gaviscon is imminent and will happen in 2006. When a generic name is published, GPs will be targeted to write prescriptions generically. The pharmacist can dispense any product which meets the generic descriptor on the prescription, and is motivated to dispense the product which provides the maximum level of profit to the pharmacy,

b) The Gaviscon Advance patent will continue to offer us protection owing to differentiation and publication of separate monographs (if ratified at the BPC meeting)

c) RB needs to maintain control of UK alginates market rather than allow competitors to dictate future of franchise'<sup>203</sup>

2.171. In determining whether to withdraw GL NHS packs, RB was aware that all of its NHS channel sales were generated by GPs who searched for products under the 'Gaviscon' name.<sup>204</sup> Having typed

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<sup>203</sup> RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 427.

<sup>204</sup> See, for example, internal RB email dated 16 February 2005 (RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009,

'Gaviscon' into their IT system and identified both GA and GL, GPs could choose which of those products to prescribe for their patient. RB was also aware that having identified a suitable branded product, GPs are encouraged to then use their 'G' button to identify any therapeutically equivalent generic products, and to provide patients with an open script that includes the applicable generic name and against which a recipient pharmacist could then choose to dispense any applicable product.<sup>205</sup>

2.172. For as long as there was no generic name applicable to GL, GPs who selected GL could not identify products which were therapeutically equivalent to GL such as Peptac by using their 'G' button. RB considered that this inability to identify generic equivalents to GL had assisted greatly in limiting market share losses to therapeutically equivalent products such as Peptac:

'For the past 8 years RB has managed to resist the genericisation of GL past the expiry of its patent in 1997.'<sup>206</sup>

'When GP's press G on their computer no generic name is brought up. This has enabled sales team to keep losses of Rx to Peptac and other generic competitors to below 5 percent of the total alginate scripts.'<sup>207</sup>

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document 70); a draft Product Launch Recommendation document for Project White Tiger, dated January 2005 (RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 55).

<sup>205</sup> RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 425.

<sup>206</sup> New Launch Recommendation Paper for White Tiger dated January 2005, RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 55.

<sup>207</sup> New Launch Recommendation Paper for White Tiger dated January 2005, RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 55.

2.173. RB recognised the significance of GP prescribing software in facilitating generic prescribing and full generic competition. In the context of discussions relating to project Altas, RB had recognised that to protect its portfolio from full generic competition it would be necessary to remove the GL product described by the generic name from GPs' IT systems:

'We need to ensure that every computer prescribing system is altered 100 percent (i.e. The current GL actually wiped off and new GL added). Ensure that the prescribing database companies are very clear that the new GL formulation is different to the BP name when issued.'<sup>208</sup>

2.174. When Project White Tiger was being developed in early 2005, RB considered the effect of the project on GPs' ability to use their prescribing software to identify generic equivalents to Gaviscon products:<sup>209</sup>

'If we do not do White Tiger, when [GPs] type 'Gaviscon' and press the 'G' key, the script will print for Raft Forming Alginate Suspension. It is then the pharmacist's choice to fill it with Gaviscon, Peptac or indeed any reimbursable product which meets the BPC monograph specification.

'If we do implement White Tiger, when they type in 'Gaviscon', the list will bring up the Gaviscon Advance SKUs. If the GP then presses the 'G' button, the script will print for the generic description of Gaviscon Advance, which until the patent expires in 2016 will only be able to be filled with Gaviscon Advance.'

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<sup>208</sup> Internal RB email dated 21 July 2003 (RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 23).

<sup>209</sup> Internal RB email dated 16 February 2005 (RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 70).

2.175. RB considered that by withdrawing GL NHS packs, its Gaviscon portfolio would be protected from 'full' generic competition as GA has no generic equivalent and pharmacies receiving a prescription relevant to GA would not be free to choose to dispense an alternative product:

'The objective would be, effectively to take away the prize from Peptac by withdrawing Gaviscon NHS liquid and forcing GPs to switch their patients over to other products – preferably GA. This would mean that when a generic name was finally published, our remaining GA business would still have no generic equivalent and therefore we would still not suffer from generic substitution of Peptac for Gaviscon.'<sup>210</sup>

2.176. RB was aware that prescriptions written generically would provide pharmacists with a choice of medicines to dispense, and that this choice would facilitate full generic competition and result in a significant downturn in performance for its Gaviscon NHS sales. RB reflected on the threat it faced as being as follows:<sup>211</sup>

'Publication of a Product Monograph for alginates will open up Gaviscon NHS Liquid business to true generic competition. When the GP types Gaviscon and presses the 'Ctrl + G' key, a generic name will be printed on the script. It will then be up to the pharmacist to fill the script with any form of generic Alginate which meets the generic descriptor, usually done based on profit maximisation for the pharmacy. Given this scenario, protection of our business was critical in

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<sup>210</sup> New Launch Recommendation Paper dated January 2005 - RB submission of 6 March 2009, in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 55.

<sup>211</sup> RB submission of 6 March 2009, in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 425.

order to prevent loss of [...] of RB's NHS business in Gaviscon Liquid.'

2.177. RB's concerns that the publication of the generic name would result in significant exposure of GL to competition, and the need therefore to withdraw GL NHS packs before the date on which a generic was published, is outlined in a document attached to an email chain of 13 December 2004:

'After successfully stalling for 8 years, we are finally expecting the granting of the gaviscon generic name. This will be via the publication of the monograph by the BPC. Our best guess is that this will occur between September and December 2005. This will mean that from this date, generic prescribing and substitution of Gaviscon NHS will be possible. This will put at risk the estimated £10.5m of business that we have tied up in Gaviscon Liquid. ... the proposed strategy which has been presented to and broadly accepted (although obviously not finalised) by the exec team, is that we do the following: From at latest June 2005 ... withdraw gaviscon liquid from NHS sale.'<sup>212</sup>

2.178. The project champion for project White Tiger outlined how a specific requirement of the strategy was to ensure that the Withdrawal took place before the generic name was published. A 'key driver' of the decision on when to withdraw GL NHS packs was the outcome of a meeting with the BPC that would enable RB to determine the likely date on which the GL generic name would be published:

'In planning our response to the threat, we have made the following basic assumptions; there will be a generic name by January 2006 at the latest and realistically this may come by

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<sup>212</sup> RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 34.

September 2005. As our plan requires the proactive withdrawal of Gaviscon Liquid before the generic name is granted, there will be an element of calculated risk in our estimation of the best time to implement the withdrawal. The key driver of this will be our meeting with the BPC in February when we will be able to judge when the likely date of publication will be and plan accordingly.<sup>213</sup>

2.179. RB was aware that if GL NHS packs remained in GP's IT systems, repeat prescriptions would be shifted to scripts written generically as soon as a generic name was published:

'Once generic name is granted [...] Gaviscon scripts become converted to generic name – computer G button and healthcare prescribing targets'.<sup>214</sup>

'because the [...] of both new and repeat scripts will be written generically, this means that the sales of the branded [Gaviscon] product will typically experience a [...] decline.'<sup>215</sup>

2.180. The importance to RB of hindering the development of full generic competition, and the need to act before the publication of a generic name, is also illustrated by a paper on Project White Tiger from January 2005, which emphasises that if the Withdrawal is not executed before the publication of the generic name sales of Peptac are likely to increase significantly:

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<sup>213</sup> New Launch Recommendation Paper dated January 2005 - RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 55.

<sup>214</sup> RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 454, p19.

<sup>215</sup> New Launch Recommendation Paper dated January 2005 (RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 55).

'If we do not act Peptac will be in a position to take control of the UK Alginates market and our entire Gaviscon NHS franchise will be under threat. It is imperative that we maintain control of our own destiny and do not allow the competition to dictate the future of one of RB's power-brands.'<sup>216</sup>

2.181. The significance of the timing was known by RB directors. Indeed, an RB director sanctioned the notification of the Withdrawal to DH having received the following advice on the need to ensure it took effect no later than June 2005:

'Delaying White Tiger 1/2/3 months risks not being able to do it at all (as monograph is targeted for production in Sept 2005 although we intend to work on delaying as previously mentioned ... )'.<sup>217</sup>

'UKHC recommendation to implement project White Tiger. Must be implemented before the generic name is granted.'<sup>218</sup>

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<sup>216</sup> New Launch Recommendation Paper dated January 2005 (RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 55).

<sup>217</sup> Internal RB email dated 5 April 2005 - RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 154. See also internal RB email dated 7 July 2003 (RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 6); RB paper attached to internal RB email chain dated 16 March 2005 (RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 99); internal RB email dated 23 March 2005 (RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 123).

<sup>218</sup> Internal RB email from dated 4 April 2005 - RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 154.



2.182. Similarly, an internal RB email dated 28 July 2005 confirms that RB Directors were aware that the Withdrawal needed to take place before the publication of a generic name to successfully 'pre-empt' the threat of full generic competition by ensuring that GL prescriptions had been transferred to GA in advance of the generic name publication:

'transfer Liquid Gaviscon prescriptions in the UK to Gaviscon Advance prescriptions to pre-empt generic threat'<sup>219</sup>

2.183. RB also considered it necessary to withdraw GL NHS packs sufficiently in advance of the introduction of a generic name in order to present the Withdrawal credibly to DH (see also paragraphs 2.195 to 2.217 below):

'The DoH and to some extent GP's themselves – are sensitive to the issue of patent management by pharmaceutical companies. They take a very dim view of what they see as efforts to manipulate the patent system, which they consider has the effect of defrauding the NHS by reducing levels of generic prescribing. For this reason, it is critical that we make the withdrawal at least three months before the granting of the generic name, and provide a convincing rationale for doing so that is of benefit to the NHS.'<sup>220</sup>

2.184. At the time of the Withdrawal, GL remained RB's most popular prescription alginate based product (GL accounted for 45.2 per

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<sup>219</sup> RB submission of 6 March 2009 in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 375.

<sup>220</sup> New Launch Recommendation Paper dated January 2005 (RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 55).

cent<sup>221</sup> of its prescription channel sales (by value) compared to GA's share of only 38 per cent).<sup>222</sup>

2.185. In 2005, in the context of the discussions surrounding project White Tiger, RB was aware that [...] was likely to mean that the Withdrawal would result in some GPs and PCOs identifying products such as Peptac as the chosen alternative to GL, such that the Gaviscon share of the prescription market would fall overall. This point is highlighted in an internal RB email exchange dated 15 February 2005.<sup>223</sup>

'Of Gaviscon Liquid Rx, [...] percent is repeat and [...] percent is New Start.

We have assumed that the [...] percent New Start business will simply transfer to Gaviscon Advance.

Of the [...] percent of business in Repeats, we have assumed that we will lose [...] percent. This loss due to a variety of factors:

- GP's getting angry and switching their repeat patients away from Gaviscon
- PCTs becoming concerned about possible rising Rx costs and directing GPs to Rx Peptac instead.'

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<sup>221</sup> RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 99.

<sup>222</sup> RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 454.

<sup>223</sup> Internal RB email dated 15 February 2005 - RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 69.

2.186. The share losses that RB anticipated as a consequence of the Withdrawal varied during the course of the discussions prior to the Withdrawal itself. The envisaged value share losses ranged from a [...] loss to Peptac<sup>224</sup> (although this was in the context of a paper designed to reassure RB sales staff) to a worst case scenario that would see a [...] per cent loss of cash turnover.<sup>225</sup> RB's working assumption was that share losses of around [...] per cent would be incurred through a [...] per cent loss of repeat prescriptions.<sup>226</sup> An RB Director approved project White Tiger on the understanding that on withdrawing GL NHS packs the Gaviscon share of prescription channel alginates sales would suffer an estimated [...] per cent loss in repeat prescriptions.<sup>227</sup>

2.187. In line with the [...] market share losses that RB anticipated, RB was also expecting the Withdrawal to lead to a decrease to its revenues and profitability when compared with (i) RB's budgeted performance for 2005 and (ii) RB's forecasted performance had GL NHS packs been retained until the anticipated date on which the generic name for GL would be published.

2.188. During the development of project White Tiger and in advance of the Withdrawal, RB's working assumption, communicated to RB directors, was that the Withdrawal would result in a £[...] decrease in annual net revenue and a £[...] decrease to annual operating

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<sup>224</sup> Internal RB email and QA paper dated 23 May 2005 - RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 267.

<sup>225</sup> Internal RB email dated 3 March 2005 - RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 151.

<sup>226</sup> RB's share loss forecasts were determined as a proportion of alginate sales in the NHS prescription channel.

<sup>227</sup> RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 144.

profit versus the budgeted performance for 2005.<sup>228</sup> It was also on the basis of these forecasts that an RB Director approved project White Tiger and the Withdrawal:

'UKHC recommendation to implement project White Tiger. Must be implemented before generic name is granted. Therefore unbudgeted hit of £[...]m top and £[...]m bottom line for business in 2005. This is right for long term health of business but causes pain because not budgeted in first year'.<sup>229</sup>

2.189. Forecasts that compared the financial implications of withdrawing or retaining NHS packs of GL anticipated that, prior to the forecast generic name publication date, withdrawing GL NHS packs would generate lower revenues and profits than retaining them. This is illustrated by the graph below, which was included in an internal RB presentation and which provides a comparison of the forecasted impact on RB's net revenue (NR) and operating profit (COP) of withdrawing or retaining GL NHS packs:<sup>230</sup>

[...]

2.190. Inevitably, there was uncertainty as to the actual impact that the Withdrawal would have on RB's performance and various possible

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<sup>228</sup> RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 430 (p.59, slide 56324). See also Q1(iii), document

<sup>201</sup> See also Q1(iii), document 412 – p28; Q2, document 5, Q2 document 35 and Q2, document 36.

<sup>229</sup> Internal RB email dated 4 April 2005 - RB submission of 6 March 2009 in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 154. See also Q1(iii), documents, 69, 82, 92, 144, 148 and White Tiger monitoring documents, eg Q1(iii), document 312.

<sup>230</sup> RB submission of 6 March 2009, in response to Q3 of the OFT's section 26 notice dated 14 January 2009, document 36.

outcomes were therefore mooted in RB's internal documents.<sup>231</sup> The White Tiger 'project champion' considered that the impact on cash turnover could vary greatly, but considered that even the 'best case' would see an [...] per cent decrease:

'Best case is that we lose [...] percent of cash turnover – i.e. [...] percent of bottle volumes – on an ongoing basis. Worst case is that we lose [...] percent of cash turnover – i.e. [...] percent of bottle volumes – on an ongoing basis.'<sup>232</sup>

2.191. As illustrated by the projections outlined above, and by the following quote from an internal RB email, RB expected that the share losses that would be suffered immediately after the Withdrawal would be sustained, and that its market share would essentially stabilise at this new level.

'We believe that all the losses will be over with the first six months of implementing the project. Once the hit is taken, that's it and the business will stabilise at its new level'.<sup>233</sup>

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<sup>231</sup> See, inter alia, internal RB email dated 13 December 2004 (RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, documents 34); Slides attached to internal RB email dated 2 March 2005 (RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 77). Only one individual suggested that the Withdrawal could make economic sense were it not for the threat of full generic competition. She could not 'quite believe I'm saying this' and noted that the forecast gains were as a consequence of [...]. Her estimates were not referred to anywhere else in the 454 documents provided in response to Q1(iii) of the section 26 notice dated 14 January 2009. Email from [...] dated 31 March 2005 - RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 143.

<sup>232</sup> Internal RB email dated 4 March 2005 - RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 151.

<sup>233</sup> Internal RB email dated 16 February 2005 - RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 70 page 2, see also Q2, document 4 and Q2, document 6. See also internal RB email

2.192. In the 454 documents<sup>234</sup> provided in response to the OFT's request for documents relevant to the Withdrawal, RB did not seek to estimate or quantify any efficiency savings that would see the Withdrawal generate improvements in profitability, revenues or market share in the longer term, or that would enable it to grow revenues and share more effectively in the medium and long term. The information communicated to an RB Director, and which informed that Director's approval of the Withdrawal, made no reference to the value and/or likelihood of longer terms benefits (other than those linked to hindering the development of full generic competition).<sup>235</sup>

2.193. RB invested resource in assessing the extent to which the performance of its NHS Gaviscon business would benefit from the Withdrawal versus a situation under which GL NHS packs had remained available as a prescription medicine. In a presentation entitled 'Healthcare Europe', which was attached to an internal RB email dated 26 May 2006,<sup>236</sup> RB reflected on the expected returns that RB had associated with the retention or withdrawal of GL NHS packs under the assumption of a generic name being published in late 2005. RB's forecast was that between 2005 and 2009 the Withdrawal would deliver incremental net revenue of £[...] and an incremental operating profit of £[...] versus the

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dated 4 March 2005, RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009 document 151, and the references to the market share losses taking place on 'an ongoing basis'.

<sup>234</sup> Contained in RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009.

<sup>235</sup> Internal RB email dated 4 April 2005 - RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 154.

<sup>236</sup> RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 430, p 21.

returns that would be generated if GL NHS packs had been retained. Whereas RB considered that withdrawing GL NHS packs would enable it to preserve a significant market share at prevailing price levels, it expected the retention of GL NHS packs to result in [...] share losses and the need to offer [...] price discounts to compete effectively.

2.194. The 'full agreement that White Tiger is right for the business' was reached on 18 March 2005 in a meeting of RB directors. The 'meeting agreements' were documented in an internal RB email dated 18 March 2005. The documents refer to the Withdrawal as being the best way to protect RB from full generic competition, and that it will involve RB in suffering revenue and profitability decreases versus its budgeted performance (which was based on the assumption that no generic name would be published in 2005):

'Project White Tiger is right for the business long term as it protects and leaves RB with viable NHS base from which to invest vs a year on year decline from generic erosion. Best case estimate is that full generic name will be granted Jan 2006.

'Full agreement that we must implement White Tiger in 2005 before a generic name is granted. Unbudgeted impact of this decision in 2005 is £[...]m top and £[...]m bottom line. All key assumptions were discussed and agreed.

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'Business will continue to place max focus on strategies to delay generic name in the interim ... best for all scenarios'<sup>237</sup>

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<sup>237</sup> RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 123.

**iii) RB's presentation of the Withdrawal to stakeholders**

2.195. RB's concerns about the potential reaction of patients and GPs to withdrawing GL NHS packs from the prescription channel led it to seek advice on the presentation of the Withdrawal from specialist consultants, including 'the leading industry consultant on DOH/PPRS management'<sup>238</sup> and an independent healthcare consulting company described as 'RB's Crisis Management PR agency'.<sup>239</sup>

2.196. RB's 'Crisis Management PR agency' produced a discussion document in February 2005. This analysed the feasibility of Project White Tiger, with particular emphasis on communications risks and potential strategies to resolve these. The PR agency agreed with RB's assessment that to withdraw a leading product would be regarded as unusual if not unique, and that that strategy was therefore 'high risk', and considered that presentation of the Withdrawal was therefore 'critical' to its success:

'Our understanding is that removing from NHS lists an apparently effective, market-leading product which is trusted by GPs and patients alike is a very unusual, if not unique, course of action. This must therefore by its very nature be a high-risk strategy – the reaction to which is difficult to judge given the lack of precedent. The positioning of the change is therefore critical.'

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<sup>238</sup> From an internal RB slide presentation 'White Tiger PR Assessment' presented to an RB director, copy circulated within RB on 17 June 2005 – RB submission dated 6 March 2009 in response to Q1 (iii) of OFT section 26 Notice dated 14 January 2009, document 348, p 13. See also document 379.

<sup>239</sup> Ibid.



'alginates represent a very effective and 'cheap' therapy for many mild gastric conditions, costing the NHS overall only £25m per year ... For this reason, they are popular both with GPs and NHS officials, and as such, any changes to the 'brand leader' will command considerable attention.'<sup>240</sup>

2.197. In discussing this as an issue that 'must be addressed in the communications', RB's PR agency also observed that the Withdrawal was unlikely to be well received by patients or GPs.<sup>241</sup>

'This is not a simple replacement/updating decision. Gaviscon Liquid is not being withdrawn – it will still be available OTC via both pharmacy and grocery outlets (GA will in future be prescription only). This however could potentially undermine the core positioning for the change which is to provide a better solution to patients at no extra cost; instead, providing a source of criticism, and be seen as a somewhat cynical act on the part of RB to force frequent Gaviscon Liquid users, who might previously have got it free on prescription, to pay for the product. Had this rather been a simple 'new/improved' replacement, patients would have been forced to get used to GA or to move to a competitor product.'

And:

'GPs as a group tend to be set in their ways and to dislike change or confusion over remedies which they have prescribed successfully for many years – and may resent the fact that RB is forcing them to rethink their decisions here. Currently the system makes Gaviscon Liquid an easy and

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<sup>240</sup> Discussion document dated 22 February 2005 – RB submission dated 6 March 2009 in response to Q1 (iii) of OFT section 26 Notice dated 14 January 2009, document 74.

<sup>241</sup> Ibid (both quotations).

natural choice – once the monograph is introduced then even the prescribing of Gaviscon Advance will require some additional action– there is therefore a strong chance that GPs will go with the generic option and the 'sale' will be lost to RB completely. In addition they [the GPs] are the front line when it comes to dealing with the patients who are uncomfortable with the change – again potentially giving them additional 'hassle'.'

2.198. Internal RB documents record that RB and its advisers concluded that attempting to justify the timing of the Withdrawal on the basis of a business rationale alone would be risky. With the assistance of RB's PR agency, a series of communications plans were devised, in which various explanations for the Withdrawal were prepared and tailored in respect of the different sets of stakeholders.

2.199. Given the sensitivity around how the Withdrawal should be presented publically, RB instructed those staff responsible for outlining the rationale of the Withdrawal to RB sales teams and externally not to refer to the protection of the Gaviscon brand against generic competition in anticipation of the imminent production of a generic name. For example, an internal RB PowerPoint slide presentation on Project White Tiger circulated on 2 March 2005 contained a slide entitled 'Public positioning of White Tiger' which noted:

'NO MENTION TO BE MADE OF GENERIC NAME DRIVER TO ANY AUDIENCE OUTSIDE OF CORE PROJECT TEAM'<sup>242</sup>

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<sup>242</sup> Internal RB email dated 2 March 2005, and attached slide presentation market 'White Tiger PR Assessment' – RB submission dated 6 March 2009, in response to Q 1(iii) of OFT section 26 Notice dated 14 January 2009, document 77. See also Q1(iii), document 246.

2.200. The OFT has identified from RB's internal documents and external correspondence with stakeholders a number of reasons that were given externally in support of the Withdrawal and its timing:

- It had always been RB's intention to convert sales of GL to the NHS into sales of GA. The timing was influenced by the fact that RB had recently completed its range of GA products (including tablets), which made it a good time to rationalise the brand completely and make a separation between the OTC and NHS businesses.
- As the second generation product that was superior (provided a stronger and longer-lasting barrier to acid reflux) RB wanted GA to be the sole preserve of GPs and the NHS.
- GA was lower in sodium than GL, and therefore had safety advantages in relation to, for example, patients with dyspepsia or hypertension.
- The Withdrawal would assist prescribers as under the current system it was often difficult for a GP to ascertain whether new patients had previously tried GL or GA, and therefore to know whether this may be an appropriate first step before moving to more expensive options such as PPIs.

2.201. Internally, RB also considered whether it could be argued that by making each set of products only available in a particular channel, the Withdrawal would help to eliminate the apparently fraudulent dispensing of OTC GL packs against prescriptions. However, the OFT understands that RB did not present this argument to external stakeholders.<sup>243</sup>

2.202. In a letter dated 6 March 2009 in response to a section 26 Notice from OFT dated 14 January 2009, RB stated that it chose to

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<sup>243</sup> RB SMFI, paragraph 2.23

withdraw GL NHS packs following the completion of its GA range and as part of its plan to replace GL with GA:

'At the same time as the withdrawal of the 500ml presentation of Gaviscon Liquid, RB introduced a 250ml presentation of Gaviscon Advance. In 2004, Gaviscon Advance tablets had been introduced for NHS prescription. The availability of a superior product in a full range of preparations and sizes for NHS prescribers, as well as the ongoing intention to achieve conversion of Gaviscon Liquid prescriptions into Gaviscon Advance prescriptions as part of a normal lifecycle management strategy formed part of the rationale for the withdrawal of Gaviscon Liquid by RB.'<sup>244</sup>

2.203. In its letter of 11 April 2005 to the DH formally announcing the date of the Withdrawal, RB explained its rationale as follows:

'As we now have a complete range of presentations and flavours available within the Gaviscon Advance® range, we have decided to rationalise the Gaviscon® brand completely to make a clear separation between the OTC and NHS businesses.

We plan to remove Gaviscon® Liquid 500ml from distribution from NHS sale from 4th June 2005, leaving doctors the simple choice of prescribing either Gaviscon Advance® liquid or tablets to meet the clinical needs of prescription patients on Alginate therapy.'<sup>245</sup>

2.204. RB also advanced a separate, though related, argument that the Withdrawal was executed to provide GPs with exclusive access to

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<sup>244</sup> OFT File Part 2a, document 1.

<sup>245</sup> Letter dated 11 April 2005 from RB to DH – RB submission dated 12 December 2008 in response to OFT section 26 Notice of 28 November 2008, OFT file part 2, document 9.56.

GA. The argument was made by RB's PR agency in a section of its discussion document (see paragraph 2.196 above) entitled 'Positioning/Initial Key Messages'. It noted:

'This change [the Withdrawal] means that the most advanced, effective product in the Gaviscon range will be available exclusively to the NHS – where it belongs; while the old established product continues to be available OTC.'<sup>246</sup>

2.205. An internal RB email exchange dated 15 February 2005, on the same subject, had noted that this rationale would be presented to a number of key stakeholders:<sup>247</sup>

'Communication plan/PR

As outlined in the launch paper, the basis of our story is that we are undertaking a strategic realignment to ensure that the NHS has the exclusive benefit of the most up-to-date alginate formulation, at no additional cost per dose. We will be promoting this message to all key target audiences as outlined in the attached communications grid.'

2.206. RB's internal documents indicate that this argument was not regarded by RB as a material factor in the decision to withdraw GL NHS packs, and was to be presented to stakeholders such as DH as a way of helping to divert attention away from the actual

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<sup>246</sup> Discussion document dated 22 February 2005 – RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 74. See also slide presentation in Q1(iii), document 263, p 17 and Q&A in Q1 (iii), document 272, p5. See also (i) the Q & A document for pharmacists – RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 notice dated 14 January 2009, document 450, p3 and (ii) the 'Pro-forma' letter, plus supporting documents, from RB dated 16 March 2005 – RB submission dated 12 December 2008 in response to OFT section 26 Notice dated 28 November 2008, document 58.

<sup>247</sup> Ibid.

rationale of pre-empting the publication of a generic name. For example, in an internal RB email exchange on 16 February 2005 in response to the question 'why do we need to withdraw Gaviscon Advance 150, 300, 600?' is the following reply:<sup>248</sup>

'Because to make the story to the DOH credible (i.e. strategic alignment of brands), we need to phase out Gaviscon Advance OTC within 12 months. NB that there will be no 2005 P&L impact as we will advise the DOH we have legally binding commercial supply contracts which will prevent us withdrawing before 2006.'

2.207. Although stakeholders were to be told that GA would be the exclusive preserve of GPs, RB's plan was that it would in fact be subsequently retained within the OTC sector albeit under the new brand name 'Gaviscon Extra Strength'. For example, an internal RB email dated 4 April 2005 notes:

'One key point we do need to firm up is what we say about OTC. As we discussed in the meeting, it is of major importance that we are able to tell GPs that the Gaviscon Advance brand will be theirs and theirs alone in the relatively near future, whilst avoiding issues among our Pharmacy customers. As I understand it the current plan is that we will re-badge OTC Advance to Extra Strength within 12 months – I have therefore reflected this timeline (although not the full plan) in the statement'<sup>249</sup>

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<sup>248</sup> Internal RB email exchanges dated 15 and 16 February 2005 – RB submission dated 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 70.

<sup>249</sup> Internal RB email dated 4 April 2005 – RB submission dated 6 March 2009 in response to Q1 (iii) of OFT section 26 notice of 14 January 2009, document 148. See also (i) internal RB email dated 8 April 2005 (RB submission dated 6 March 2009 in response to Q1 (iii) of OFT section 26 Notice dated 14 January 2009, document 175)

2.208. After the Withdrawal, OTC packs of GA were not in fact withdrawn or re-branded.<sup>250</sup>

2.209. RB also considered an argument that, because GA and GL were sold in both the OTC and prescription channels, this was giving rise to the fraudulent dispensing of OTC packs against an NHS prescription whereby pharmacists were over-reimbursed by the NHS as a result of claiming that they had fulfilled prescriptions with OTC stock. This point was presented in RB's PR agency's 'Positioning/Initial Key Messages' as follows:

'The clear positioning of Gaviscon Advance in the NHS only, and Gaviscon Liquid in OTC also ensures that there can be no opportunity for fraud in prescription fulfilment. There have been cases in the past where, with medicines available both as pharmaceutical supplies and OTC, pharmacists could charge the NHS for 'additional' product by supplying prescriptions from OTC supplies.'<sup>251</sup>

2.210. In the internal documents provided by RB in which the Withdrawal is considered, the concern is mentioned only as a possible external justification and is not in fact presented externally. The documents make no reference to RB having sought to measure the detriment caused by this problem, or to having considered whether it would merit the withdrawal of its leading NHS channel alginate product.

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and (ii) the RB submission dated 6 March 2009 in response to Q1 (iii) of OFT section 26 Notice dated 14 January 2009, document 70.

<sup>250</sup> Annexe 2 of RB submission dated 10 December 2009, in response to questions 3 and 4 of the section 26 request dated 24 November 2009 (OFT file part 6, document 105A.02).

<sup>251</sup> Discussion document dated 22 February 2005 – RB submission dated 6 March 2009 in response to Q1 (iii) of OFT section 26 Notice dated 14 January 2009, Document 74.

2.211. Prescribing data indicates that prescriptions of OTC GL continued or even increased as a consequence of the decision to withdraw it as a prescription medicine. This is reflected in RB internal documents, for example an internal RB email dated 4 April 2006 which notes that:<sup>252</sup>

'6.4% of scripts are still being written for Gaviscon original, 32% of these scripts are being filled with 500ml according to the IMS data, and the remainder are being filled with OTC packs, mainly 600ml, which is used to fill 47% of the scripts...'

with the result that:

'On an MAT basis there has been a £1.2m increase in the value of OTC packs that are being dispensed against Gaviscon prescriptions.'<sup>253</sup>

2.212. To seek to persuade stakeholders that the Withdrawal was favourable, RB sought to stress the benefits of GA versus GL. A key part of the messages to stakeholders was that GA had considerably less sodium than GL. For example, the March 2005 Q&A for GPs and Pharmacists stated:

'What are the benefits of Gaviscon Advance over Gaviscon?

... Gaviscon Advance contains 63% less sodium than Gaviscon Original.'<sup>254</sup>

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<sup>252</sup> Internal RB email dated 4 April 2006 – RB submission dated 6 March 2009 in response to Q1 (iii) of OFT section 26 Notice dated 14 January 2009, document 413.

<sup>253</sup> Ibid.

<sup>254</sup> Draft RB internal document entitled 'White Tiger Q&A' dated 17 March 2005 – RB submission dated 6 March 2009 in response Q1 (iii) of OFT section 26 Notice dated 14 January 2009, document 109.



2.213. Internal RB documents nevertheless suggest that for a small minority of patients GA would be unsuitable because of its potassium content, in the same way as GL's sodium content might make it unsuitable for others.<sup>255</sup>

2.214. Despite the apparent benefits of GA, RB did not withdraw GL from the OTC channel and was in fact considering [...]<sup>256</sup>

2.215. In the 'Overall White Tiger Message' document the following reason is given as an additional rationale for splitting Gaviscon into two channels:

'Gaviscon's unique positioning as a successful brand both OTC and NHS has created some significant challenges for the NHS.

Firstly, when making an Rx decision for a GORD patient, it is often difficult for a GP to ascertain whether the patient has previously tried Gaviscon [GL] or Gaviscon Advance, and therefore to know whether this may be an appropriate first step before moving to more expensive options such as PPIs.<sup>257</sup>

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<sup>255</sup> Internal RB email dated 26 August 2003 – RB submission dated 6 March 2009 in response to Q1(vi) of OFT section 26 Notice dated 14 January 2009, document 38, which states: 'One word of caution on the proposed sodium/potassium bicarbonate mix is that it is not just patients on dialysis who would be affected, but potentially patients taking antihypersensitive drugs such as ACE inhibitors. Some databases and prescribing advisers already suggest that patients on ACEs should not take Gav Advance because of its potassium content.'

<sup>256</sup> See, for example, RB submission dated 6 March 2009 in response Q1(i) of OFT section 26 Notice dated 14 January 2009, document 311. This project [...]

<sup>257</sup> Internal RB email exchanges dated 15 and 16 February 2005 – RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 69.

2.216. There is very little indication elsewhere in RB's papers that this was an issue for GPs and the NHS before the Withdrawal.

2.217. It is also apparent that RB's overall strategy would have exacerbated this problem rather than helped to solve it. As outlined above, as part of the Withdrawal process (and contrary to its statement to stakeholders such as DH) RB was planning to 're-badge' GA as Gaviscon Extra Strength in the OTC channel. This would have meant that when a patient visited a GP, they would have been even less clear as to whether they had tried GA, having been sold it under a different brand name.

**iv) The process of withdrawing GL NHS packs**

2.218. Despite GL's position as RB's leading alginate product in the NHS prescription channel and RB's assessment that withdrawing GL NHS packs would result in a decrease to its market share and prompt a negative response from patients and GPs, RB chose to make arrangements to withdraw NHS packs of GL in June 2005.

2.219. As noted in paragraph 2.203 above, on 11 April 2005 Britannia Pharmaceuticals, on behalf of RB, wrote to DH to inform it of the intention to withdraw and de-list GL NHS packs. Britannia stated that GL NHS packs were being withdrawn following the launch of GA tablets and the completion of the GA portfolio, and with a view to ensuring less confusion for GPs and patients:

'As we now have a complete range of presentations and flavours available within the Gaviscon Advance® range, we have decided to rationalise the Gaviscon® brand completely to make a clear separation between the OTC and NHS businesses. ... This rationalisation will be less confusing for both doctors and patients and will clearly differentiate the OTC and Rx brand.

'All existing patients on Gaviscon® tablets or liquid will be able to be switched to Gaviscon Advance® products easily

and we will be carrying out and [sic] educational and informational programme to assist all concerned.

'Costs to the NHS will be neutral as Gaviscon Advance<sup>®</sup> is priced pro rata to Gaviscon Liquid, dose for dose. At the same time we will also launch a 250ml bottle of Gaviscon Advance<sup>®</sup> (in both flavour variants) which we intend to price at £2.70, equivalent to one month's supply of current Gaviscon Liquid<sup>®</sup> 500ml. We would kindly like you to approve our launch price proposal. ...

'... As we will be operating to a planned schedule, I would be grateful if we could receive your approval by the end of April.'<sup>258</sup>

2.220. DH responded as follows:

'I can confirm that our records have been updated with respect to the discontinuation of Gaviscon Liquid 500ml and your proposed price of Gaviscon Advance 250ml (£2.70) which is acceptable to the Department'.<sup>259</sup>

2.221. DH has since confirmed to the OFT that its examination of the Withdrawal would have been 'minimal', and that its role 'was essentially to ensure that the pricing of the products (GA and GL)

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<sup>258</sup> Letter dated 11 April 2005 from Britannia Pharmaceuticals to DH (RB submission of 12 December 2008 in response to OFT section 26 notice dated 28 November 2008, OFT file part 2 document 9.56).

<sup>259</sup> Letter dated 25 April 2005 from DH to Britannia Pharmaceuticals Limited (RB submission of 12 December 2008 in response to OFT section 26 notice dated 28 November 2008, document 57).

was such that the dosage price would not increase for the NHS'.<sup>260</sup>

2.222. RB also wrote to companies that supply and/or update the prescription software used by GPs to inform them of the Withdrawal and to advise them to reflect this in their databases. RB wrote a standard letter to the software companies. The letter to Multilex<sup>261</sup> noted simply:

'This is to advise you that RB is making the following changes to its product portfolio and your records will therefore require updating accordingly.

The following products will be withdrawn from sale as of 4th June 2005:

Gaviscon Liquid Aniseed 500ml

Gaviscon Liquid Peppermint 500ml'<sup>262</sup>

2.223. Although NHS presentation packs were withdrawn, in its SMFI RB states that GL remains available for prescribing in OTC packs (150ml, 300ml and 600ml).<sup>263</sup> EMIS and GPass have confirmed that certain OTC medicines are listed on GP prescribing software. However, a note is raised in respect of these products to alert the GP to the fact that the medicine is available only in OTC

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<sup>260</sup> Note of meeting between OFT and DH on 9 June 2009 (OFT file part 3, document 33A).

<sup>261</sup> Multilex is a drug database which supplies prescribing software companies.

<sup>262</sup> Letter from RB to First Databank Europe Ltd. - RB submission dated 6 March 2009, in response to Q 1(iii) of OFT section 26 Notice dated 14 January 2009, document 270.

<sup>263</sup> RB SMFI, paragraph 2.3

presentation packs.<sup>264</sup> From 1 July 2005, DH added the 600ml OTC pack of GL to the Drug Tariff at Part VII.<sup>265</sup> This allows for proportional reimbursement by reference to that pack size in accordance with clause 8C of the Tariff, at the manufacturer's list price for the pack.<sup>266</sup> However, whilst it is possible for GPs to prescribe OTC packs of GL, OFT analysis of data retrieved from the websites of NHS Information Centres in England, Scotland, Wales and Northern Ireland shows that GPs use this option to a limited extent only.<sup>267</sup>

**v) RB's assessment of the success of the Withdrawal**

2.224. RB's internal documents from the period following the Withdrawal confirm that, at the time of the Withdrawal, RB's expectation remained that the Withdrawal would result in its share and performance declining. Indeed, the extent of this performance decline represented the benchmark against which the 'success' of project White Tiger was then assessed. For example, in a presentation entitled 'Project White Tiger Review' dated 23 March 2006, a graph was presented that concluded that the total Gaviscon share of alginate prescriptions had 'as predicted' fallen

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<sup>264</sup> See note of telephone conversation between OFT and EMIS dated 7 January 2010 (OFT File Part 7, document 2A), and note of telephone conversation between OFT and GPass dated 11 January 2010 (OFT File Part 7, document 7.01).

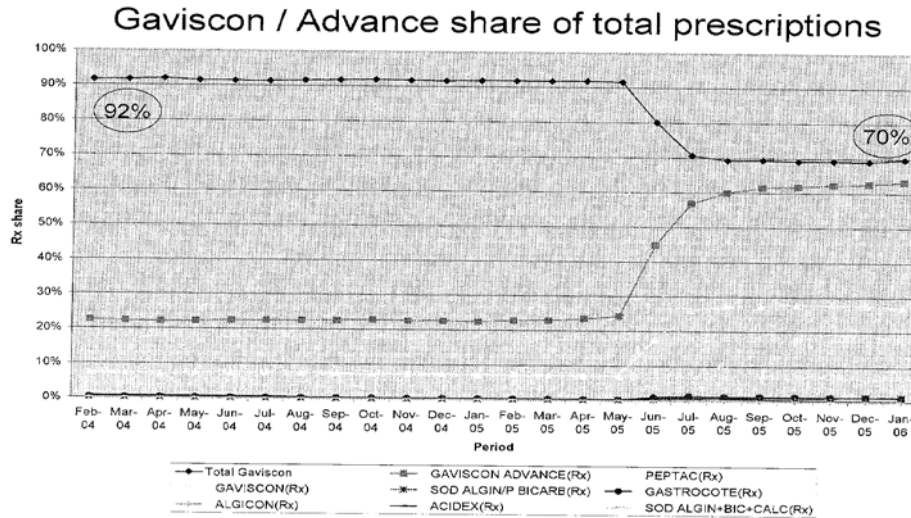
<sup>265</sup> See sub-section H(iv)(b) below for further details on the Drug Tariff.

<sup>266</sup> RB SMFI, footnote 7 (paragraph 2.3)

<sup>267</sup> In 2004, before the Withdrawal, 74 per cent of all liquid Gaviscon (GL and GA) packs prescribed were GL. After the Withdrawal, in 2006, only nine per cent of liquid Gaviscon scripts were written for GL (the figures when accounting for the double concentration or half-dosage volume of GA are correspondingly similar at 54 per cent and four per cent respectively).

from a stable 92 per cent between February 2004 and May 2005, to a stable 70 per cent between July 2005 to January 2006.<sup>268</sup>

**Figure 2.3: RB's reflection on its predicted share losses (by volume) following the Withdrawal<sup>269</sup>**



- As predicted, share loss from WT
- Last 2 periods showing slight upward trend

Source: Xponent Fastrack data to Jan 06

2.225. The same presentation indicates that this share loss was expected to result in a fall in net revenues from £[...] in 2004, to £[...] in 2005 and to an anticipated £[...] in 2006. Product contribution was also expected to decline from £[...] in 2004, to £[...] in 2005, and to £[...] in 2006.<sup>270</sup>

<sup>268</sup> Internal RB slide presentation circulated on 16 March 2006 - RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 404, p7.

<sup>269</sup> Ibid

<sup>270</sup> Ibid, (slide 57056), p 15.

2.226. When assessing the success of project White Tiger in 2006, RB's internal documents do not consider whether any efficiency gains had been realised and whether they may eventually justify the share, revenue and profitability decline suffered by RB after the Withdrawal. Rather, RB assessed the share losses suffered and concluded that the Withdrawal was justified only as it enabled RB to earn greater returns than it expected to realise when faced with full generic competition.<sup>271</sup>

2.227. Internal RB documents that are dated after the Withdrawal measure the success of project White Tiger by reference to RB's ability to hinder the development of full generic competition, and its ability to ensure that it was not disclosed as the actual rationale of the Withdrawal. In an internal slide presentation which appears to date from early 2006 (in a slide entitled 'White Tiger Implementation Update') one of RB's measures of success was as follows:<sup>272</sup>

'No mention of generic name as motivator for withdrawal'

2.228. In another internal slide from the same presentation RB concluded:<sup>273</sup>

'In retrospect was WT [White Tiger] still the right thing to do?'

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<sup>271</sup> RB submission of 6 March 2009 in response to Q2 of the OFT's section 26 notice dated 14 January 2009, document 24.

<sup>272</sup> Internal RB slide presentation – (2005 – exact date uncertain) - RB submission dated 6 March 2009 in response to Q1(i) of OFT section 26 Notice dated 14 January 2009, document 267,p2.

<sup>273</sup> Internal RB slide presentation – (2005 – exact date uncertain) - RB submission dated 6 March 2009 in response to Q1(i) of OFT section 26 Notice dated 14 January 2009, document 267, p 15.

**YES – [...] proportion of Gaviscon protected from generic threat...**

**...[...] of Liquid business on generic name publication likely to have been even more swift and complete than anticipated.'**

[Emphasis in original]'



### 3 LEGAL BACKGROUND

#### A. Introduction

3.1. This Part sets out the legal framework within which the OFT has considered the evidence presented in this Decision:

- Section B covers the Chapter II prohibition and the application of section 60 of the Act (consistency with European Union law).
- Section C covers the application of Article 102 TFEU.
- Section D sets out the relevant case law in relation to the concept of an 'undertaking' and attribution of liability for infringements and includes the OFT's consideration of these issues in this case.
- Section E deals with dominance and market definition.
- Section F sets out the concept of abuse and the relevant framework for assessing abuse.
- Section G covers effect on trade within the UK and between Member States.
- Section H covers the burden and standard of proof.

3.2. The legal provisions prohibiting an abuse of a dominant position are contained in section 18(1) of the Act and Article 102 TFEU<sup>274</sup> (formerly Article 82 of the EC Treaty). Both provisions are relevant to this case, by reason of *Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on*

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<sup>274</sup> The Treaty of Lisbon (OJ C306, 13 December 2007), which came into force on 1 December 2009, amended the *Treaty Establishing the European Community* (EC Treaty) which has been renamed the *Treaty on the Functioning of the European Union* (TFEU).

*competition laid down in Articles 81 and 82 of the Treaty*<sup>275</sup> ('the Modernisation Regulation') and the *Competition Act 1998 and Other Enactments (Amended) Regulation 2004*.<sup>276</sup> The relevant parts of both provisions are therefore set out below.

## **B. The Chapter II prohibition**

### **i) General**

3.3. Section 18(1) of the Act imposes the Chapter II prohibition<sup>277</sup> which provides that any conduct on the part of one or more undertakings which amounts to the abuse of a dominant position in a market is prohibited if it may affect trade within the United Kingdom (the UK).<sup>278</sup>

3.4. Section 18(2) of the Act lists some types of conduct that the prohibition is aimed at preventing.<sup>279</sup> However, the list is illustrative only and not exhaustive; the Chapter II prohibition can apply to conduct not specifically listed.

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<sup>275</sup> OJ L1, 4 January 2003, p1.

<sup>276</sup> SI 2004/1261.

<sup>277</sup> The Chapter II prohibition does not apply in cases in which it is excluded pursuant to section 19 of the Act. None of the excluded cases are applicable in respect of the infringement that is the subject of this Decision.

<sup>278</sup> 'United Kingdom' in section 18 means the UK or any part of it (section 18(3) of the Act).

<sup>279</sup> Section 18(2) states that conduct may constitute an abuse of a dominant position if it consists, in particular, in: '(a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions; (b) limiting production, markets or technical development to the prejudice of consumers; (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of the contracts'.

3.5. In order to find an infringement of the Chapter II prohibition, the OFT must establish that:

- at the time of the alleged infringement the undertaking held a dominant position within the UK or any part of it
- the undertaking abused that dominant position, and
- such abuse may have affected trade within the UK or any part of it.

**ii) Application of Section 60 – consistency with European Union law**

3.6. Section 60(1) of the Act sets out the principle that, so far as is possible (having regard to any relevant differences between the provisions concerned), questions arising in relation to competition within the UK are to be dealt with in a manner which is consistent with the treatment of corresponding questions arising in European Union (EU) law in relation to competition within the EU. In particular, under section 60(2) of the Act, the OFT must act (so far as is compatible with the provisions of the Act) with a view to ensuring that there is no inconsistency with the principles laid down by the TFEU and the European Courts<sup>280</sup> and any relevant decision of the European Courts. In addition, under section 60(3) of the Act, the OFT must have regard to any relevant decision or statement of the European Commission (the Commission).

3.7. Article 102 TFEU is the provision in EU competition law equivalent to the Chapter II prohibition. Accordingly, the interpretation of Article 102 TFEU in the case law of the European Courts is

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<sup>280</sup> The European Courts means the Court of Justice of the European Union (formerly the European Court of Justice (ECJ)) and the General Court (formerly the Court of First Instance (CFI)). In the remainder of this Decision, references to the decisions of the ECJ and CFI (which were renamed following the entry into force of the Treaty of Lisbon (OJ C306, 13 December 2007) on 1 December 2009) are referred to respectively as decisions of the Court of Justice and General Court.

relevant when applying the Chapter II prohibition. This is independent of the OFT's separate duty to apply Article 102 TFEU in the present case, as to which see paragraphs 3.8 to 3.10 below.

### **C. Application of Article 102 TFEU**

- 3.8. Article 102 TFEU prohibits, as incompatible with the common market, any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it, insofar as it may affect trade between Member States.
- 3.9. Since the entry into force of the Modernisation Regulation on 1 May 2004,<sup>281</sup> the OFT is required to apply Article 102 TFEU in addition to the Chapter II prohibition if an abuse of a dominant position 'may affect trade between Member States'.<sup>282</sup>
- 3.10. Since the conduct that is the subject of this Decision occurred after 1 May 2004, the OFT considers that it is under an obligation to apply Article 102 TFEU if RB's conduct 'may affect trade between Member States'. The OFT sets out the principles relevant to the determination of this question below at paragraphs 3.57 to 3.66 and sets out its conclusions at Part 7 of this Decision. As set out there, the OFT considers that RB's conduct fulfils this criterion, and thus that Article 102 TFEU is applicable in the present case.

### **D. Relevant case law in relation to 'undertaking'**

#### **i) The notion of an undertaking**

- 3.11. The Chapter II prohibition and/or Article 102 TFEU apply to conduct on the part of one or more 'undertakings'. In order to

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<sup>281</sup> Article 45 of the Modernisation Regulation.

<sup>282</sup> Article 3 of the Modernisation Regulation.

demonstrate that there has been an infringement, it is therefore necessary to establish that RB is an undertaking.

3.12. The term 'undertaking' is not defined in the Act or in the TFEU. It is a wide term that the Court of Justice has held to cover 'every entity engaged in an economic activity, regardless of the legal status of the entity and the way in which it is financed'.<sup>283</sup>

3.13. Accordingly, the key consideration in establishing whether an entity is an undertaking is whether it is engaged in 'economic activity'. The Court of Justice has defined 'economic activity' broadly as activity 'of an industrial or commercial nature' consisting in offering 'goods and services' on a given market.<sup>284</sup>

3.14. The term 'undertaking' therefore includes any natural or legal person that is capable of carrying on commercial or economic activities.

3.15. The OFT considers that both Reckitt Benckiser Healthcare (UK) Limited and its parent company Reckitt Benckiser Group plc are engaged in an economic activity and constitute undertakings for the purposes of the Act and the TFEU.

## ii) **Attribution of liability for infringements**

3.16. Since Reckitt Benckiser Healthcare (UK) Limited was directly involved in the conduct that is the subject of this Decision, as per the relevant case law,<sup>285</sup> liability for the resulting infringement, and

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<sup>283</sup> Case C-41/90 *Höfner and Elser v Macroton* [1991] ECR I-1979, paragraph 21.

<sup>284</sup> Case C-118/85 *Commission v Italy* [1987] ECR 2599, paragraph 7.

<sup>285</sup> Case C-279/98 P *Cascades v Commission* [2000] ECR I-9693, at paragraph 78; Case 286/98P *Stora Kopparbergs Bergslags v Commission* [2000] ECR I-9925, paragraph 37; Case C-248/98P *KNP BT v Commission* [2000] ECR I-9641, at paragraph 71; Case C-297/98 P *SCA Holding v Commission* [2000] ECR I-10110, paragraph 27.

the consequential financial penalty that the OFT has imposed, has been attributed to it.

- 3.17. Where a parent company exerts decisive influence on the policy of a subsidiary such that the latter does not enjoy real autonomy in determining its own course of action on the market, liability may be attributed to the parent company for the actions of the subsidiary.<sup>286</sup> As recently confirmed by the Court of Justice in *Akzo Nobel*,<sup>287</sup> the exercise of decisive influence can be presumed where a subsidiary is wholly owned by its parent. The burden then shifts to the parent to adduce evidence capable of rebutting the presumption by proving that the subsidiary acted autonomously.
- 3.18. Indicia of decisive influence other than the parent's shareholding in the subsidiary can also be relied on.<sup>288</sup> Such indicia have been found to include a parent being active on the same or adjacent markets to its subsidiary,<sup>289</sup> direct instructions being given by a

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<sup>286</sup> Case 48/69, etc., *ICI v Commission* [1972] ECR 619, at paragraphs 130 onwards; Case 107/82 *AEG v Commission* [1983] ECR 3151 paragraphs 47 onwards; and Case 286/98 P *Stora Kopparbergs Bergslags v Commission* [2000] ECR I-9925, paragraphs 26-29.

<sup>287</sup> Case C-97/08P *Akzo Nobel NV v. Commission*, 10 September 2009. See also *Durkan Holdings Limited and others v Office of Fair Trading* [2011] CAT 6, paragraph 22(a).

<sup>288</sup> Case C-97/08P *Akzo Nobel NV v. Commission*, paragraphs 60 to 62; Case C-286/98 P *Stora Kopparbergs Bergslags AB v Commission* [2000] ECR I-9925, paragraphs 23 and 27-29; Case 107/82 *AEG-Telefunken v Commission* [1983] ECR 3151. See also *Durkan Holdings Limited and others v Office of Fair Trading* [2011] CAT 6, paragraphs 31 to 92.

<sup>289</sup> Opinion of Advocate-General Mischo in Case C-286/98 P *Stora Kopparbergs Bergslags AB v Commission* [2000] ECR I-9925, paragraph 49.

parent to a subsidiary<sup>290</sup> or the two entities having shared directors.<sup>291</sup>

- 3.19. It should also be noted that the Court of Justice has recently confirmed that events such as organisational changes should not enable liability for competition law breaches to be evaded.<sup>292</sup> Where the original legal entity responsible for an infringement no longer exists, it is necessary to consider whether there is functional and economic continuity between the original entity and any new entity into which it may have merged.<sup>293</sup> This involves considering whether the physical and human assets which were responsible for the infringement have been acquired by another entity.<sup>294</sup>
- 3.20. In light of the above, as Reckitt Benckiser Healthcare (UK) Limited is a wholly owned subsidiary of Reckitt Benckiser Group plc (and until 2007 its predecessor, Reckitt Benckiser plc),<sup>295</sup> the OFT has presumed that Reckitt Benckiser Group plc exercised decisive influence over its subsidiary and is therefore also liable for the conduct of its subsidiary.

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<sup>290</sup> Case T-48/69 *ICI Ltd v Commission* [1972] ECR I-619, paragraphs 132-133.

<sup>291</sup> *Sepia Logistics Limited v OFT* [2007] CAT 13, paragraphs 77 to 80.

<sup>292</sup> Case C-280/06 *Autorita Garante della Concorrenza e del Mercato v Ente Tabacchi Italiani – ETI SpA and Philip Morris* [2007] ECR I-10893, paragraphs 41 and 43.

<sup>293</sup> Commission decision in *PVC*, OJ L74, 17 March 1989, pages 1-20; Joined Cases C-40/73 and others *Suiker Unie v Commission* [1975] ECR 1663, paragraphs 75-87.

<sup>294</sup> See, for example, Case T-6/89 *Enichem Anic v Commission* [1991] ECR II-1623, paragraphs 237-239 and *C-297/98 P SCA v Commission* (above), paragraphs 24-28.

<sup>295</sup> Reckitt Benckiser plc was formed when Reckitt & Colman plc merged with Benckiser N.V. in 1999.

3.21. Moreover, in this regard it is relevant that the evidence seen by the OFT demonstrates the involvement of senior management including members of the Board and/or Executive Committee of Reckitt Benckiser Group plc (and its predecessor, Reckitt Benckiser plc) in the decision making process relevant to the conduct which forms the subject matter of this Decision (see paragraphs 2.181 to 2.194 above).

3.22. Financial penalties that are imposed both on a parent and subsidiary may be imposed jointly and severally.<sup>296</sup> Accordingly, the OFT has attributed liability to both Reckitt Benckiser Group plc and Reckitt Benckiser Healthcare (UK) Limited on a joint and several basis for the infringement and for the resulting financial penalty that the OFT has imposed.

## **E. Dominance**

### **i) Market definition**

3.23. Market definition provides a framework for competition analysis and is a key step in identifying any competitive constraints that an undertaking may face. For the purposes of the Chapter II prohibition and/or Article 102 TFEU, the OFT will not consider an undertaking to be dominant unless that undertaking has substantial market power.<sup>297</sup> The definition of the relevant economic market(s) in which an undertaking operates is usually the first step in assessing whether that undertaking has market power.<sup>298</sup>

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<sup>296</sup> Cases 6 & 7/73 *Commercial Solvents* [1974] ECR 223, at paragraph 41; *Pre-Insulated Pipe Cartel* OJ 1999 L24/1; Case T-9/99 R *HFB Holdings v Commission* [2002] ECR II 1487, paragraphs 522 to 532 and paragraphs 54 to 68; upheld on appeal, Case C-189/02 P etc. *Dansk Rørindustri A/S v Commission* [2005] ECR I-5425, paragraphs 103 to 130.

<sup>297</sup> See *Abuse of a Dominant Position* (OFT402), paragraph 4.11.

<sup>298</sup> See *Market Definition* (OFT403), paragraph 2.1.



3.24. The relevant market typically has two dimensions: the relevant goods or services (the product market) and the geographic extent of the market (the geographic market).<sup>299</sup> The OFT's assessment of the relevant market definition in this case is set out in Part 4 of this Decision.

**ii) Definition of dominance**

3.25. The Court of Justice defined a dominant position as:

'a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers'.<sup>300</sup>

3.26. The Court of Justice also held that:

'such a position does not preclude some competition ... but enables the undertaking which profits by it, if not to determine, at least to have an appreciable influence on the conditions under which ... competition will develop, and in any case to act largely in disregard of it so long as such conduct does not operate to its detriment'.<sup>301</sup>

3.27. As stated above, the OFT will not consider an undertaking to be dominant unless that undertaking has substantial market power. Market power is not an absolute term but a matter of degree, and

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<sup>299</sup> The OFT's approach to market definition is set out in the competition law guideline *Market definition* (OFT403), which follows a similar approach to that of the European Commission as set out in the *Commission Notice on the definition of the relevant market for the purposes of Community competition law* (OJ 1997 C372/5).

<sup>300</sup> Case 27/76 *United Brands v EC Commission* [1978] ECR 207, paragraph 2.

<sup>301</sup> Case 85/76 *Hoffmann-La Roche v Commission* [1979] ECR 461, paragraph 39.

the degree of market power held by an undertaking will depend on the circumstances of each case.

- 3.28. In assessing whether an undertaking has substantial market power within the relevant market, the OFT will first consider market shares. There are no market share thresholds for defining dominance, nor can an undertaking's market share, on its own, determine whether that undertaking is dominant. However, market shares are an important factor in assessing dominance, and the Court of Justice has stated that dominance can be presumed, in the absence of evidence to the contrary, if an undertaking has a market share persistently above 50 per cent.<sup>302</sup>
- 3.29. In addition to the market share of the undertaking suspected of holding a dominant position, the OFT will consider the position of other undertakings operating in the same market and how market shares have changed over time.<sup>303</sup> An undertaking is more likely to be dominant if its competitors enjoy relatively weak positions or if it has enjoyed a high and stable market share.<sup>304</sup>
- 3.30. The OFT will also consider the extent to which an undertaking faces competitive constraints. Important constraints include the presence of actual or potential competitors, including the relative strength of those competitors, and barriers to entry. Other factors such as strong buyer power from the undertaking's customers can also be relevant. The OFT will consider evidence from all indicators in the round when assessing market power.<sup>305</sup>

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<sup>302</sup> Case C62/86, *AKZO Chemie BV v Commission* [1993] 5 CMLR 215. See also *Assessment of Market Power* (OFT415), paragraph 2.12.

<sup>303</sup> See *Assessment of Market Power* (OFT415), paragraphs 3.3.

<sup>304</sup> *Ibid*, paragraph 4.2.

<sup>305</sup> The OFT's approach to assessing dominance is set out in more detail in its competition law guideline *Abuse of a dominant position* (OFT402).

3.31. The OFT's assessment of dominance in this case is set out in Part 5 of this Decision.

## **F. Abuse**

### **i) The concept of Abuse**

3.32. The holding of a dominant position is not in itself prohibited under section 18(1) of the Act and/or Article 102 TFEU. It is the abuse of a dominant position which is prohibited. As pointed out by the Court of Justice in *Michelin v Commission*:

'A finding that an undertaking has a dominant position is not in itself a recrimination but simply means that, irrespective of the reasons for which it has such a dominant position, the undertaking concerned has a special responsibility not to allow its conduct to impair genuine undistorted competition on the common market.'<sup>306</sup>

3.33. The Court of Justice has also held that the actual scope of the special responsibility imposed on a dominant undertaking must be considered in the light of the specific circumstances of each case.<sup>307</sup>

3.34. The Court of Justice has defined the concept of an abuse as:

'an objective concept relating to the behaviour of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to

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<sup>306</sup> Case 322/81 *Michelin v Commission* [1983] ECR 3451, paragraph 57. See also Case T-228/97 *Irish Sugar v Commission* [1999] ECR II-2969, paragraph 112.

<sup>307</sup> Case C-333/94 P *Tetra Pak v Commission* [1996] ECR I-5951, [1997] 4 CMLR 662, paragraph 24.

methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance or the degree of competition still existing in the market, or the growth of that competition'.<sup>308</sup>

- 3.35. The Chapter II prohibition and/or Article 102 TFEU list examples of abuses that are prohibited but this list is illustrative and not exhaustive. The Chapter II prohibition and/or Article 102 TFEU apply equally to conduct not specifically listed where that conduct has the potential to exploit customers or exclude competitors from the market. For example, the Court of Justice held in *Compagnie Maritime Belge*:<sup>309</sup>

'It is settled case-law that the list of abusive practices contained in Article 86 of the Treaty is not an exhaustive enumeration of the abuses of a dominant position prohibited by the Treaty (Case 6/72 *Europemballage and Continental Can v Commission* [1973] ECR 215, paragraph 26). It is, moreover, established that, in certain circumstances, abuse may occur if an undertaking in a dominant position strengthens that position in such a way that the degree of dominance reached substantially fetters competition (*Europemballage and Continental Can*, paragraph 26)'.<sup>309</sup>

- 3.36. To establish an abuse, it is necessary to take account of whether the dominant undertaking has had recourse to methods different from those which condition normal competition and whether that

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<sup>308</sup> Case 85/76 *Hoffmann-La Roche v Commission* [1979] ECR 461, paragraph 91. This passage has since often been cited in the European Courts and in the Competition Appeal Tribunal (CAT). For example, see *Genzyme v Office of Fair Trading* [2004] CAT 4, paragraphs 482 to 485; *Napp v Director General of Fair Trading* [2002] EWCA 796, paragraphs 23 to 27.

<sup>309</sup> Joined Cases C-395/96 P and C-396/96 P *Compagnie Maritime Belge Transports SA v European Commission*, [2000] ECR 2000 Page I-01365, paragraphs 112 - 113.

conduct has the effect of weakening or distorting competition. For example, in *Aberdeen Journals* the Competition Appeal Tribunal ('CAT') stated that:<sup>310</sup>

'the question of whether a certain pricing practice by a dominant undertaking is to be regarded as abusive for the purposes of the Chapter II prohibition is a matter to be looked at in the round, taking particularly into account (i) whether the dominant undertaking has had 'recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators' [...]; and (ii) whether such conduct has the effect of weakening or distorting competition in the relevant market, having regard to the special responsibility of a dominant firm not to impair genuine undistorted competition'.

3.37. In its judgment 1 July 2010 in *AstraZeneca*<sup>311</sup> the General Court confirmed that the abuse of a dominant position can include misleading regulators and misusing regulatory procedures. The Commission described the second abuse in that case as concerning AZ's 'misuse of government procedures'<sup>312</sup> by its 'requests to the public authorities to deregister the marketing authorisations'.<sup>313</sup> It held that the use of public procedures and regulations, including administrative and judicial processes, may, in specific circumstances, constitute an abuse, as the concept of

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<sup>310</sup> *Aberdeen Journals Ltd v Office of Fair Trading* [2003] CAT 11, paragraph 350.

<sup>311</sup> Case T-321/05 *AstraZeneca v Commission*. OJ C 221/33, judgment of 1 July 2010, currently under appeal before the Court of Justice of the European Union (Case C-457/10 P, *AstraZeneca v Commission*, pending).

<sup>312</sup> Commission Decision 15 June 2005 - Case COMP/A. 37.507/F3 *AstraZeneca* [2006] 5 CMLR 287 (*AstraZeneca* decision), paragraph 817.

<sup>313</sup> *Ibid*, paragraph 819.

abuse is not limited to behaviour in the market only and misuse of public procedures and regulations may result in serious anticompetitive effects on the market.<sup>314</sup>

3.38. In addition, due to the 'special responsibility' incumbent on dominant firms not to allow their behaviour to impair genuine undistorted competition on the market, conduct which may be permissible in a normal competitive situation may amount to an abuse if carried out by a dominant firm.<sup>315</sup> Therefore an undertaking in a dominant position may be deprived of the right to adopt a course of conduct or take measures which would be unobjectionable if adopted or taken by non-dominant undertakings.

**ii) Legal framework for assessing abuse**

**a) Introduction**

3.39. This Section sets out the legal framework within which the OFT has assessed RB's conduct in Part 6 of this Decision. The assessment of whether the conduct of a dominant undertaking amounts to an abuse requires the consideration of (i) whether the relevant conduct constitutes competition on the merits, and (ii) whether it tends to restrict competition on a relevant market.

**b) Competition on the merits**

3.40. It is well established in the case law that a dominant undertaking must not resort to methods falling outside 'competition on the merits' and must not adopt a strategy of using its economic strength and/or strong existing market position to impair undistorted competition, including that competition which still remains in the market or the growth of that competition in

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<sup>314</sup> Ibid, paragraph 328.

<sup>315</sup> Case T-203/01 *Michelin v Commission* [2003] ECR II-4071.

future.<sup>316</sup> Therefore, by its nature, the application of the Chapter II prohibition and/or Article 102 TFEU involves the assessment of whether the individual behaviour of a dominant firm deviates from 'normal' or 'fair' or 'undistorted' competition, or from 'competition on the merits'.

3.41. To determine whether a dominant undertaking has had 'recourse to methods different from those which condition normal competition', it is relevant to consider the rationale for the dominant company's conduct. For example, in *AKZO*<sup>317</sup> (in the context of a predation case) the Court of Justice stated that, as a general rule, pricing below average variable cost ('AVC'), by means of which a dominant undertaking seeks to eliminate a competitor, must be regarded as abusive, since it would not normally be commercially rational for an undertaking to price at levels that did not even cover AVC.

3.42. The General Court recently emphasised in *AstraZeneca* the importance of 'competition on the merits' in determining whether conduct by a dominant undertaking that tends to exclude competitors is abusive.<sup>318</sup> Upholding the Commission's approach, the General Court ruled that:

'whilst the fact that an undertaking is in a dominant position cannot deprive it of its entitlement to protect its own commercial interests when they are attacked [...], it cannot use regulatory procedures in such a way as to prevent or make more difficult the entry of competitors on the market,

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<sup>316</sup> See, for example, Case 85/76 *Hoffmann-La Roche v Commission* [1979] ECR 461, paragraph 91.

<sup>317</sup> Case C-62/86 *AKZO Chemie v Commission* [1993] 5 CMLR 215, paragraphs 71 and 72.

<sup>318</sup> Case T-321/05 *AstraZeneca v Commission*, paragraph 812. See also paragraphs 672, 675, 804, 816 and 817.

in the absence of grounds relating to the defence of legitimate interests of an undertaking engaged in competition on the merits or in the absence of objective justification.<sup>319</sup>

- 3.43. The second abuse at issue in *AstraZeneca* involved AZ's withdrawal of its marketing authorisations<sup>320</sup> (at the expiry of the relevant exclusivity period<sup>321</sup>) for the capsule form of its Losec product, thereby precluding competitors from relying on the documentation in AZ's marketing authorisation dossier to obtain generic marketing authorisations through the abridged procedure, as well as the ability of parallel importers to obtain import licenses.
- 3.44. The Commission found that AZ's conduct infringed Article 102 TFEU. It accepted that pharmaceutical law did not prevent the holder of a marketing authorisation from withdrawing that authorisation, and stated that 'single acts involving the launch, the withdrawal or request for deregistration of a pharmaceutical product would not normally be regarded as an abuse'<sup>322</sup> thereby reaffirming the principle of commercial freedom. However, as AZ had adopted an exclusionary strategy involving requests for selective deregistration of marketing authorisations for reasons unrelated to interests protected by the legislation, such conduct could not be deemed as normal competition or reasonable steps to protect the dominant undertaking's own commercial interests.<sup>323</sup>

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<sup>319</sup> Case T-321/05 *AstraZeneca v Commission*, paragraph 672. See also paragraphs 675, 804, 812, 816 and 817.

<sup>320</sup> See footnote 77 above.

<sup>321</sup> See footnote 76 above.

<sup>322</sup> *AstraZeneca* decision, paragraph 792.

<sup>323</sup> *Ibid*, paragraph 821.



## Intent

3.45. The establishment of an abuse does not require the finding of intent. The General Court ruled in *AstraZeneca* that:

'proof of the deliberate nature of the conduct and the bad faith of the undertaking in a dominant position is not required for the purpose of identifying an abuse of a dominant position.'<sup>324</sup>

3.46. The General Court however continued by stating that:

'[this] does not lead to the conclusion that the intention to resort to practices falling outside the scope of competition on the merits is in all events irrelevant, since that intention can still be taken into account to support the conclusion that the undertaking concerned abused a dominant position, even if that conclusion should primarily be based on an objective finding that the abusive conduct actually took place.'<sup>325</sup>

3.47. The General Court therefore acknowledged that evidence of a dominant undertaking's intent could serve a useful role in confirming the abusive nature of the conduct. Accordingly, intention may be a relevant element in assessing whether behaviour amounts to an abuse, since intent evidence can inform an assessment of whether conduct is objectively without merit.

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<sup>324</sup> Case T-321/05 *AstraZeneca v Commission*, paragraph 356.

<sup>325</sup> Case T-321/05 *AstraZeneca v Commission*, paragraphs 359. See also paragraphs 814 and 849. See also, Case 27/76 *United Brands v Commission* [1978] ECR 207, paragraph 189.

3.48. In its Guidance on Article 102 TFEU,<sup>326</sup> the Commission also stated that evidence of intent is a factor relevant to the assessment of a dominant undertaking's conduct, as direct evidence of any exclusionary strategy may be helpful in interpreting a dominant undertaking's conduct.

#### Objective justification

3.49. It is open to a dominant undertaking to argue that apparently anti-competitive conduct is in fact justified, provided that the grounds relied on are more than simply the commercial advantage of the undertaking itself.<sup>327</sup> It is incumbent upon the dominant undertaking to provide all the evidence necessary to demonstrate that its conduct is objectively justified. It then falls to the OFT to make an assessment of whether the conduct being examined is objectively justified.

3.50. In its Guidance on Article 102 TFEU, the Commission indicated that a dominant undertaking may show that its conduct is objectively justified by demonstrating that the relevant conduct is either objectively necessary or produces substantial efficiencies which outweigh any anticompetitive effects on consumers. The consideration of the justifications put forward by the dominant undertaking will involve an assessment of whether the conduct in question is indispensable and proportionate to the goal allegedly pursued by the dominant undertaking.<sup>328</sup>

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<sup>326</sup> *Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings* [2009] OJ C45/7, paragraph 20.

<sup>327</sup> See for example Case 27/76 *United Brands v Commission* [1978] ECR 207, paragraphs 189-190.

<sup>328</sup> *Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings* [2009] OJ C45/7, paragraphs 28-31.

**c) Effect on Competition**

3.51. The Court of Justice has held that the concept of abuse covers conduct that has 'the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition'.<sup>329</sup>

3.52. However, evidence of actual effects are not necessary to establish an infringement of the Chapter II prohibition and/or Article 102 TFEU. In *Tomra*,<sup>330</sup> the General Court endorsed earlier case law and stated that, to establish an infringement under Article 102 TFEU, it is sufficient for the Commission to show that the abusive conduct by an undertaking tends to restrict competition, or that the conduct is capable of having that effect. The General Court made clear that it is not necessary for the Commission to demonstrate the actual effects of the agreements on the market.<sup>331</sup>

'[...] for the purposes of establishing an infringement of Article 82 EC, it is not necessary to show that the abuse under consideration had an actual impact on the relevant markets. It is sufficient in that respect to show that the abusive conduct of the undertaking in a dominant position tends to restrict competition or, in other words, that the conduct is capable of having that effect (*Michelin II*, paragraph 239, and *British Airways v Commission*, paragraph 293).'

3.53. Similarly, in *AstraZeneca*, The General Court held:

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<sup>329</sup> Case 85/76 *Hoffman-La Roche & Co AG v Commission* [1979] ECR 461, paragraph 91.

<sup>330</sup> Case T-155/06 *Tomra v Commission*. OJ C 288/31, judgment of 9 September 2010, currently under appeal before the Court of Justice of the European Union (Case C-549/10 P, *Tomra v Commission*, pending).

<sup>331</sup> Case T-155/06 *Tomra v Commission*, paragraph 289.

'[...] in so far as it is established that [...] the deregistrations of the marketing authorisations were capable of constituting an obstacle to the market entry of generic products and to parallel imports, the applicants' arguments disputing the effects of those deregistrations in practice cannot affect the classification of the conduct in question as an abuse of a dominant position.'<sup>332</sup>

3.54. The General Court also rejected the appellant's argument that the indirect nature of any competitive effects, due to the necessary action by the national authority, should preclude a finding of abuse:

'As the Commission rightly observes, where it is established that behaviour is objectively of such a nature as to restrict competition, the question whether it is abusive in nature cannot depend on the contingencies of the reactions of third parties.'<sup>333</sup>

3.55. It is also well established in the case law that 'where one or more undertakings in a dominant position actually implement a practice whose aim is to remove a competitor, the fact that the result sought is not achieved is not enough to avoid the practice being characterised as an abuse of a dominant position.'<sup>334</sup>

3.56. In Part 6, the OFT assesses whether RB's conduct is an abuse of a dominant position.

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<sup>332</sup> Case T-321/05 *AstraZeneca v Commission*, paragraph 826.

<sup>333</sup> *Ibid*, paragraph 360.

<sup>334</sup> Joined Cases T-24/93, T-25/93, T-26/93 and T-28/93 *Compagnie Maritime Belge and others v. Commission*, paragraph 149. See also Case T-321/05 *AstraZeneca v Commission*, paragraphs 602 and 605.

## **G. Effect on trade**

### **i) Introduction**

3.57. It is necessary for the purposes of the Chapter II prohibition that the conduct of a dominant undertaking 'may affect trade within the United Kingdom'. Likewise, it is necessary for the purposes of Article 102 TFEU that the conduct 'may affect trade between Member States'.

3.58. In this Section, the OFT addresses the legal principles underlying these requirements in turn. The OFT's application of these principles to RB's conduct is set out in Part 7 of this Decision.

### **ii) Effect on trade within the United Kingdom**

3.59. By virtue of section 18(1) of the Act, the Chapter II prohibition applies only to conduct if it 'may affect trade within the United Kingdom'.

3.60. For the purposes of the Chapter II prohibition, the UK means the UK or any part of it where a dominant position is held.<sup>335</sup> The OFT considers that conduct that is an abuse of a dominant position within the UK will in practice also affect trade there.

3.61. To infringe the Chapter II prohibition, the conduct which amounts to an abuse of a dominant position does not actually have to affect trade, as long as it is capable of affecting trade. Moreover, effect on trade within the UK is a purely jurisdictional test to demarcate the boundary line between the application of EU competition law and national competition law. The test is not read as importing a requirement that the effect on trade should be appreciable.<sup>336</sup>

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<sup>335</sup> Section 18(3) of the Act.

<sup>336</sup> See the final judgment of the CAT in *Aberdeen Journals Limited v Office of Fair Trading* [2003] CAT 11, at paragraphs 459 to 460.

### iii) Effect on trade between Member States

- 3.62. As noted above, Article 102 TFEU prohibits only abusive conduct by a dominant position which 'may affect trade between Member States'. Four elements must be fulfilled for this jurisdictional test to be satisfied.
- 3.63. First, the conduct must affect 'trade between Member States'; so trade between at least two Member States must be affected. The term 'trade' includes all forms of economic activity.<sup>337</sup> It should be noted that an abuse that covers a single Member State is also presumed capable of affecting trade between Member States where the abuse makes it more difficult for competitors from other Member States to penetrate that market.<sup>338</sup>
- 3.64. Second, there must be an influence on trade patterns. The European Courts have consistently held that in order for this condition to be satisfied 'it must be possible to foresee with a sufficient degree of probability on the basis of a set of objective factors of law or fact that the agreement or practice may have an influence, direct or indirect, actual or potential, on the pattern of trade between Member States.'<sup>339</sup> A harmful effect on the market is not necessary to satisfy this element as the conduct in question merely has to alter the normal flow of trade or cause the market to develop differently from the way it would have developed absent the abuse.<sup>340</sup>

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<sup>337</sup> See, for example, Case 172/80, *Zuchner v Bayerische Vereinsbank* [1981] ECR 2021.

<sup>338</sup> Case 322/81, *NV Nederlandsche Banden Industrie Michelin v Commission* [1983] ECR 3461, paragraph 51.

<sup>339</sup> See Case 56/65 *Société Technique Minière* [1966] ECR 282, paragraph 7; Case 42/84 *Remia and Others* [1985] ECR 2545, paragraph 22 and Joined Cases T-25/95 etc., *Cimenteries CBR* [2000] ECR II-491, paragraph 3930.

<sup>340</sup> See, for example, Case 71/74, *Frubo v Commission* [1975] ECR 563, paragraph 38.

3.65. Third, it is sufficient that the abuse 'may affect trade'. It is not necessary to demonstrate that the conduct actually affects trade between Member States but only that the conduct is 'capable' of having such effect.<sup>341</sup> In addition, the influence on the trade pattern may be direct or indirect.<sup>342</sup>

3.66. Fourth, any effect on trade arising from the abuse must be appreciable.<sup>343</sup> This element requires that the effect on trade between Member States must not be insignificant. Appreciability is assessed primarily by reference to the market position and importance of the undertaking(s) concerned on the market for the products in question.<sup>344</sup> An abuse of dominant position concerning the whole of a Member State will normally be considered to have an appreciable effect on trade between Member States.<sup>345</sup>

## H. Burden and standard of proof

3.67. The burden of proving an infringement of the Chapter II prohibition lies upon the OFT. The CAT held in *Napp* that:

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<sup>341</sup> See, for example, Case T-228/97, *Irish Sugar plc v Commission* [1999] ECR II-2969, paragraph 170.

<sup>342</sup> See, for example, Case T-86/95, *Compagnie Generale Maritime and others v Commission* [2002] ECR II-1011, paragraph 148.

<sup>343</sup> See Case 5/69 *Völk v Vervaecke* [1969] ECR 295, paragraphs 5/7; and Case 22/71 *Béguelin* [1971] ECR 949, paragraph 16.

<sup>344</sup> Case 5/69 *Völk v Vervaecke* [1969] ECR 295, paragraphs 5/7. See also the European Commission's *Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty*, OJ 2004 C 101/81, paragraph 44.

<sup>345</sup> European Commission's *Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty*, OJ 2004 C 101/81, paragraph 96.

'As regards the burden of proof, the Director<sup>346</sup> accepts that it is incumbent upon him to establish the infringement, and that the persuasive burden of proof remains on him throughout'

and

'In our view it follows from Article 6(2) [of the European Convention on Human Rights] that the burden of proof rests throughout on the Director to prove the infringements alleged'.<sup>347</sup>

3.68. However, this burden does not preclude the OFT from relying, where appropriate, on evidential presumptions.<sup>348</sup> In *Napp* the CAT went on to say:

'That approach does not in our view preclude the Director, in discharging the burden of proof, from relying in certain circumstances, on inferences or presumption that would, in the absence of any countervailing indications, normally follow from a given set of facts, for example that dominance may be inferred from very high market shares (Case 85/76 *Hoffman-La Roche v Commission* [1979] ECR 461, paragraph 41); that sales below average variable costs may,

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<sup>346</sup> References to the 'Director' are to the Director General of Fair Trading. As from 1 April 2003, the Enterprise Act 2002 transferred the functions of the Director General of Fair Trading to the OFT.

<sup>347</sup> *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading*, [2002] CAT 1, at paragraphs 95 and 100. The CAT confirmed this approach in the Replica Kit judgment *JJB Sports plc v Office of Fair Trading* [2004] CAT 17, paragraphs 164, 928 and 931. See, more recently, *Durkan Holdings Limited and others v Office of Fair Trading* [2011] CAT 6, paragraph 93.

<sup>348</sup> *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading*, [2002] CAT 1, at paragraph 95.



in the absence of rebuttal, be presumed to be predatory (see the opinion of advocate General Fennelly in Cases C-395/96P and 396/96P *Compagnie Maritime Belge v Commission* [2000] ECR I-1442 at paragraph 127)'.<sup>349</sup>

3.69. As regards the standard of proof, the CAT held that:

'formally speaking, the standard of proof in proceedings under the Act involving penalties is the civil standard of proof, but that standard is to be applied bearing in mind that infringements of the Act are serious matters attracting severe financial penalties. It is for the Director to satisfy us in each case, on the basis of strong and compelling evidence, taking account of the seriousness of what is alleged, that the infringement is duly proved, the undertaking being entitled to the presumption of innocence, and to any reasonable doubt there may be'.<sup>350</sup>

3.70. This statement was elaborated upon by the CAT in its ruling in the *Replica Kit* appeals, where it stated that:

'It also follows that the reference by the Tribunal to 'strong and compelling' evidence at [109] of *Napp* should not be interpreted as meaning that something akin to the criminal standard is applicable to these proceedings. The standard remains the civil standard. The evidence must however be sufficient to convince the Tribunal in the circumstances of the particular case, and to overcome the presumption of innocence to which the undertaking concerned is entitled'.<sup>351</sup>

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<sup>349</sup> Ibid. paragraph 110.

<sup>350</sup> Ibid. paragraph 109.

<sup>351</sup> *JJB Sports PLC v Office of Fair Trading* [2004] CAT 17, at paragraph 204. See also *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2004] CAT 24, paragraphs 164 and 165.

3.71. In other words, the standard of proof is no higher than the balance of probabilities. This is consistent with recent decisions of the House of Lords, in other contexts but of general application, confirming that there is only one civil standard of proof and that is on the preponderance or balance of probabilities.<sup>352</sup>

3.72. In *Re D* Lord Carswell stated that 'in some contexts a court or tribunal has to look at the facts more critically or more anxiously than in others before it can be satisfied to the requisite standard'.<sup>353</sup> He emphasised, however:

'These are all matters of ordinary experience, requiring the application of good sense on the part of those who have to decide such issues. They do not require a different standard of proof or a specially cogent standard of evidence, merely appropriately careful consideration by the tribunal before it is satisfied of the matter which has to be established.'

3.73. In *Re B*, Baroness Hale said:<sup>354</sup>

'Neither the seriousness of the allegation nor the seriousness of the consequences should make any difference to the standard of proof to be applied in determining the facts. The inherent probabilities are simply something to be taken into account, where relevant, in deciding where the truth lies.'

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<sup>352</sup> See *Re B* [2009] 1 AC 11 paragraph 13, and *Re D (Northern Ireland)* [2008] 1 WLR 1499, paragraph 28.

<sup>353</sup> *Re D (Northern Ireland)* [2008] 1 WLR 1499, paragraph 28.

<sup>354</sup> *Re B* [2009] 1 AC 11, paragraph 70.

## 4 THE RELEVANT MARKET

### A. Introduction

4.1. The OFT finds that, for the reasons set out in this Part, the relevant market in this case is no wider than the supply of alginates and antacids in the UK prescription channel. In particular:

- The OFT finds that qualitative evidence (for example, prescribing guidelines and information on the modes of action and therapeutic uses of the different products in the treatment area) and quantitative evidence (for example, sales and pricing data and market event analysis) suggests that the sales terms of PPIs and H2RAs do not significantly constrain those of alginates.
- The OFT finds that the sales terms of alginates and antacids in the OTC channel do not constrain the sales terms of alginates and antacids in the prescription channel.
- The OFT finds that the relevant geographic market is the UK.

4.2. RB has confirmed that it does not contest the OFT's finding that the relevant market is no wider than the supply of alginates and antacids in the UK prescription channel.<sup>355</sup>

4.3. This Part is structured as follows:

- Section B outlines the framework for assessing the relevant market, including those issues that are of particular relevance to assessments in the pharmaceutical sector.

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<sup>355</sup> RB SMFI, paragraph 3.1. However, in its SMFI RB stated that the OFT's assessment of the relevant market (as set out in the SO) included various factual inaccuracies, and the OFT has considered these points below

- Section C describes the focal products in this case, and sets out the key considerations for determining the relevant product market in this case.
- Section D sets out the OFT's assessment of the relevant product market. The OFT's assessment draws upon qualitative evidence such as the Anatomical Therapeutic Chemical (ATC) and BNF classification systems, the modes of action of the different products in the treatment area, the therapeutic uses of the different products as described by prescribing literature, and internal RB documents in which it considers the competitive constraints relevant to Gaviscon sales terms in the prescription channel. The OFT also assesses quantitative evidence including sales and pricing trends and an assessment of how certain developments in the treatment area have affected the sales and pricing of other products.
- Section E considers the extent to which sales terms in the OTC and prescription channels constrain one another. The OFT's assessment considers the purchasing and pricing mechanisms in each channel, the effect of OTC prices on prices in the prescription channel, and internal RB documents in which it makes relevant assessments.
- Sections F considers the relevant geographic market.
- Section G summarises the OFT's conclusions as to the relevant market in this case.

## **B. Framework for defining the relevant market**

### **i) Introduction**

- 4.4. This Section begins by setting out a general framework for defining the relevant market. Some specific characteristics of the pharmaceutical sector, and their relevance to the assessment of

the relevant market, are then set out. The analysis of the relevant market in *AstraZeneca* is then summarised.

**ii) The hypothetical monopolist test**

- 4.5. There are usually two dimensions to the definition of the relevant market: a product dimension (the products which are regarded as interchangeable or substitutable by the consumer, and are therefore part of the same relevant market), and a geographic dimension (which determines the geographic boundaries of the relevant market).
- 4.6. Competition authorities normally define the relevant product and geographic markets by using the conceptual framework known as the 'hypothetical monopolist test'.<sup>356</sup>
- 4.7. The hypothetical monopolist test assumes that there is a hypothetical monopolist of the 'focal' product (the product under investigation) which operates in a 'focal' area (the geographic area under investigation where the focal product is sold). The test then asks whether it would be profitable for the hypothetical monopolist to increase the price of the focal product by a small but significant amount (for example, five to 10 per cent) above competitive levels for a sustained period of time.<sup>357</sup>
- 4.8. If such an increase in the price of the focal product would be profitable, the test is complete and the focal product sold by the hypothetical monopolist is (usually) the relevant market.

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<sup>356</sup> See paragraphs 2.5 to 2.13 of *Market Definition* (OFT403) and paragraphs 15 to 19 of the *Notice of the European Commission on the Definition of the Relevant Market for the purposes of Community Competition Law*, OJ 1997 C372/5, [1998] 4 CMLR 177.

<sup>357</sup> This increase is usually referred to as SSNIP, a small but significant non-transitory increase in price.

- 4.9. If the price increase would not be profitable (for example, because a sufficiently large number of customers would switch some of their purchases to other substitute products), the test continues by assuming that the hypothetical monopolist controls both the focal product and its closest substitute. If necessary the process is repeated, including other substitute products until the smallest collection of products for which the hypothetical monopolist can profitably impose a price increase is found. This collection of the focal product and its closest substitutes is then the relevant product market.
- 4.10. The same principles apply when defining the relevant geographic market. In particular, the test asks whether the hypothetical monopolist of the focal product can profitably sustain prices five to 10 per cent above competitive levels in the focal geographic area. If such a price is sustainable, the focal area is then the relevant geographic market. Otherwise, the test is repeated over wider geographic areas until the narrowest area in which an increase in price is profitable is found.
- 4.11. Following a price rise, customers may switch some of their purchases from the focal product to other substitute products (demand-side substitution). Also, undertakings that do not currently supply a product might be able to supply it at short notice and without incurring substantial sunk costs (supply-side substitution). The OFT, however, 'will not factor supply-side substitution into the market definition unless it is reasonably likely to take place, and already has an impact by constraining the supplier of the product or group of products in question'.<sup>358</sup>

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<sup>358</sup> See *Market Definition* (OFT403), paragraph 3.18. See also *Notice of the European Commission on the Definition of the Relevant Market for the purposes of Community Competition Law*, OJ 1997 C372/5, [1998] 4 CMLR 177, paragraph 13: 'From an economic point of view, for the definition of the relevant market, demand substitution constitutes the most immediate and effective disciplinary force on the suppliers of a given product, in particular in relation to their pricing decisions.'

- 4.12. Evidence of demand-side substitution may come from a number of different sources, for example, company documents, instances of substitution in the recent past, views of customers and competitors, switching costs, product characteristics, patterns in price changes and (if available) demand elasticities.<sup>359</sup> Evidence of supply-side substitution may include the views of potential suppliers (in particular, on whether they have spare capacity) and customers.<sup>360</sup>
- 4.13. When considering the hypothetical monopolist test, it is worth emphasising that it is rarely possible to rely on the observed results of an actual five to 10 per cent increase in the price of the focal product above competitive levels, and thus to demonstrate in that way the actual effects of such an increase on the profitability of such a price rise. Given this, the OFT normally uses the hypothetical monopolist test as a conceptual framework, and the likely outcome of the test is a matter of judgement using both the qualitative and quantitative information available. Ultimately, it is for the OFT to decide what evidence it uses in order to reach a conclusion on market definition. The OFT is under no obligation to conduct a hypothetical monopolist test or any other specific test.<sup>361</sup>
- 4.14. The application of the hypothetical monopolist test in dominance cases is complicated by the fact that the current price of the focal product may be substantially higher than the competitive level, for

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<sup>359</sup> See *Market Definition* (OFT403), paragraph 3.7, for a brief discussion of how this evidence may be used for market definition purposes.

<sup>360</sup> See *Market Definition* (OFT403), paragraph 3.16.

<sup>361</sup> In *Aberdeen Journals Limited v Office of Fair Trading*, [2003] CAT 11, paragraph 258, the CAT said that 'there is no hierarchy of evidence under the 1998 Act on such issues as market definition. It is for the Director to decide what evidence he considers is sufficient for his decision, and for the Tribunal to decide whether that evidence is sufficient or not.'

example because the dominant undertaking has market power and has already raised the price to its profit-maximising level. Given this, a further increase in price might induce consumers to purchase other products. In these circumstances, however, it would be wrong to conclude that the undertaking under investigation lacks market power and to include these other products in the same relevant market as the focal product.<sup>362</sup> Caution must therefore be exercised in the assessment of the evidence on demand-side substitution when market conditions are distorted by the presence of market power and prices are likely to differ substantially from their competitive levels.<sup>363</sup> This can be a particular problem in markets where products are protected by patents.

### iii) **Market definition in the pharmaceutical sector**

4.15. In its Notice on Market Definition, the Commission notes that:

'Product characteristics and intended use are insufficient to show whether two products are demand substitutes. Functional interchangeability or similarity in characteristics may not, in themselves, provide sufficient criteria, because the responsiveness of customers to relative price changes may be determined by other considerations as well. Conversely, differences in product characteristics are not in themselves sufficient to exclude demand substitutability,

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<sup>362</sup> This problem is usually referred to as the 'cellophane fallacy' after a US case involving cellophane products, see *US v El Du Pont de Nemours & Co*, [1956] 351 US 377.

<sup>363</sup> See *Market Definition* (OFT403), paragraphs 5.4 to 5.6. See also *Notice of the European Commission on the Definition of the Relevant Market for the purposes of Community Competition Law*, OJ 1997 C372/5, [1998] 4 CMLR 177, paragraph 19: 'In particular, for the investigation of abuses of dominant positions, the fact that the prevailing price might already have been substantially increased will be taken into account.'



since this will depend to a large extent on how customers value different characteristics.<sup>364</sup>

4.16. These principles apply in the pharmaceutical sector, where often a doctor can prescribe different products for a specific illness. In particular, the Commission has repeatedly rejected the proposition that products that are used to treat the same medical condition are necessarily to be regarded as substitutes. For example, in *AstraZeneca* the Commission noted that:

'In determining the functional substitutability of medicines it is not enough, for the purposes of product market definition, to state that different medicines are prescribed for the same general illness or disease.'<sup>365</sup>

4.17. In *Ciba-Geigy/Sandoz*, the Commission stated that:

'The interchangeability of products depends in principle not on their physical, technical or chemical properties but on their functional substitutability as viewed by those supervising their consumption ... (T)he market definition cannot be based simply on whether different medicines are prescribed for the same illness (i.e. in the same indication group). The criterion is that prescription is based on fundamentally the same medical grounds. For such prescription practice, account can be taken of whether the

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<sup>364</sup> See *Notice of the European Commission on the Definition of the Relevant Market for the purposes of Community Competition Law*, OJ 1997 C372/5, [1998] 4 CMLR 177, paragraph 36.

<sup>365</sup> Commission Decision, Case COMP/A. 37.507/F3, *AstraZeneca*, 15 June 2005, paragraph 381.

medicines correspond to each other, for example in terms of active principle, tolerance, toxicity, and side effects.<sup>1366</sup>

- 4.18. What primarily matters for the definition of the relevant product market is the extent to which different product types can be expected to materially constrain the conduct of a given undertaking:

'When products such as pharmaceutical products can be broadly used for the same purpose but differ in terms of price, quality, consumer preferences or other significant attributes, the products are considered to be differentiated. Although differentiated products may 'compete' in some dimensions, a relevant market in competition cases should only include those products that are capable of significantly constraining an undertaking's behaviour and of preventing it from behaving independently of an effective competitive pressure.'<sup>1367</sup>

- 4.19. The pharmaceutical sector also has certain specific features which need to be taken into account when defining the relevant markets. First, the pharmaceutical market is highly regulated, with regulation covering market authorisation of pharmaceutical products as well as pricing and reimbursement rules. Second, for products which are dispensed by prescription the ultimate consumer (the patient) is usually not the same person as the decision-maker (the doctor). Third, while doctors are the main determinant of demand for pharmaceutical products by

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<sup>366</sup> Commission Decision IV/M.737 *Ciba-Geigy/Sandoz*, paragraph 21. The same point was also made in case COMP/M.1397 – *Sanofi/Synthelabo* (paragraph 31), as well as in a number of other merger decisions in the pharmaceutical sector. The OFT adopted the same approach in the *Genzyme* and *Napp Pharmaceutical* decisions, of 27 March 2003 and 30 March 2001, respectively.

<sup>367</sup> Commission Decision, Case COMP/A. 37.507/F3, *AstraZeneca*, 15 June 2005, paragraph 370.

prescription, their decisions are not typically driven by price considerations;<sup>368</sup> doctors tend to choose between different medicines depending on which product is therapeutically most appropriate and effective. Fourth, neither patients nor doctors pay for the bulk of the cost of prescription medicines and as a result governments tend to adopt schemes to control the public expenditure on prescription medicines. These features can affect the extent to which demand for a product, and the behaviour of other suppliers, would respond to a change in its price.

- 4.20. In the UK, pricing and reimbursement is covered by the PPRS (described in detail at paragraphs 2.116 to 2.120 above). In addition, while doctors may not choose which medicine to prescribe based on prices (or indeed have limited awareness of the prices of different pharmaceutical products), their prescribing behaviour may nevertheless be indirectly informed by price insofar as they are increasingly encouraged to prescribe generic (rather than branded) products,<sup>369</sup> to follow prescribing guidelines (for example, through use of pre-approved formularies) and to meet certain budgetary objectives at local level.

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<sup>368</sup> In fact, a recent study by the OFT found that doctors' ability to rank branded drugs in order of price was no better than chance; see box 2.3, page 23 of the OFT market study *The Pharmaceutical Price Regulation Scheme*, February 2007.

<sup>369</sup> For example, in England the proportion of the total number of prescriptions which are written generically (irrespective of whether the product is available as a generic or not) has steadily increased from 63 per cent in 1998 to 83 per cent in 2008; in terms of the cost to the NHS, generic prescriptions accounted for 50 per cent and 70 per cent of total expenditure in 1998 and 2008, respectively. See Table 7 of *Prescriptions Dispensed in the Community, Statistics for 1998 to 2008: England*, published by the NHS Information Centre in July 2009.

**iv) Market definition in *AstraZeneca***

4.21. This sub-section sets out the Commission's approach in *AstraZeneca* (*AstraZeneca* decision)<sup>370</sup> which was subsequently upheld by the General Court in its Judgment of 1 July 2010 (*AstraZeneca* judgment)<sup>371</sup>.

4.22. The OFT considers the *AstraZeneca* case to be of particular relevance because:

- the case focused on PPIs and H2RAs, which are also used to treat dyspepsia, acid reflux or GORD (see paragraphs 2.53 to 2.66 above) and
- *AstraZeneca* provides a relatively recent example of a market definition analysis in the pharmaceutical sector. The theoretical framework adopted by the Commission for the definition of the relevant market in the pharmaceutical sector was upheld by the General Court.<sup>372</sup>

4.23. The Commission found that PPIs form a separate product market, as distinguished from other GORD treatments, in particular H2RAs (referred to in the *AstraZeneca* decision as H2 blockers) but also alginates and antacids.

4.24. In defining the relevant market the Commission considered the specific features of the pharmaceutical sector as well as important product characteristics such as the mode of action and therapeutic uses of the medicines under consideration, taking into account the

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<sup>370</sup> Commission Decision, Case COMP/A. 37.507/F3, *AstraZeneca*, 15 June 2005.

<sup>371</sup> Case T-321/05 *AstraZeneca v Commission*. OJ C 221/33, judgment of 1 July 2010, currently under appeal before the Court of Justice of the European Union (Case C-457/10 P, *AstraZeneca v Commission*, pending).

<sup>372</sup> See *AstraZeneca* judgment, paragraphs 61 to 222.

ATC classification system. The Commission further assessed demand, price and non-price factors and looked at contemporaneous business documents of the party under investigation.<sup>373</sup>

- 4.25. As a starting point in analysing the product characteristics of the medicines under investigation the Commission referred to the ATC classification system as follows:

'Medicines are classified into groups at five different levels. The fourth ATC level normally takes into consideration the mode of action and the narrowest classes (individual active substances) are defined at the fifth ATC level. The third ATC level allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use. This level is generally used as the starting point for enquiring about market definition in competition cases. However, it is appropriate to carry out analyses at other ATC levels if the circumstances of a case show that sufficiently strong competitive constraints faced by the undertakings involved are situated at another level, and that, therefore, there are indications that the third ATC level does not lead to a correct market definition.'<sup>374</sup>

- 4.26. The Commission further considered that the 'mode of action' of pharmaceuticals in this sector was a key product characteristic. The Commission argued that the early and rapid success of PPIs, which contributed to its view that PPIs were a distinct product that was not constrained by other medicines in the area, was partly due to their unique mode of action. It noted that PPIs had a direct blocking effect on the proton pump in the stomach's cells,

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<sup>373</sup> See *AstraZeneca* decision, paragraphs 358 to 504.

<sup>374</sup> *Ibid*, paragraph 371.

the source of acid secretion in the stomach.<sup>375</sup> Other medicines in this category each dealt with acid secretion in a different way. The Commission concluded:

'As a result, the PPIs have a mode of action which is fundamentally distinct from that of the H2 blockers and – even more so – from those of other categories of medicines used within the field of acid-related gastrointestinal diseases or conditions.'<sup>376</sup>

- 4.27. The Commission also examined the 'therapeutic uses' of H2RAs and PPIs, noting that for a significant patient population suffering from conditions such as dyspepsia, acid reflux or GORD, only prescription PPIs provide a sufficiently appropriate and effective response.<sup>377</sup>
- 4.28. The Commission argued that the fact that PPIs were used to treat some of the same symptoms, diseases and conditions as other medicines was insufficient to argue that they were in the same market as those medicines. AstraZeneca had argued that PPIs must have been in the same market as H2RAs at least for a period since the two products were often used to treat the same conditions after PPIs entered the market. The Commission disagreed, arguing that:

'it must be recalled that the relevant market is not determined on the basis that certain products competed against each other in a broad sense but on the basis of whether such products were sufficiently substitutable to

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<sup>375</sup> Ibid, paragraph 374.

<sup>376</sup> Ibid, paragraph 376.

<sup>377</sup> Ibid, paragraph 386.

significantly constrain each other's market power, in particular as regards pricing.<sup>378</sup>

- 4.29. With regard to the therapeutic uses, the Commission also referred to the 'step-up' or 'step-down' approach to treating GORD-related conditions, in which medicines of various strengths or uses, from antacids to PPIs, may be used as part of a continuum or as complements in finding the appropriate treatment for a particular individual. It argued that 'the concept of the 'step-up' or 'step-down' approach implies by its very nature a hierarchy of medicines used in the treatment of acid-related gastrointestinal conditions, diseases and conditions'.<sup>379</sup> The Commission rejected a view that would see the complementary use of alginates with PPIs or H2RAs as implying that there is a continuum between them sufficient to put them in the same product market.<sup>380</sup>
- 4.30. To complete its assessment of the relevant market, the Commission considered sales and price trends, including an analysis of how various 'natural events' (such as the launch of generic and branded PPIs and changes in promotional activity) had affected sales within the treatment area.
- 4.31. The General Court confirmed the approach of the Commission in analysing the 'mode of action' and 'therapeutic uses' of medicines in the treatment area. The General Court also endorsed the Commission's assessment of the ATC classification system as a preliminary step in a market definition assessment in the pharmaceutical sector.<sup>381</sup>

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<sup>378</sup> Ibid, paragraph 370.

<sup>379</sup> Ibid, paragraph 389.

<sup>380</sup> Ibid, paragraphs 334 and 389.

<sup>381</sup> *AstraZeneca* judgment, paragraph 149 to 155.

'it is necessary to take account of differences between medicines' modes of action where they give rise to different therapeutic uses and to disregard them where the medicines in question have a similar therapeutic use.'<sup>382</sup>

'since doctors are primarily guided by the therapeutic effect of medicines when choosing what to prescribe, the prices of medicines whose therapeutic uses differ have limited impact on their level of consumption. In so far as they determine doctors' choices, non-price factors, such as therapeutic use, therefore also constitute, alongside price-based indicators, a relevant factor for the purposes of market definition.'<sup>383</sup>

4.32. The General Court also found that the specific circumstances of the pharmaceutical sector (for example, the extent of price regulation) did not undermine the use of pricing data in market definition analysis, but noted that the specific features of the sector must be recognised when determining the significance of such data:

'the specific features which characterize competitive mechanisms in the pharmaceutical sector do not negate the relevance of price-related factors in the assessment of competitive constraints, although those factors must be assessed in their specific context.'<sup>384</sup>

4.33. Finally, the General Court not only upheld the specific framework applied for defining the relevant market, but also the Commission's conclusion that PPIs form a separate product market, as distinguished from other GORD treatments, in particular H2RAs:

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<sup>382</sup> Ibid, paragraph 153.

<sup>383</sup> Ibid, paragraph 187.

<sup>384</sup> Ibid, paragraph 183.



'the Court finds that that evidence, some of which was produced by the applicants themselves, constitutes, in the present case, a body of relevant data that is sufficient to establish to the requisite legal standard the conclusion that the Commission reached, namely that H2 blockers did not exercise a significant competitive constraint over PPIs during the period between 1993 and 2000.'<sup>385</sup>

### **C. The focal products in this case**

4.34. As outlined above at paragraphs 2.31 to 2.34, the RB products which are the focus of the allegations in this case are GL and GA. The allegations concern the alleged foreclosure of Peptac/Acidex, a product manufactured by Pinewood.<sup>386</sup> The focal products were described at paragraphs 2.35 to 2.42 above.

4.35. These products are each 'alginates' and are typically used to treat dyspepsia and other symptoms of acid-related conditions. As outlined above at paragraph 2.49, NICE defines dyspepsia as 'any symptom of the upper gastrointestinal tract, present for four weeks or more, including upper abdominal pain or discomfort, heartburn, acid reflux, nausea, or vomiting.'<sup>387</sup> According to this definition dyspepsia is a complex of symptoms, not a diagnosis. It may be triggered by eating and drinking habits, stress, medication, and pregnancy. It may also have other causes, including GORD and peptic ulcer disease (see Part 22E.ii).

4.36. As set out at Part 2E.ii) above, dyspepsia can be treated in several ways. In particular, the list of non-surgical treatments includes

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<sup>385</sup> Ibid, paragraph 220.

<sup>386</sup> Other alginate products, such as Gastrocote and Algicon have different ingredients to GL and Peptac/Acidex and were therefore not covered by the ARFOS generic name.

<sup>387</sup> See NICE CG17, page 42.

PPIs, H2RAs, alginates and antacids. A key issue in determining the relevant product market in this case is therefore the extent to which PPIs and H2RAs compete with alginates, and our assessment of this is set out in Part 4D below. However, as is explained below, the question of whether antacids are in the same market as alginates can be left open in this case, because the outcome of such analysis does not have a material impact on the assessment of RB's dominance (see Part 5 below).<sup>388</sup> In what follows, the OFT has therefore not considered in detail the extent to which alginates compete with antacids.

## **D. The relevant product market**

### **i) Introduction**

4.37. The OFT has considered a wide and diverse range of evidence in order to assess whether alginates and anti-ulcerants (H2RAs and PPIs) are in the same relevant market, including:

- evidence on product characteristics and intended use (in particular, the ATC, European Pharmaceutical Market Research Association (EPHRA) and the BNF classification systems, and the different modes of action of alginates and anti-ulcerants)
- the therapeutic uses of the various products, as set out in the guidelines and literature used by prescribers (the 'prescribing literature')
- RB's internal documents (including a survey of GPs that RB commissioned) and the extent to which they suggest that its commercial strategy was influenced by H2RAs and PPIs

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<sup>388</sup> In particular, this is because the importance of antacids (both in terms of volumes and value of sales) in the prescription channel is negligible, as explained in Part 2H.iii)c) above.

- sales trends and changes in treatment cost within the market at an aggregate level, and the impact of certain events within the treatment area.

ii) **The ATC, EPhMRA and the British National Formulary classification systems**

4.38. The Commission,<sup>389</sup> the General Court<sup>390</sup> and the OFT<sup>391</sup> have noted in previous decisions that a starting point for defining the relevant product market in the case of pharmaceutical products is the ATC classification system, which is recognised and used by the World Health Organisation (WHO), and the corresponding system developed by EPhMRA. The OFT also notes that the relevant paragraphs of the BNF provide a useful indication of which products may belong to the same market. As a first stage in identifying the products that may belong to the relevant market in this case, this Section therefore considers the position of alginates

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<sup>389</sup> Commission Decision IV/M.737 *Ciba-Geigy/Sandoz* OJ (1997) L201/1; Commission Decision IV/M.950 *Hoffmann-La Roche/Boehringer Mannheim* OJ (1998) L234/14; Commission decision IV/M.1403 *Astra/Zeneca* OJ (1999) C335/3; Commission Decision IV/34.279/F3 *Adalat* OJ (1996) L201/1; Commission Decision IV/M.072 *Sanofi/Sterling Drug* OJ (1991) C156/0; Commission Decision IV/M.323 *Procordia/Erbamont* OJ (1993) C128/0; Commission Decision *Rhone Poulenc/Cooper* OJ (1994) C113/0; Commission Decision IV/M.457 *La Roche/Syntex* OJ (1994) C278/3; Commission Decision IV/M.500 *AHP/Cyanamid* OJ (1994) C278/3; Commission Decision IV/M.555 *Glaxo/Wellcome* OJ (1995) C65/3; Commission Decision IV/M.495 *Behringwerke AG/Armour Pharmaceutical Co.* OJ (1995) C134/4; Commission Decision IV/M.587 *Hoechst/Marion Merrell Dow* OJ (1995) C193/5; Commission Decision IV/M.631 *Upjohn/Pharmacia* OJ (1995) C294/9; Commission Decision IV/M.1229 *American Home Products/Monsanto* CMLR 5 [1998] 664; Commission Decision IV/M2312 *Abbott/Basf* dated 28/02/01 OJ [2001] C149/23; Commission Decision IV/M.1878 *Pfizer/Warner-Lambert* dated 22 May 2000, OJ [2000] C210/9.

<sup>390</sup> Case T-321/05 *AstraZeneca v Commission*. OJ C 221/33, judgment of 1 July 2010.

<sup>391</sup> See Decision No. CA98/2/2001, *Napp Pharmaceutical Holdings Limited*, 30 March 2001, and Decision No. CA98/3/2003, *Genzyme Limited*, 27 March 2003.

in relation to other medicines within the ATC and EPhMRA classification systems, as well as their positions in the BNF.

- 4.39. The purpose of the ATC system is to serve as a tool for drug utilisation research in order to improve quality of drug use. The ATC classification system divides active substances into groups according to their composition and therapeutic properties. At the first level, the system divides drugs into 14 main groups based on the physiological organ or system on which they act. The second level divides drugs into pharmacological/therapeutic subgroups. The third and fourth levels divide drugs into chemical/ pharmacological/therapeutic subgroups. The fifth level is the chemical substance.<sup>392</sup>
- 4.40. The third level of the ATC classification system (ATC3) groups together pharmaceutical products by reference to their therapeutic indications. On this basis, the ATC3 can be used as a starting point for an operational market definition.<sup>393</sup> In some cases, however, ATC3 may not be an appropriate basis for defining the relevant product market and it may be necessary to begin the market analysis at other levels of the ATC classification. For example, in instances where the pharmaceuticals forming part of a certain ATC3 class have clearly differing therapeutic indications, it may be appropriate to apply a narrower market definition.<sup>394</sup> The European Commission has noted the following:

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<sup>392</sup> More information about the ATC system can be found on the WHO Collaborating Centre for Drug Statistics Methodology website, [www.whocc.no/atcddd/atcssystem.html](http://www.whocc.no/atcddd/atcssystem.html)

<sup>393</sup> See for example, Decision No. CA98/2/2001, *Napp Pharmaceutical Holdings Limited*, 30 March 2001, paragraph 47.

<sup>394</sup> See, for example, Case IV/M.1378, *Hoechst/Rhone-Poulenc* OJ (1999) C254/5. In general, as noted above, the Commission considers that ATC3 can be a useful starting point when defining relevant product markets, because medicines in a specific ATC3 class cannot typically be substituted for products belonging to other ATC3 classes. However, since the ATC list is merely a statistical classification system, the Commission

'However, it is appropriate to carry out analyses also at other ATC levels, or a mixture thereof, if the circumstances of a case show that sufficiently strong competitive constraints faced by the undertakings involved are situated at another level and there are indications that ATC3 class does not lead to a correct market definition. The Commission has previously departed from the ATC3 class in cases where the market investigation indicated that another market definition was more appropriate, for example the ATC4 class or medicines based on the same active pharmaceutical ingredient (molecule level).'<sup>395</sup>

4.41. The ATC classification system was originally based upon another system, the Anatomical Classification system, which was developed by EPhMRA and the Pharmaceutical Business Intelligence and Research Group. In the EPhMRA system, pharmaceutical products are classified in groups at three or four different levels. The ATC classification system modified and extended the EPhMRA system by adding a therapeutic/ pharmacological/chemical subgroup as the fourth level and a chemical substance subgroup as the fifth level.<sup>396</sup>

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has also taken the view that 'it is in certain cases necessary to deviate from it when defining relevant markets for competition analysis. For example, it may be necessary to analyse pharmaceutical products at a higher, lower or mixed level or to further subdivide the ATC3 classes on the basis of demand-related criteria.' See paragraph 12 of the Commission's decision in case COMP/M.3544, *Bayer Healthcare/Roche (OTC business)*, of 19 November 2004.

<sup>395</sup> See paragraph 16 of the recent decision COMP M.5476, *Pfizer /Wyeth*, of May 2009, and the references provided therein.

<sup>396</sup> Although work to achieve a better harmonisation is in progress, there are still many differences between the two classification systems. These differences originate from the fact that the EPhMRA classification system mainly serves the marketing and research needs of pharmaceutical companies, while the ATC system is used in international drug utilisation research. This difference in the main purpose also explains why the EPhMRA and ATC classification systems are product- and substance-based, respectively.

- 4.42. Both the ATC and EPhMRA classification systems are regularly updated and widely used in the pharmaceutical sector. In particular, the EPhMRA system is used by Intercontinental Medical Statistics (IMS) when producing marketing research statistics for the pharmaceutical industry.
- 4.43. In the EPhMRA classification system plain antacids and combinations of antacids with alginic acid are listed in the A2A class ('Antacids, antiflatulents, carminatives'). Gaviscon (alongside other alginates) is included in this class.<sup>397</sup> Anti-ulcerants such as H2RAs and PPIs are listed in the A2B class ('Anti-ulcerants'). There is also a third class, A2C ('Other stomach disorder preparations'), which includes herbal preparations and plain alginic acid.<sup>398</sup> The EPhMRA classification system therefore puts alginates in a different third level class from PPIs and H2RAs, as summarised in Table 1 of Annexe C of this Decision.
- 4.44. In the ATC system, the second-level group A02 'Drugs for acid-related disorders' comprises three third-level groups (see Table 2 of Annexe C of this Decision). Alginates are not explicitly listed in the ATC classification system.<sup>399</sup> However, the MHRA<sup>400</sup> marketing authorizations for Gaviscon products state that Gaviscon products belong to A02BX group, putting them in the same third level group

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<sup>397</sup> RB confirmed this in its response dated 18 August 2009 to the OFT's section 26 notice dated 28 July 2009 (OFT File Part 5, document 1).

<sup>398</sup> See the EPhMRA's Anatomical Classification Guidelines 2009, pp. 3 – 4, at: [www.ephmra.org/PDF/ATC%20Guidelines%202009.pdf](http://www.ephmra.org/PDF/ATC%20Guidelines%202009.pdf)

<sup>399</sup> There are several reasons why a substance is not included in the WHO ATC classification system. It may be that no request has been made, for example, by the manufacturer; or the substance lacks an international non-proprietary name (INN) or a British Approved Name (BAN), as was the case for Gaviscon until recently.

<sup>400</sup> See for example, 'Medicines and Healthcare products Regulatory Agency' (MHRA) marketing authorization for Gaviscon Advance UK/H/0222/001/E02 UK MA no: PL 00063/0097.

as PPIs (A02BA) and H2RAs (A02BC) but in a fourth level group that excludes both of those product types.

- 4.45. In its PPRS Market Study<sup>401</sup> the OFT noted that 'to treat a given condition, GPs choose between groups of medicines that are therapeutically substitutable ... Often, but by no means always, the list of products appearing in a relevant 'Paragraph' of the British National Formulary (BNF) represents the available scope for choice.'<sup>402</sup> Furthermore, the OFT wrote that 'members of the same BNF Paragraph are all designed to treat the same condition of a specific part or system of the body (though some may have alternative uses)' and 'a BNF paragraph can therefore in some cases be considered in broad terms to constitute a 'market' for drugs to treat a given medical condition.'<sup>403</sup>
- 4.46. Chapter 1 of the BNF covers the gastro-intestinal system, within which there are nine sections. The relevant sections for this case are 1.1 (dyspepsia and GORD) and 1.3 (antisecretory drugs and mucosal protectants). Within section 1.1, paragraphs 1.1.1 and 1.1.2 list 'Antacids and simeticone' and 'Compound alginates and proprietary indigestion preparations', respectively. Gaviscon and Peptac are included in paragraph 1.1.2. In contrast, within section 1.3, paragraphs 1.3.1 and 1.3.5 list H2RAs and PPIs, respectively.
- 4.47. Although the ATC classification indicates that alginates, PPIs and H2RAs belong to the same third level group, the EPhMRA

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<sup>401</sup> OFT Report on *The Pharmaceutical Price Regulation Scheme*, February 2007.

<sup>402</sup> See OFT Report on *The Pharmaceutical Price Regulation Scheme*, February 2007, paragraph 2.31.

<sup>403</sup> See OFT Report on *The Pharmaceutical Price Regulation Scheme*, February 2007, paragraphs 2.32 and 2.33. The OFT also cautioned that 'however, it is important to note that in Competition Act investigations or merger decisions, appropriate market definitions may be wider or narrower than the Paragraph according to the individual circumstances and the specific question being addressed.'

classification system groups alginates separately from PPIs and H2RAs at equivalent levels. The BNF include alginates in a separate paragraph to PPIs and H2RAs. An analysis of these classification systems is therefore inconclusive and further qualitative and quantitative analysis is necessary to determine the extent of substitutability between alginates and PPIs/H2RAs.

**iii) Modes of action of alginates and anti-ulcerants**

4.48. As outlined at Part 2E.iii) above, alginates and anti-ulcerants have very different modes of action. In particular, alginates do not stop acid secretion in the stomach. Rather, they act by forming a natural raft (derived from seaweed) which floats on top of the stomach contents and prevents acid reflux; the raft then dissolves after a few hours. In contrast, PPIs and H2RAs both block the production of gastric acid, albeit in different ways.

4.49. These material differences in modes of action help to explain why alginates cause virtually no side effects compared to PPIs and H2RAs. The BNF notes that the use of PPIs is associated with such side-effects as 'gastro-intestinal disturbances (including nausea, vomiting, abdominal pain, flatulence, diarrhoea, constipation), and headache' and that the use of H2RAs is associated with such side-effects as 'diarrhoea and other gastro-intestinal disturbances, altered liver function tests, headache, dizziness, rash and tiredness.'<sup>404</sup> Alginates' lack of side effects makes them particularly appropriate for the treatment of heartburn during pregnancy.

4.50. This evidence is by itself insufficient to determine whether alginates and anti-ulcerants are demand-side substitutes. The OFT notes, however, that the differing modes of action represents an

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<sup>404</sup> British National Formulary No. 58 (and previous editions throughout the 2000s) – Section 1.3.1 'Histamine H2-receptor antagonists'. See also the letter dated 11 July 2008 from Pinewood, paragraphs 4.23 to 4.25 (OFT file part 1 document 48).



indicator that alginates are very different treatments to PPIs and H2RAs, which is consistent with the further analysis presented below.

**iv) Therapeutic uses as set out in the prescribing literature**

**a) Introduction**

4.51. The NICE Guidelines on the management of dyspepsia in primary care and recommendations issued by PCOs both provide GPs with prescribing guidance on the therapeutic uses of alginates, antacids, H2RAs and PPIs.<sup>405</sup> Their advice therefore provides useful information on the prescribing decision-making procedures that GPs are encouraged to adopt when determining the appropriate treatment in this area, and provides a valuable insight into the appropriate product market definition in this case.

**b) The NICE Guidelines on the management of dyspepsia in primary care**

4.52. The NICE Guideline in relation to dyspepsia and GORD (CG17) starts with 'referral guidance for endoscopy' and 'common elements of care', followed by guidance on 'interventions for uninvestigated dyspepsia' and reflux-like symptoms<sup>406</sup> and 'interventions for GORD'.

4.53. NICE recommends that dyspepsia should be treated empirically, in other words without a formal diagnosis through an endoscopy, unless the patient presents alarm signs or symptoms.<sup>407</sup> Only those

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<sup>405</sup> A summary of the relevant prescribing literature is given in paragraphs 2.57 to 2.65 above.

<sup>406</sup> NICE CG17, pages 84 to 93. NICE CG17 recommends that 'patients with uninvestigated 'reflux-like' symptoms should be managed in the same way as patients with uninvestigated dyspepsia' (page 15).

<sup>407</sup> Alarm signs include dyspepsia with gastro-intestinal bleeding, difficulty swallowing, unintentional weight loss, abdominal swelling and persistent vomiting; see NICE CG17, page 7.

patients who present alarm signs upon presentation to the GP should be referred for an endoscopy (about 10 per cent of patients with dyspepsia symptoms).<sup>408</sup> Other patients should be treated in accordance with its recommendations for uninvestigated dyspepsia and uninvestigated 'reflux-like' symptoms, which are described below.<sup>409</sup>

- 4.54. The NICE Guidelines identify 'common elements of care'<sup>410</sup> which should be offered to all patients with symptoms of dyspepsia. In particular, it states that 'self treatment with antacid and/or alginate therapy may continue to be appropriate for many patients, either prescribed or purchased over-the-counter and taken as required for immediate symptom relief. However, additional therapy becomes appropriate to manage symptoms which persistently affect patients' 'quality of life''.
- 4.55. It further states that for long-term symptom management, GPs should encourage patients to reduce medication stepwise, by lowering dose, trying 'on demand use' and by returning to self-treatment with antacid and/or alginate therapy.
- 4.56. The guidance on 'uninvestigated dyspepsia' and 'uninvestigated reflux-like symptoms' recommends applying the 'common elements of care', outlined above, as appropriate. GPs should recommend life-style changes and promote the use of antacids and alginates. If there is no improvement, however, GPs should prescribe a full dose of PPIs for one month, or test for the presence of the bacterium *Helicobacter pylori* (*H. pylori*) in the stomach and, if present, treat it.

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<sup>408</sup> NICE CG17, pages 80 to 81.

<sup>409</sup> NICE CG17, page 78.

<sup>410</sup> NICE CG17, pages 70 to 72.

- 4.57. Similarly, at the final step in the treatment, a 'return to self care', the guidance recommends that antacids/alginates are taken as required, as described in the 'common elements of care' section (see paragraph 4.54 above).
- 4.58. It follows that the NICE Guidelines indicate that, with respect to uninvestigated dyspepsia and uninvestigated reflux-like symptoms, PPIs should be prescribed where there has been no response to the initial treatment with alginates.
- 4.59. The NICE Guidelines for 'GORD'<sup>411</sup> define GORD as 'endoscopically-determined oesophagitis or endoscopy negative reflux disease.' Hence, this section of the guidance applies only to patients who meet the referral criteria for an endoscopy. The referral guidance for an endoscopy, in turn, states that only patients with alarm signs, and certain patients who did not respond to acid suppression and H. pylori eradication therapy, should be referred for an endoscopy.
- 4.60. The GORD management section of the NICE Guidelines therefore relates to patients who present alarm signs and symptoms to start with, or who did not respond to acid suppression (PPIs/H2RAs) therapy. Alginates are not recommended for this category of patients, even as a first-line treatment.
- 4.61. Overall, the NICE Guidelines suggest that PPIs and H2RAs are not close substitutes for alginates because they have different therapeutic uses. In particular, PPIs – alone or as part of an H. pylori eradication therapy – are the recommended choice for GPs to treat both uninvestigated dyspepsia with alarm signs and symptoms, and for dyspepsia which is found, after an endoscopy (which is only conducted for patients showing alarm signs and symptoms), to be caused by GORD. In contrast, the use of alginates (and antacids) is recommended as an initial remedy in

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<sup>411</sup> NICE CG17, pages 96 to 120.

empirical treatment of uninvestigated dyspepsia and uninvestigated 'reflux-like' symptoms or as part of a 'step-down' or 'step-off' approach for the long-term management of dyspepsia.<sup>412</sup>

**c) PCO recommendations**

4.62. PCO recommendations to GPs provide further evidence of the perceived therapeutic uses of the medicines in the treatment area. Through an internet search the OFT has identified several documents that were published by health authorities (including PCTs) across the UK which record the recommendations that these organisations made after GL was withdrawn. A summary of the recommended alternatives to GL post-withdrawal is shown in Table 4.1 below.

**Table 4.1: List of products recommended by health authorities following the withdrawal of Gaviscon Liquid from the NHS channel**

| <b>Health authority / Organisation</b> | <b>Publication title</b>                                               | <b>Date</b> | <b>Recommended alternatives</b> |
|----------------------------------------|------------------------------------------------------------------------|-------------|---------------------------------|
| Bolton PCT                             | Withdrawal of Gaviscon Liquid 500ml (Peppermint and Aniseed) NHS packs | June 2005   | Acidex; Peptac                  |
| Brighton and Hove City PCT             | City scripts – Prescribing newsletter                                  | June 2005   | Peptac; Gaviscon Advance        |

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<sup>412</sup> RB submitted in its SMFI, paragraphs 3.2 to 3.9, that the analysis of the NICE Guidelines that was presented in the SO was factually inaccurate. RB considers that NICE does **not** draw a distinction between mild and more severe symptoms for the treatment of GORD and uninvestigated dyspepsia. In RB's view, NICE recommends the prescription of PPIs first-line, in preference to alginates, for all degrees of symptom severity. For the reasons set out above, the OFT disagrees with RB's interpretation of the NICE recommendations on GORD and uninvestigated dyspepsia in this regard.

|                                          |                                                   |                         |                                   |
|------------------------------------------|---------------------------------------------------|-------------------------|-----------------------------------|
| Bury PCT                                 | Letter to GPs                                     | May 2005                | Peptac; Gaviscon Advance          |
| Calderdale and Huddersfield PCT          | Action following the withdrawal of Gaviscon       | July 2005               | Peptac                            |
| Darlington PCT                           | Prescribing memo - Gaviscon                       | June 2005               | Mucogel; Gastrocote; Peptac       |
| Eastern Health and Social Services Board | Gaviscon Liquid Discontinued                      | June 2005               | Peptac                            |
| Grampian Medicines Information Centre    | Withdrawal of Gaviscon Liquid 500mL NHS packs     | May 2005                | Peptac                            |
| Lothian NHS                              | Withdrawal of Gaviscon tablets and liquid (500mL) | August / September 2005 | Peptac                            |
| Oxfordshire PCT                          | Gaviscon suspension                               | October 2005            | Peptac; Algicon; Gaviscon Advance |

Source: Internet, including results of a Google search containing the terms 'gaviscon withdrawal nhs' (performed Monday 30 March 2009)

- 4.63. All of the health organisations listed above recommended another alginate after the Withdrawal, and many of them chose Peptac, the best known equivalent to GL. The OFT could not identify any health organisation that recommended switching to a H2RA or PPI following the Withdrawal. This indicates that these health authorities were not satisfied that PPIs and H2RAs were suitable alternatives to alginates to such an extent that they could be prescribed in place of the withdrawn GL.
- 4.64. Overall, it is apparent that NICE and other health authorities regard alginates as having different therapeutic uses to PPIs and H2RAs. This implies that there is likely to be limited substitution between alginates and PPIs/H2RAs.

**v) Reckitt Benckiser's contemporaneous documents**

**a) Introduction**

4.65. The OFT has assessed RB's contemporaneous documents to determine the extent to which its decision-making and competitive strategy in respect of alginates has been influenced by PPIs and H2RAs. In the further sub-sections below, the OFT has assessed those internal RB documents that consider (b) RB's assessments of the market structure of the treatment area; (c) the impact of the Withdrawal and (d) RB's response to competitor activity. At sub-section (e) the OFT has considered documents in which RB makes representations to external stakeholders.

4.66. Of most significance to an analysis of market definition is objective evidence that relates to the parameters of competition such as considerations of a pricing response to the entry of a new competitor product, commentary around how a new product launch is affecting sales and assessments of how changes to RB's own product portfolio may have an impact upon the sales and pricing strategies of its competitors.

4.67. The OFT has also considered RB's strategies in relation to 'educating' NICE, PCTs and DH about the circumstances in which alginates should be prescribed. These documents relate to RB's attempts to convince stakeholders that the benefits of alginates are such that they should be prescribed in response to a wider range of symptoms. In these documents RB was seeking to persuade stakeholders such as NICE to change the guidelines they issue. As such they can be seen as attempts by RB to extend the market (by seeking changes to the guidance that is used by decision-makers in the treatment area) rather than as an assessment of how the market works in practice. Many of the documents focus on encouraging co-prescribing. Where the documents encourage replacing PPIs with alginates, the arguments relate to circumstances where RB considers that it is more appropriate to prescribe alginates than PPIs, rather than arguments that alginates are an equally effective treatment option as PPIs.

**b) RB's assessment of the treatment area**

- 4.68. The OFT has considered those RB documents in which it assesses the market structure of the treatment area. RB's assessment of the structure of the market provides a useful insight into the extent to which it considers alginates and PPIs/H2RAs to be substitutable, and helps to provide context for its assessment of (i) how the Withdrawal would affect alginates sales and (ii) how competitor activity relating to PPI/H2RA products would impact upon Gaviscon.
- 4.69. RB's market assessments include a survey of 201 GPs that it commissioned from Medix and that was undertaken in March 2008.<sup>413</sup> In this survey, GPs indicated that alginates and PPIs are frequently prescribed to patients presenting the symptoms of GORD.<sup>414</sup> In particular, alginates are more often prescribed to patients presenting mild GORD symptoms (82 per cent of the sample), than to those who present moderate or severe GORD symptoms (32 per cent and 14 per cent of respondents, respectively).<sup>415</sup>

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<sup>413</sup> Appendix 3 of the RB submission dated 1 June 2009, in response to Q5 of the OFT section 26 notice dated 18 May 2009 (OFT File Part 3, document 26.04).

<sup>414</sup> GPs were asked which products they prescribe for the treatment of GORD in an average week and were given the possibility of choosing multiple options (so that the totals exceed 100 per cent). The results show that 86 per cent, 70 per cent, and 17 per cent of the responding GPs prescribe omeprazole, lansoprazole and esomeprazole (all PPIs) respectively; 68 per cent and 31 per cent of the sample responded that they prescribe GA and Peptac respectively; 40 per cent of GPs indicated that they prescribe ranitidine (an H2RA).

<sup>415</sup> The wording of question 5 in the RB survey is as follows: 'For what particular types of patients do you currently prescribe alginates (for example, GA, Peptac, etc.) for the treatment of GORD? Please select all that apply.' As a result of the possibility of multiple choices, the total in this question exceeds 100 per cent.

4.70. The survey also found there to be circumstances in which GPs often chose to co-prescribe alginates with other products (for example, PPIs) to treat patients' symptoms. GPs reported that they co-prescribe PPIs and alginates in the following circumstances:

- patients with 'breakthrough symptoms' (50 per cent of the sample)
- patients whose symptoms 'are not adequately controlled by PPIs' (35 per cent)
- a 'step-down approach from a high dose of PPIs to a low dose of PPIs' (10 per cent), and
- as 'part of a step-off treatment from a low dose of PPIs' (15 per cent).

4.71. RB's survey therefore suggested that PPIs and H2RAs are either regarded as complements to alginates (for example, for the treatment of breakthrough symptoms) or are used as treatments in circumstances in which alginates are not considered suitable (for example, PPIs are appropriate for serious conditions whereas alginates are suitable for mild conditions of GORD).<sup>416</sup>

4.72. RB's internal documents reveal that its view of GP prescribing practices is based on a perception that treatments may be subdivided between those for mild to moderate GORD and those for moderate to severe GORD. This is consistent with the assessment of therapeutic uses outlined above. An RB 'Market Research Project' document dated 12 July 2000, states that:

'GP's current perceptions of the market split into two areas, mild GORD cases where only symptom relief is required,

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<sup>416</sup> As set out at paragraph 2.21 above, the OFT also commissioned a survey of GPs. The findings of the OFT's survey have not been included in this Part, as the results were inconclusive and do not add to the evidence and analysis discussed in this Part.



which is currently the territory for Gaviscon and then severe GORD where healing is required, at the present time this is H2 but more notably, PPI territory. GPs will make an assumption with regard to the need for healing based on the severity of symptoms described by the patient ie. Significant pain must mean some degree or risk of damage.<sup>417</sup>

4.73. In the same document, RB outlines the indications relevant to different brands and makes a clear distinction between those relevant to PPIs and those relevant to alginates. For example, the GA indications are described as 'symptomatic relief of mild to moderate GORD' whereas the omeprazole (a PPI) indications are described as 'healing of oesophageal lesions' and 'treatment on demand for Moderate to Severe GORD'.<sup>418</sup>

4.74. A more recent RB document,<sup>419</sup> a presentation entitled '*Gaviscon Advance 2006 Campaign*', describes the detailing literature that is to be used by RB representatives to encourage GPs to prescribe GA. The relevant slides include the following:

'The 7 Stages – First-Line

- First-line for patients suffering mild to moderate heartburn, reflux oesophagitis or hiatus hernia.
- Patients with more severe reflux for whom PPI is not required:
  - where healing not required / no oesophagitis

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<sup>417</sup> RB submission dated 6 March 2009 in response to Q1 (iii) of the OFT's section 26 Notice dated 14 January 2009, document 1.

<sup>418</sup> Ibid.

<sup>419</sup> RB submission dated 6 March 2009 in response to Q2 of OFT section 26 Notice dated 14 January 2009, document 79.

- Patients with more severe reflux for whom a PPI is contra-indicated or not suitable

#### The 7 Stages – Co-Rx

- Combined prescribing of Gaviscon Advance with a low dose PPI for patients requiring instant relief of breakthrough symptoms:
    - For patients moved from high to low dose when reviewed [...]
    - For patients who report breakthrough symptoms
    - For patients likely to suffer breakthrough on a low dose PPI
    - For patients who can start with a low dose PPI first-line'
- 4.75. It is apparent that RB is not seeking to promote GA as a direct competitor to PPIs. Consistent with the prescribing literature, RB's sales approach is to stress GA's use in treating mild to moderate symptoms of heartburn, or to be used for more severe symptoms where PPIs are contra-indicated. RB also suggests that GA may be used as a complementary product to PPIs, and its sales literature stresses its use in providing the symptomatic relief for breakthrough symptoms that is not managed by PPIs.
- 4.76. RB's sales literature therefore seeks to stress that GA may be used as a complementary treatment to PPIs, to deal with immediate symptom relief, or as a treatment on its own for mild symptoms or where PPIs are contra-indicated. To the extent that RB seeks to persuade GPs that alginates may be substitutable with PPIs, it is limited to those circumstances in which RB is seeking to persuade a GP that in certain circumstances it may be preferable to prescribe a low-dose PPI with alginates and instead of a high dose PPI.

**c) The withdrawal of Gaviscon Liquid NHS packs**

4.77. The OFT has examined the internal documents in which RB considered the impact of the Withdrawal from the prescription channel of its leading alginate product, GL. If RB regarded PPIs and H2RAs as close competitors to its portfolio of Gaviscon products, its internal documents would be expected to demonstrate a significant concern that after the withdrawal of its leading product a significant number of GPs would choose to instead prescribe PPIs or H2RAs. Instead, RB's internal documents focus on the potential to lose significant sales to another alginate - Peptac. This expectation is outlined in a number of internal documents, for example:<sup>420</sup>,

'If we withdraw GL to replace with advance the first thing the majority of PCT's would look to substitute repeats with would be Peptac.'<sup>421</sup>

'The risk with advance as a replacement, is these GP's simply move to Peptac which is closer to Gav Liquid.'<sup>422</sup>

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<sup>420</sup> See also internal RB email dated 7 March 2003 and paper entitled 'Project White Tiger PCT Strategy' – RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 79; Slides from internal RB presentation of 11 March 2005 – RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 Notice of 14 January 2009, document 95; Slide from internal RB presentation of 16 March 2005 – RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 Notice of 14 January 2009, document 100; Q&A document circulated within RB on 20 May 2005 – RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 Notice of 14 January 2009, document 267.

<sup>421</sup> RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 Notice dated 14 January 2009, document 13.

<sup>422</sup> RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 Notice dated 14 January 2009, document 14.

'From my POV [point of view] the big win is buying ourselves a window of opportunity to withdraw Original Gaviscon from sale within the NHS with the objective of converting 100 percent of sales into Advance – based on the assumption that there would not be loss of business risk as Advance (liquid or tabs) would be the only option in the market at the time of withdrawal.'<sup>423</sup>

4.78. In its SMFI,<sup>424</sup> RB notes that, when assessing the risks associated with the Withdrawal, some of its internal documents do express a concern that it may result in switching to products other than alginates. For example, an internal email dated 1 April 2005 notes that 'key drivers of ongoing demand will be: 1. What % of repeat prescriptions we lose to Peptac, to OTC purchase or to a therapy switch'.<sup>425</sup> Similarly, a presentation on Project White Tiger dated March 2005 includes as a 'key risk' the prospect that 'GPs switch patients to other products'.<sup>426</sup> This is reflected in other emails which note that market share loss may result from 'GPs choosing to switch their patients out of alginates altogether'<sup>427</sup> or '[...]%

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<sup>423</sup> Internal RB email dated 13 May 2004, RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's s.26 Notice dated 14 January 2009, document 28.

<sup>424</sup> RB SMFI, paragraphs 3.11 and 3.12.

<sup>425</sup> RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 Notice dated 14 January 2009, document 144.

<sup>426</sup> RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 Notice dated 14 January 2009, document 99.

<sup>427</sup> RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 Notice dated 14 January 2009, document 70. RB suggests in its SMFI (paragraph 3.12(a)) that this implies switching to PPIs.

repeat prescriptions lost (switched to alginate / other treatments by practice managers / GPs / PCT recommendation)'.<sup>428</sup>

- 4.79. The OFT recognises that certain RB documents do refer to the risk of switching to non-alginate treatments, and it is possible that RB may have been referring to such other treatments as antacids, H2RAs, PPIs or life-style changes. Nevertheless, while RB did identify and articulate the risk of substantial sales losses to Peptac, its internal documents do not document a concern in respect of any other specified product or product category. Further, switching to Peptac is the concern that is evident in all relevant correspondence, whereas RB's vague reference to switching to other treatments/products are only evident in a small number of documents.
- 4.80. In this context it is significant that once the Withdrawal was implemented, RB closely monitored the impact on its sales lost to Peptac and some other alginate products. There is no reference to similar monitoring of non-alginate products such as PPIs and H2RAs. In addition to measuring how many PCTs and PCOs had switched from GL to GA, there were regular updates of the number of GP practices that had been 'switching to Peptac' and how many PCTs and PCOs were 'recommending [a] switch to Peptac'.<sup>429</sup>

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<sup>428</sup> RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 Notice dated 14 January 2009, document 154.

<sup>429</sup> See, for example, (i) internal RB email dated 3 June 2005, RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 Notice of 14 January 2009 document 302 (in the months after the withdrawal these updates were almost made daily see also documents 320, 324 and 326); (ii) internal RB email dated 10 June 2005, RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 Notice dated 14 January 2009, document 327; (iii) internal RB email dated 17 June 2005, RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 Notice dated 14 January 2009 – document 349; internal RB email dated 19 July 2005 – RB

4.81. In a more developed summary of events, circulated within RB on 7 June 2005, sections on 'competitor response' and 'anticipated impact' noted only developments relating to Peptac and none about PPIs or H2RAs. The summary noted:

'Competitor Response

Pinewood have launched a Peppermint variant of Acidex (one of their many licences held on behalf of generic and private label suppliers) and it is anticipated that a Peptac Peppermint will be launched within two months.

Anticipated Impact

Overall, despite some challenging issues raised by the PCO universe and the unexpected early price drop on Peptac,<sup>430</sup> the losses to date remain within the parameters to which we planned the project.<sup>431</sup>

4.82. RB's internal documents do not cite any other instances of actual competitor reaction, in particular from manufacturers of H2RAs and PPIs. This indicates that RB concentrated on alginates, and that they considered that the threat to its Gaviscon products would come from other alginates, namely Peptac.<sup>432</sup>

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submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 Notice dated 14 January, document 368.

<sup>430</sup> It was noted that the price cut on Peptac was also due to a coincidental DH campaign against branded generics.

<sup>431</sup> Internal RB email and paper dated 7 June 2005 – RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 Notice of 14 January 2009 – document 312.

<sup>432</sup> Extract of spreadsheet circulated within RB on 28 July 2005 – RB submission dated 6 March 2009 in response to Q1 (iii) of OFT section 26 Notice dated 14 January 2009, document 374.

- 4.83. RB also produced summaries of the weekly changes to sales of products in the market. These comparisons (which were often very detailed, by individual practice in some cases) were always between the Gaviscon products and other alginate products and did not include PPIs or H2RAs.<sup>433</sup>
- 4.84. In its SMFI,<sup>434</sup> RB argued that a number of the documents referred to by the OFT do in fact include references to competing with PPIs,<sup>435</sup> such that the OFT was wrong to find that RB had not monitored switching to PPIs/H2RAs following the Withdrawal. The documents referred to by RB relate to RB's strategy to convince stakeholders that the benefits of alginates are such that they should be prescribed in response to a wider range of symptoms and that alginates may, for example, be co-prescribed with dose of PPIs. The OFT notes that such documents therefore relate to marketing rather than sales monitoring, and that these references do not therefore contradict the observation that following the Withdrawal RB monitored switching to alginates but not to PPIs/H2RAs.
- 4.85. In documents that reviewed the White Tiger strategy, the competitor analysis also focused on competition from alginates, primarily Peptac. For example, around 11 months after the Withdrawal, on 9 May 2006, a draft Executive Summary about the

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<sup>433</sup> For example, a spreadsheet circulated within RB on 28 July 2005 compared the number of scripts produced by each UK practice for GL and GA with those of Algicon, Gastrocote and Peptac (Extract of spreadsheet circulated within RB on 28 July 2005, RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009 document 374).

<sup>434</sup> RB SMFI, paragraph 3.14.

<sup>435</sup> RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 Notice dated 14 January 2009 - documents 326, 349 and 421.

project was produced.<sup>436</sup> The report contained an assessment of the success of the Withdrawal which noted that 46 per cent of PCOs had responded negatively, recommending that GPs switched prescriptions from GL to Peptac. The report also noted that the only competitor to respond was Pinewood with Peptac. This indicates that, not only was RB concerned only with the response of other alginate suppliers, but that only alginate suppliers were concerned with the Withdrawal:

'The only competitor who reacted to Project White Tiger was Peptac, and they targeted PCOs with cost arguments ...

Although we experienced a significant loss in market share in volume terms (from 92 percent to 70 percent), we maintained a predicted level of loss in value market share, which is currently stable at 85 percent value share.'

4.86. RB's internal evidence in relation to the Withdrawal is therefore consistent with a lack of substitutability between alginates and PPIs or H2RAs. On withdrawing GL, RB did not foresee any material competitive response from PPIs and H2RAs or significant sales losses to these product categories. The evidence on switching, including the analysis conducted by RB and the analysis by the OFT which is set out in Part 4Dv)d) below, confirms that its expectations were correct.

**d) Reckitt Benckiser's assessment of competitor strategies**

4.87. In the OFT's section 26 Notice dated 29 July 2009, RB was asked to provide those internal research and strategy documents in which it had assessed the impact of the generic entry of PPIs and H2RAs on sales of alginate products in general and Gaviscon products in particular.

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<sup>436</sup> Internal RB email dated 9 May 2006 circulating a 'Project White Tiger review paper', RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 421.



- 4.88. In response, RB noted that it 'does not, in general, produce specific research and strategy documents relating to the launch of new competitor products to Gaviscon, but considers any launches or other competitor activity more generally in the brand review documents produced for Gaviscon'.<sup>437</sup>
- 4.89. In the brand review documents provided by RB, RB makes consistent reference to its strategy for defending its business from the threat of generic alginate products such as Peptac. These documents suggest that RB considered the primary competitor product to Gaviscon to be Peptac. This is demonstrated in documents where RB identified Peptac as the 'key threat' and the main competitor.<sup>438</sup>
- 4.90. In addition, RB's internal documents demonstrate that RB went to considerable efforts to protect itself against competition from generic alginates. One such response, the Withdrawal, is the subject of this Decision. RB also considered other means by which to protect itself from competition from generic alginate products, including price decreases. For example, an undated internal RB presentation entitled 'Gaviscon – 2001 Business Review'<sup>439</sup> noted that PCOs were directing GPs to prescribe Peptac. The presentation identifies that a 'key activity' to be implemented

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<sup>437</sup> Covering letter to RB response, dated 18 August 2009, to OFT section 26 notice of 28 July 2009 (OFT file part 5, document 58).

<sup>438</sup> See, for example: RB presentation entitled 'Gaviscon NHS Update' dated 20 July 2001 (RB submission of 6 March 2009 in response to Q1(i) of OFT section 26 notice dated 14 January 2009, document 83); RB internal presentation entitled 'Situation Analysis', dated 2000 (RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, document 3); RB internal presentation entitled 'Gaviscon NHS Volume Share', dated April 2000 (RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, document 5).

<sup>439</sup> RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, document 13.

when a generic name relating to Gaviscon is granted is [...] in order to 'tie up as much [...] [prescription] business as possible to[...] and deter competitors'.

- 4.91. Another proposal in the same document is to [...]. The objective was to [...]' A further presentation document in relation to this proposal, dated February 2006 entitled 'Gaviscon Advance - GI Category Meeting',<sup>440</sup> includes a slide detailing 'Market Dynamics to be considered' which does not include any consideration of PPIs or H2RAs.
- 4.92. Similarly, an RB undated business review document entitled '2002 NHS'<sup>441</sup> lists a 'post generic action plan' which includes [...]
- 4.93. The only documents that consider material changes to RB's competitive strategy in the context of PPIs do not suggest that RB considered PPIs to be substitutable with alginates to any meaningful extent, and do not consider how RB should respond to product and/or price changes for PPIs and/or H2RAs. Rather, these documents are consistent with the analysis in Part 4Div) above which suggests that alginates and PPIs may sometimes be prescribed together as complementary treatments.<sup>442</sup> In particular, RB considered whether a [...] with a [...] would ensure that Gaviscon (rather than a competing alginate) was co-prescribed

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<sup>440</sup> RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, document 64.

<sup>441</sup> RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, document 22.

<sup>442</sup> In fact, in RB's internal documents the view that alginates and PPIs are complementary is expressed (see RB submission of 6 March 2009 in response to Q1(iii) of OFT section 26 notice dated 14 January 2009, document 296).

with PPIs. This is demonstrated by an internal RB email dated 23 July 2003, which advocates a [...].<sup>443</sup>

- 4.94. The OFT notes that while RB refers to the emergence of generic competition to PPIs as a threat to the Gaviscon portfolio<sup>444</sup> in various strategy documents, there are no corresponding documents in which RB considers [...] as a means of responding to such events (this is consistent with the analysis of selected 'natural events' at Part 4Dvi)vi)d) below, which finds that Gaviscon price levels do not respond to significant PPI/H2RA price changes). This contrasts starkly with RB's preoccupation with competition from alginate suppliers such as Pinewood (see paragraph 4.89 above).
- 4.95. RB's internal documents also note prescribing trend changes that affect, for example, the proportion of 'first-line' prescriptions that are issued for PPIs and alginates.<sup>445</sup> These documents state that PPIs are increasingly being prescribed as 'first-line' treatments at the expense of Gaviscon. However, sales data (see paragraphs 4.108 to 4.118 below) confirms that the competitive interaction that RB refers to can only have affected a modest proportion of Gaviscon sales in the prescription channel and/or may simply

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<sup>443</sup> RB submission of 6 March 2009 in response to Q1(vi) of OFT section 26 notice dated 14 January 2009, document 12.

<sup>444</sup> See, for example, RB submission of 6 March 2009 in response to Q1(iii) of OFT section 26 notice dated 14 January 2009, document 24; RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, documents 9, 11, 12, 14 and 22 .

<sup>445</sup> See, for example, RB submission of 18 May 2009 in response to question 2 of the section 26 notice dated 18 August 2009, document 15. RB states that it requires 'clinical evidence' to support its 'current detail story' to ensure that it can 'Defend GA from the continued onslaught of PPIs' which 'are now seen as 1<sup>st</sup> line for GORD as clinically effective and now cost effective (since loss of omeprazole patent)'. See also, for example, RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, documents 31, 36, 42 and 43.

reflect an increased preference of GPs for using a step-down approach rather than a step-up approach (such that PPIs were increasingly prescribed as first-line treatments before treatment was stepped down to alginates, rather than vice versa).

4.96. The above evidence suggests that RB considered other alginates to represent a potential competitive constraint such that, had GL faced full generic competition, it would have been necessary to decrease its price to retain market share. While RB lists generic PPI competition as a 'threat', its internal documents do not suggest that RB considered responding by [...] or [...] in respect of Gaviscon sales made in the prescription channel. While, as may be expected of two product types that are used to treat different symptom types and strength in the same treatment area, RB considers there to be some competitive interaction between PPIs/H2RAs and alginates, RB's internal documents imply that it did not consider PPIs and H2RAs to exert significant competitive pressure on Gaviscon in the NHS channel.

**e) Reckitt Benckiser's representations to stakeholders**

4.97. RB provided the OFT with a number of documents which set out the ways in which Gaviscon, as an alginate product, stands apart from H2RAs and particularly PPIs by virtue of its mode of action, efficacy, cost and/or its actual or potential therapeutic applications. RB made such points in the context of representations designed to convince organisations such as NICE and PCTs that it was appropriate to prescribe alginates in a greater number of circumstances than it was suggested in the NICE Guidelines outlined in Part 4Div)iv)b) above.

4.98. For example, in a presentation entitled 'Gaviscon NHS Update' dated 20 July 2001,<sup>446</sup> under the heading 'Upgrade – Key Selling

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<sup>446</sup> RB submission of 6 March 2009 in response to Q1(i) of OFT section 26 notice dated 14 January 2009, document 83.

Messages', RB considers alginates to be the most appropriate first-line therapy for the management of mild to moderate GORD. In a letter to DH dated 23 March 2000,<sup>447</sup> RB notes that PPIs are 'overprescribed' and that stepped therapy starting with alginates/antacids is best for many patients – with PPIs used for the most resistant conditions.

- 4.99. A letter from RB to the National Guidelines Support and Research Unit, Centre for Health Services Research dated 26 April 2002<sup>448</sup> encloses RB's submission to the process for producing a 'Clinical Guideline for the Primary Care Management of Adult Patients with Dyspepsia'. RB's submission sets out the advantages of alginates over PPIs and the differences between the two types of products. The points made by RB include the observation that for all patients who have undergone endoscopy but have no underlying disease, the focus of therapy should be symptom control rather than healing, and control of symptoms should begin with lifestyle advice followed by a step-up approach.<sup>449</sup> In relation to the mode of action of alginates, RB argues that '[a]lthough acid plays a

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<sup>447</sup> RB submission of 12 December 2008 in response to OFT section 26 notice dated 28 November 2008, document 17.

<sup>448</sup> RB submission of 18 August 2009 in response to Q5 of OFT section 26 notice dated 28 July 2009, document 2.

<sup>449</sup> RB's view that symptom control is the most important aspect of GORD management, and one which is not satisfactorily addressed by PPIs, is also reflected in other documents, such as: RB undated presentation entitled 'Proposed GI Activities for 2003' (RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, document 26), which proposes to 'Get 'maintenance of symptom control after healing with PPI' indication on Advance PL'; an RB presentation dated 30 June 2003 entitled 'NHS Business Review and 2003 Balance to Go - National Conference, Redworth Hall' (RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, document 31) which, in the context of presenting research findings on GORD therapy objectives, suggests that although healing may be a bonus with use of PPIs and H2RAs, 'the consideration that drives treatment is patient symptoms'.

central role, GORD is primarily a motility disorder and it is the transient relaxations of the LOS [lower oesophageal sphincter] that are responsible for 80 per cent of reflux episodes' and that the advantages of alginates are that they are fast acting, have a non-systemic mode of action and do not cause 'rebound hypersecretion' of acid.

- 4.100. The same document also presents arguments in relation to the appropriateness and cost effectiveness of prescribing PPIs as a first-line treatment or for milder symptoms. RB asserts that prescribing of PPIs is less cost-effective at the milder end of the disease scale where it can be managed with alternative therapies. Furthermore, RB recommends that dyspepsia clinics should be set up to encourage step-down and step-off from PPIs where PPIs are inappropriate but still prescribed. RB also views that in the long term those clinics should focus on a step-up approach.
- 4.101. In correspondence with NICE, RB made further assertions to the same effect.<sup>450</sup> RB argues that symptom control should be the main priority in effective management and that, whereas the symptoms of dyspepsia are recurrent and intermittent, PPIs' mode of action does not provide adequate symptom control when taken on-demand. Therefore intermittent, on-demand use of PPIs is not appropriate from a patient satisfaction point of view. (RB also observes here that only one PPI is licensed for on-demand use and that alginates are licensed for use in pregnancy, which is a major cause of heartburn/dyspepsia, whereas PPIs/H2RAs are not). Finally, RB argues that a low-dose PPI with a doubling of dosage if

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<sup>450</sup> In a submission to NICE dated 18 August 2003, in response to the first draft of a *Clinical Guideline for the Treatment of Dyspepsia*, RB stated: 'We believe that [recommending long-term low dose use of PPIs with little incentive to step down or off] is a fundamentally incorrect approach to the disease, given that there is now good evidence that it is possible successfully to use step therapy in significant numbers of patients, with concomitant savings to the NHS.' RB submission of 18 August 2009 in response to Q5 of OFT section 26 notice dated 28 July 2009, document 4.

symptoms recur may be less cost-effective than the use of an alginate in conjunction with a low-dose PPI.

4.102. The push to promote to GPs, PCTs and NICE the co-prescribing of GA with PPIs and the use of a step-down/off approach appears to have been a significant project for RB in order to increase sales of GA in the prescription channel. A major part of RB's premise for promoting co-prescribing, as can be seen from the above, was that the over-prescription and inappropriate prescription of PPIs was not cost-efficient for the NHS. RB also focused on the benefits of GA in treating aspects of GORD which were not treated by PPIs or H2RAs, such as 'acid rebound', 'acid breakthrough symptoms' and the prevention of reflux of other stomach contents, such as bile and pepsin, which may damage the oesophagus.<sup>451</sup>

4.103. An internal presentation by RB dated 20 February 2007<sup>452</sup> in relation to research carried out on the effect of marketing activity

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<sup>451</sup> Documents in which RB set out the differences between GA and PPIs in the context of its promotion of co-prescribing include inter alia: RB submission of 6 March 2009 in response to Q1(vi) of OFT section 26 notice dated 14 January 2009, document 12; RB submission of 6 March 2009 in response to Q1(vi) of OFT section 26 notice dated 14 January 2009, document 14; RB submission of 6 March 2009 in response to Q1(iii) of OFT section 26 notice dated 14 January 2009, document 366; RB submission of 6 March 2009 in response to Q2 of OFT section 26 notice dated 14 January 2009, document 79; RB submission of 12 December 2008 in response to OFT section 26 notice dated 28 November 2008, document 28/29; RB submission of 18 August 2009 in response to Q4 of OFT section 26 notice dated 28 July 2009, document 32; RB submission of 18 August 2009 in response to Q4 of OFT section 26 notice dated 28 July 2009, document 42; RB submission of 18 August 2009 in response to Q4 of OFT section 26 notice dated 28 July 2009, document 59; RB submission of 18 August 2009 in response to Q1 of OFT section 26 notice dated 28 July 2009, document 7; RB submission of 18 August 2009 in response to Q2 of OFT section 26 notice dated 28 July 2009, document 8; RB submission of 18 August 2009 in response to Q2 of OFT section 26 notice dated 28 July 2009, document 11.

<sup>452</sup> RB submission of 18 August 2009 in response to Q3 of OFT section 26 notice dated 28 July 2009, document 5.

to GPs ('detailing') on changes in GPs' prescribing habits suggests that the main way to [...]. The document states that 'Gaviscon has immediate opportunities to address the [...]' It continues [...]. Recommendations of the research include to [...]

4.104. RB's view of alginates as a complementary product to PPIs is also demonstrated in an internal RB email dated 2 June 2005, which states: 'Position Gaviscon Advance as complementary to managing breakthrough symptoms of PPI therapy ... [and] ... as the first point of call for heartburn symptoms.'<sup>453</sup>

**f) Overall assessment of RB's contemporaneous documents**

4.105. RB's contemporaneous documents indicate that only alginates are considered by RB to be significant competitors to its Gaviscon portfolio. While RB devoted significant time and resource to determining its response to the publication of a generic name relevant to GL and competing alginates such as Peptac/Acidex, its internal strategy documents [...] This lack of internal documents analysing the impact of, and proposing responses to, generic entry of H2RAs and PPIs is consistent with the different therapeutic uses of these products relative to alginates as set out in prescribing guidelines and put into practice by GPs.

4.106. As outlined above, RB's representations to NICE and others in relation to the circumstances in which alginates may be prescribed is not objective evidence of PPIs and H2RAs providing a competitive constraint on alginates. Such arguments have the potential to influence the competitive environment in the treatment area, but do not amount to evidence of the extent to which alginates and PPIs/H2RAs have competed with one another in reality. In any case, many of the arguments presented by RB are in fact (i) designed to encourage the complementary prescribing of

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<sup>453</sup> RB submission of 6 March 2009 in response to Q1(iii) of OFT section 26 notice dated 14 January 2009, document 296.



two fundamentally distinct products, rather than to suggest that alginates and PPIs/H2RAs are generally interchangeable treatments and/or (ii) stress the differing modes of action and therapeutic uses of PPIs/H2RAs and the need to observe a 'step therapy' whereby alginates are used to treat milder symptoms and PPIs/H2RAs are used to treat more severe symptoms.

4.107. While certain of these documents imply an element of competition between PPIs and alginates (in the sense that RB is arguing that increasing the co-prescription of alginates with PPIs can facilitate a decrease in the volumes of PPIs that are prescribed), it is apparent from the majority of RB's internal documents that such competition was [...].

**vi) Sales trends of alginates and anti-ulcerants**

**a) Introduction**

4.108. This Section examines NHS data relating to sales trends of the various treatments for acid-related diseases (including PPIs, H2RAs, and alginates) in the prescription channel and, in particular, the extent to which those trends suggests that PPIs and H2RAs exerted a significant competitive constraint on alginates.

4.109. In the NHS data presented below, the value of sales is expressed in terms of 'Net Ingredient Cost' (NIC), which is the amount that the NHS pays to dispensers for each medicine before discounts and excluding any dispensing costs or fees. The value of sales is reported in nominal terms given that, under the terms of the PPRS, prices are not adjusted for inflation and list prices will only vary as a result of agreed portfolio-wide price cuts and a manufacturer's response to them.

4.110. Volume figures are reported in terms of number of items prescribed. The Information Centre of the NHS defines a prescription item as a single item prescribed by a doctor (or dentist/nurse) on a prescription form. Accordingly, if a prescription form includes three medicines it is counted as three prescription

items. Since data on sales volumes does not take into account the different pack types and sizes of each product, the OFT's analysis focuses upon the value of sales.<sup>454</sup>

4.111. It should be noted that the data used in this Section relates to prescriptions in England only, since the OFT was able to obtain detailed (at product level) quarterly data for that country only. There is no reason, however, to expect that sales trends should be very different in the rest of the UK. In addition, England accounts for approximately 80 per cent of total sales of alginates and antacids in the UK, both in volume and value terms. The conclusions on market definition reached by considering data for England only can therefore be taken as valid for the UK as a whole.

4.112. The data supplied by the NHS to the OFT spans almost 20 years (1991 – 2008) and provides a significant insight into the instances and extent of competitive interaction between PPIs, H2RAs, and alginates. Specifically, it is possible to observe sales of the two most successful PPIs (Losec and Zoton) over key phases of their life-cycles (from launch to after patent expiry), sales of other PPIs which are still protected by a patent, and also how generic

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<sup>454</sup> This view is also clearly articulated in the *AstraZeneca* decision, paragraph 394: 'AZ asserts that volume (in particular measured in terms of the number of prescriptions) is a better reflection of competition in the pharmaceutical market than sales measured by value. AZ's contention cannot be accepted. The products at stake in this case are differentiated in nature (for example, in terms of dosage forms, pack sizes and strength). For such products sales in value and their associated market share will – according to the Notice on market definition [paragraph 55] – usually better reflect the relative position and strength of each supplier. This guidance is also relevant to the pharmaceutical sector. Considering the differentiated nature of the products in terms of for example, strengths and pack sizes different prescriptions are not necessarily comparable. Sales in terms of value therefore better reflect the position on the market than the number of prescriptions written by doctors'.

competition among H2RAs has affected sales of other products within the treatment area.<sup>455</sup>

**b) Analysis of sales by value and volume**

4.113. The value of sales of each category of treatment for dyspepsia and other acid-related diseases (alginates, PPIs, H2RAs, and other treatments for dyspepsia)<sup>456</sup> prescribed by GPs in England from the first quarter of 1991 to the third quarter of 2008 are shown in Figure 4.1 below. The sales volumes of the different product types during the period between Q1 1991 and Q3 2008 are shown in Figure 4.2.

4.114. For the purpose of this analysis, the OFT has considered three distinct phases. Each of these phases is characterised by specific sales patterns within the treatment area, against which it is possible to make inferences about the competitive interactions of the different product types. The three relevant phases are as follows:

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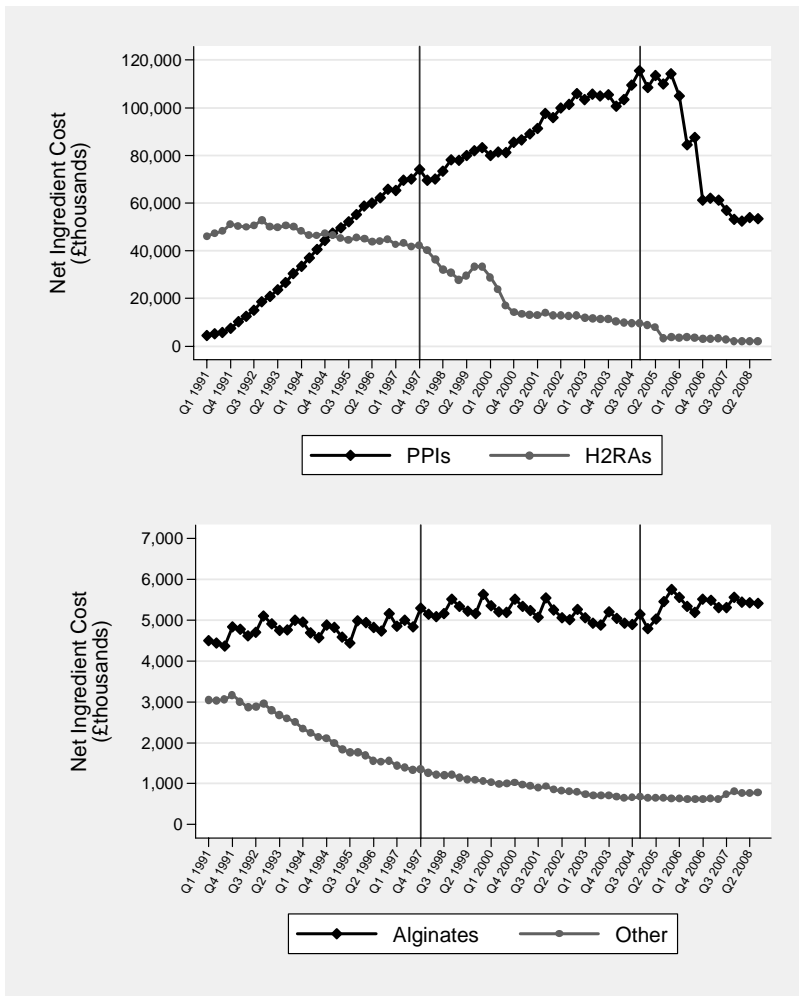
<sup>455</sup> The OFT notes that the analysis in this Section and Section 4D.vi)d) considers data for the treatment area as a whole and not for individual micro-diagnoses (such as those referred to in the NICE Guidelines, see paragraphs 2.57 to 2.65 above). The OFT is satisfied that, to the extent that a significant competitive interaction existed between alginates and PPIs/H2RAs in respect of a micro-diagnosis that exhibited material sales volumes, such trends would be observed in an analysis of the treatment area as a whole. In particular, the OFT notes that given the considerable timescales considered, and the number of significant market events that took place in that period (see paragraphs 4.124 to 4.142 below), data for the treatment area as a whole would be expected to highlight any material competitive interactions between alginates and PPIs/H2RAs. This is because, to the extent there had been material competitive interaction between alginates and PPIs/H2RAs in respect of a micro-diagnosis that exhibited significant sales volumes, the events considered would be expected to impact upon the sales and pricing trends of the treatment area as a whole.

<sup>456</sup> 'Other' is a residual category and includes all drugs which are not H2RAs, PPIs, or alginates, for example, antacids and sodium bicarbonate.

- from Q1 1991 to Q4 1997, when the value and volume of sales of PPIs expanded rapidly and this led to a rapid expansion of the value and volume of sales in the whole treatment area
- from Q1 1998 to Q4 2004, when the volume and value of sales of PPIs continued to grow (although the value of sales grew at a significantly lower rate than the volume) and the value and volume of sales of H2RAs declined markedly. This resulted in the overall value of sales for the whole therapeutic area remaining broadly constant while the volume of sales continued to increase, and
- from Q1 2005 to Q3 2008, when the volume of sales of PPIs continued to grow but the value of sales of PPIs declined rapidly due to the availability of generic equivalents for the most popular branded products.

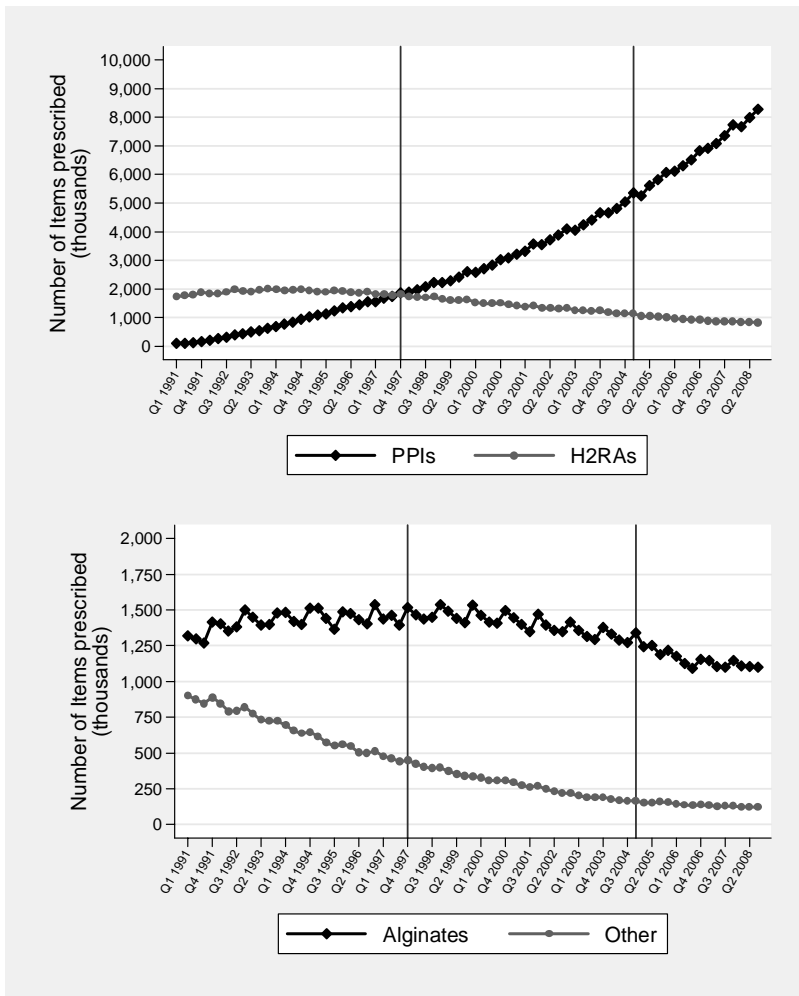
4.115. Table 4.2 below presents details of the annual growth rates of sales values and sales volumes of the different product categories for each period.

**Figure 4.1: Value of sales (in nominal terms) of PPIs, H2RAs, alginates and other treatments for dyspepsia prescribed by GPs in England, Q1 1991 – Q3 2008**



Source: OFT analysis of data provided by the NHS Information Centre

**Figure 4.2: Number of items prescribed of PPIs, H2RAs, alginates and other treatments for dyspepsia prescribed by GPs in England, Q1 1991 – Q3 2008**



Source: OFT analysis of data provided by the NHS Information Centre

**Table 4.2: Annual percentage growth rates of treatments for acid-related conditions, Q1 1991 to Q3 2008**

| Product category | Q1 1991 to Q4 1997 |        | Q1 1998 to Q4 2004 |        | Q1 2005 to Q3 2008 |        | Q1 1991 to Q3 2008 |        |
|------------------|--------------------|--------|--------------------|--------|--------------------|--------|--------------------|--------|
|                  | Value              | Volume | Value              | Volume | Value              | Volume | Value              | Volume |
| Alginates        | 2.4                | 2.1    | - 0.4              | -1.8   | 1.4                | -5.2   | 1.1                | -1.0   |
| H2RAs            | - 1.3              | 0.7    | - 20.6             | -6.5   | - 39.2             | -8.4   | - 17.4             | -4.2   |
| PPIs             | 44.1               | 47.7   | 6.4                | 15.4   | - 20.0             | 11.8   | 14.5               | 26.8   |
| Other            | - 11.9             | -10.2  | - 9.8              | -14.0  | 3.7                | -8.5   | - 7.7              | -11.4  |
| All categories   | 11.3               | 4.9    | 0.9                | 5.5    | - 19.5             | 6.9    | 0.4                | 5.4    |

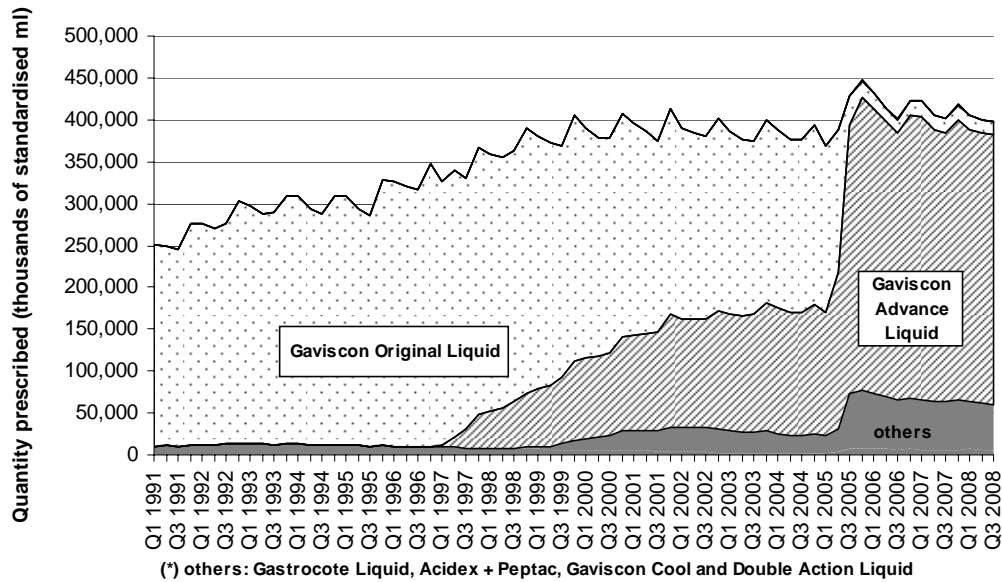
Source: OFT analysis of data provided by the NHS Information Centre.

4.116. In contrast to the large changes in sales volumes and values of PPIs and H2RAs highlighted at paragraph 4.118, the sales volumes and values of alginates remained broadly constant. Overall, in the period from Q1 1991 to Q3 2008 the value of sales of alginates increased steadily and gradually, by approximately one per cent per annum.

4.117. After Q2 2005 there was a slight decrease in alginate volumes, as measured by prescription items, as a result of switching from GL to GA following the Withdrawal. GA is twice as concentrated as GL but was made available in the same bottle sizes as were used for GL prior to the Withdrawal. As patients would require half as many bottles of GA as they would for the same treatment using GL, this would be expected to reduce the number of prescription items. This effect was envisaged by RB prior to the Withdrawal. RB anticipated that switching from GL to GA would result in its volume share of the market declining at a greater rate than its

value share.<sup>457</sup> Figure 4.3 below confirms that, aside from the dosage affect attributable to switching from GL to GA, consumption of alginates was in fact broadly unchanged between Q3 2005 and Q3 2008.

**Figure 4.3: Quantity of alginates prescribed in liquid form (in standardised units)<sup>458</sup> in England, Q1 1991 – Q3 2008**



4.118. Overall, therefore, while a significant volatility is observed in the sales trends of H2RAs and PPIs between 1991 and 2008, sales of alginates have increased gradually and steadily. The sales trends observed suggest no meaningful interaction between the sales of PPIs and alginates. In contrast, the significant decline of H2RAs

<sup>457</sup> Internal RB slide presentation circulated on 16 March 2006 – RB submission of 6 March 2009 in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 404.

<sup>458</sup> To adjust for the fact that GA is twice the concentration of GL, the prescribing volumes of GL and Peptac are divided by two in the above analysis.



that took place alongside the growth of PPIs suggests that sales of H2RAs were constrained by PPIs. The lack of effective competitive interaction between anti-ulcerants (PPIs and H2RAs) and alginates strongly suggests that alginates are in a separate market.

**c) Changes in treatment costs of alginates and anti-ulcerants**

4.119. This sub-section considers the extent to which H2RA and PPI price changes have affected the pricing of alginates, and in particular to whether there is evidence that changes in the price of each product type constrained one another. The respective treatment costs – calculated using a representative sample of PPIs, H2RAs, and alginates<sup>459</sup> – are shown (in nominal terms) in Figure 4.4 below.

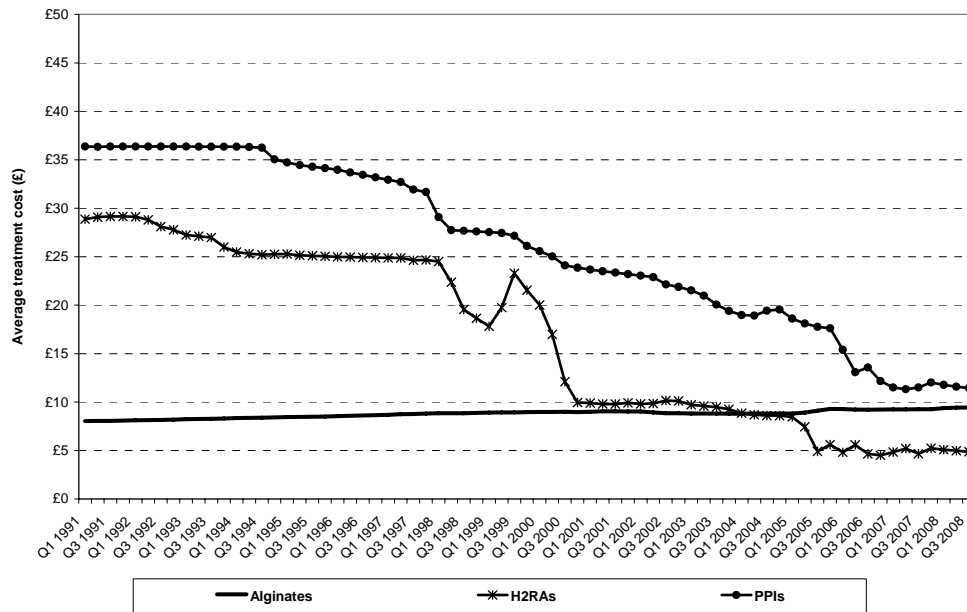
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<sup>459</sup> The sample includes any branded or generic product which reported a share of total Net Ingredient Cost (NIC) equal to five per cent or more in at least one year between 1991 and 2008 in the NHS dataset. The products included were:

- Alginates: Gastrocote tablets; Gaviscon Advance Liquid; Gaviscon Advance tablets; Gaviscon Original Liquid; Gaviscon Original tablets; Peptac Liquid
- H2RAs: Axid and nizatidine capsules 150mg; Tagamet and cimetidine tablets 400mg; Zantac and ranitidine tablets 150mg; Zantac and ranitidine tablets 300mg
- PPIs: Losec and omeprazole capsules 10mg; Losec and omeprazole capsules 20mg; Losec MUPS tablets 20mg; Nexium tablets 20mg and 40mg; Pariet tablets 20mg; Zoton and lansoprazole capsules 15mg; Zoton and lansoprazole capsules 30mg.

The duration of the treatment was set at 28 days, which is the duration of a typical treatment with PPIs and H2RAs as per product literature (retrieved from the specialist website Medicines Compendium <http://emc.medicines.org.uk>) and BNF indications. Together, the products included in the sample account on average for at least 87 per cent of total sales value (as expressed by NIC) in each category. The average treatment cost of each category (as shown in the figure above) is calculated by taking the weighted average of the treatment costs of all products included in the sample (see above) for each category and by using values of sales (in terms of NIC) as weights.

**Figure 4.4: Average cost (in nominal terms) of treating dyspepsia for 28 days using H2RAs, PPIs, and alginates in England, Q1 1991 – Q3 2008**



Source: OFT analysis of data provided by the NHS Information Centre

4.120. As shown in Figure 4.4 above, between Q1 1991 and Q3 2008 the treatment costs of both H2RAs and PPIs decreased considerably whereas the treatment costs of alginates increased slightly. In particular, the cost of a four-week treatment with H2RAs decreased from about £30 in Q1 1991 to about £5 in Q3 2008, and for PPIs the corresponding decrease was from £36 to £12. This means that a four-week treatment in Q3 2008 cost about 17 per cent and 30 per cent – in the case of H2RAs and PPIs, respectively – of the original cost in Q1 1991. In contrast, the treatment cost for alginates in Q3 2008 was £9.40, 17 per cent higher than the cost of £8 in Q1 1991.

4.121. In the case of PPIs and H2RAs, the significant price reductions reflect the generic entry and competition that emerged following the expiry of the patents for products such as Zantac and Losec, as set out at paragraph 4.128 below.

4.122. Overall, the evolution of treatment costs shown in Figure 4.4 above suggests that alginates faced very different competitive conditions to those faced by anti-ulcerants such as PPIs and H2RAs. Whereas entry of generic PPIs led to reductions in the price of PPIs and H2RAs, the fact that the treatment costs of alginates remained broadly constant, and even increased slightly, indicates that the declining prices of PPIs and H2RAs did not exert any downward pressure on the price of alginates.

4.123. Furthermore, when the significant decrease in the pricing differential between alginates and H2RAs/PPIs is considered in the context of the stable sales values and volumes of alginates described above, this assessment strongly suggests that alginates are in a separate market to PPIs/H2RAs. It implies that were a hypothetical alginate monopolist able to increase its price by a small but significant amount (assuming this was permitted under the PPRS) and hence alter the differential in treatment costs between alginates and PPIs/H2RAs, this would not be expected to result in significant switching to PPIs or H2RAs such that it would be unprofitable.

**d) Analysis of selected 'natural events'**

4.124. This sub-section considers how certain significant events in respect of a given product type (for example, generic entry in the H2RA and PPI categories) have affected the sales of other products (for example, alginates) within the treatment area under consideration in this case.<sup>460</sup> As outlined in Table 4.3 below, the

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<sup>460</sup> See paragraph 38 of the *Notice of the European Commission on the Definition of the Relevant Market for the purposes of Community Competition Law*: 'Evidence of substitution in the recent past: In certain cases, it is possible to analyse evidence relating to recent past events or shocks in the market that offer actual examples of substitution between two products. When available, this sort of information will normally be fundamental for market definition. If there have been changes in relative prices in the past (all else being equal), the reactions in terms of quantities demanded will be determinant in establishing substitutability. Launches of new products in the past can

treatment area has been characterised by a number of significant 'events' since 1991, including the launch and withdrawal of branded medicines, and the launch of branded generic and generic medicines.

**Table 4.3: Summary of 'natural events' relating to H2RAs, PPIs, and alginates**

| <b>Product category</b> | <b>Date</b> | <b>Event</b>                                                          |
|-------------------------|-------------|-----------------------------------------------------------------------|
| H2RAs                   | Q3 1997     | Entry of generic Ranitidine formulations (generic versions of Zantac) |
|                         | Q3 2000     | Entry of generic Famotidine formulations (generic versions of Pepcid) |
|                         | Q3 2002     | Entry of generic Nizatidine formulations (generic versions of Axid)   |
| PPIs                    | Q2 1994     | Launch of Zoton (Lansoprazole)                                        |
|                         | Q4 1996     | Launch of Protium (Pantoprazole)                                      |
|                         | Q3 1998     | Launch of Pariet (Rabeprazole Sodium)                                 |
|                         | Q3 1999     | Launch of Losec MUPS (Omeprazole)                                     |
|                         | Q3 2000     | Launch of Nexium (Esomeprazole)                                       |
|                         | Q2 2002     | Entry of generic Omeprazole formulations (generic versions of Losec)  |
|                         | Q4 2005     | Entry of generic Lansoprazole                                         |

also offer useful information, when it is possible to precisely analyse which products have lost sales to the new product.'

|           |         |                                                    |
|-----------|---------|----------------------------------------------------|
|           |         | formulations (generic versions of Zoton)           |
| Alginates | Q1 1997 | Launch of Gaviscon Advance                         |
|           | Q3 1998 | Launch of Peptac Liquid                            |
|           | Q2 2005 | Withdrawal of Gaviscon Liquid from the NHS channel |

Source: OFT analysis of data provided by the NHS Information Centre.

Note: The first generation of H2RAs (for instance cimetidine, for which the branded names include Tagamet) was already off-patent in Q1 1991.

4.125. The OFT has considered the following events in detail:

- the entry of Zoton (Lansoprazole) in Q2 1994
- the entry of a generic Ranitidine formulations (generic versions of Zantac) in Q3 1997
- the entry of a generic Omeprazole formulations (generic versions of Losec) in Q2 2002
- the withdrawal of Gaviscon Original from the prescription channel in Q2 2005, and
- the entry of a generic Lansoprazole formulations (generic versions of Zoton) in Q4 2005.

4.126. These events have been selected as they involve the leading brands and formulations in each product area. The OFT has divided its analysis of the selected events into those relevant to PPI/H2RA products and those relevant to alginates. This enables separate consideration of the extent to which (i) PPI/H2RA events impact upon alginates and (ii) alginate events impact upon PPIs/H2RAs, which in turn provides insights into the extent to which each

product type constrains the other and whether any constraint is symmetrical or asymmetrical.<sup>461</sup>

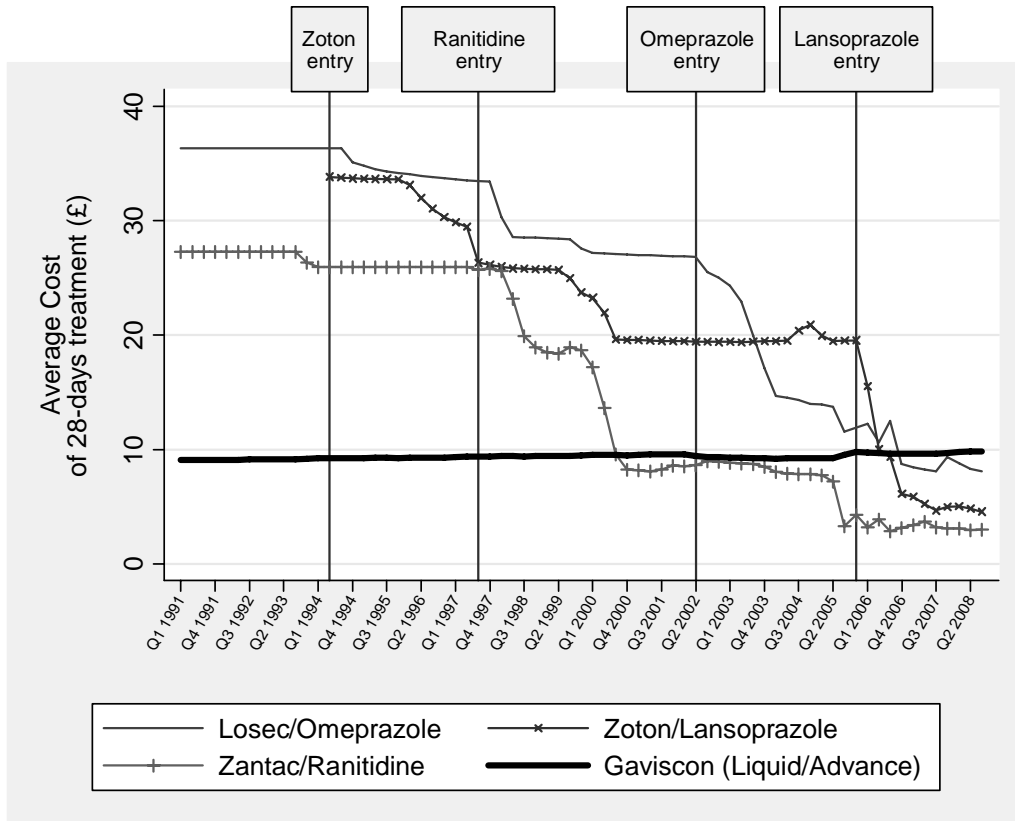
4.127. Figure 4.5 below demonstrates how the events relevant to PPI and H2RA formulations have impacted upon the prices of the leading formulations in the treatment area.<sup>462</sup>

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<sup>461</sup> In *AstraZeneca* the Commission found the competitive interaction between PPIs and H2RAs to be asymmetrical in that PPIs constrained H2RAs but H2RAs did not constrain PPIs (*AstraZeneca* decision, paragraphs 358 to 405 and 489).

<sup>462</sup> For Figure 4.5 above and Figures 4.6 and 4.8 below the OFT has used the same methodology as described in footnote 459 above. In other words, the average treatment cost of each set of products (Zoton/lansoprazole, for example) is calculated by taking the weighted average of the treatment costs of all relevant formulations of Zoton and lansoprazole in the sample using values of sales (in terms of NIC) as weights.

**Figure 4.5: Average cost (in nominal terms) of treating dyspepsia for 28 days using selected H2RAs, PPIs, and alginates in England, Q1 1991 – Q3 2008**

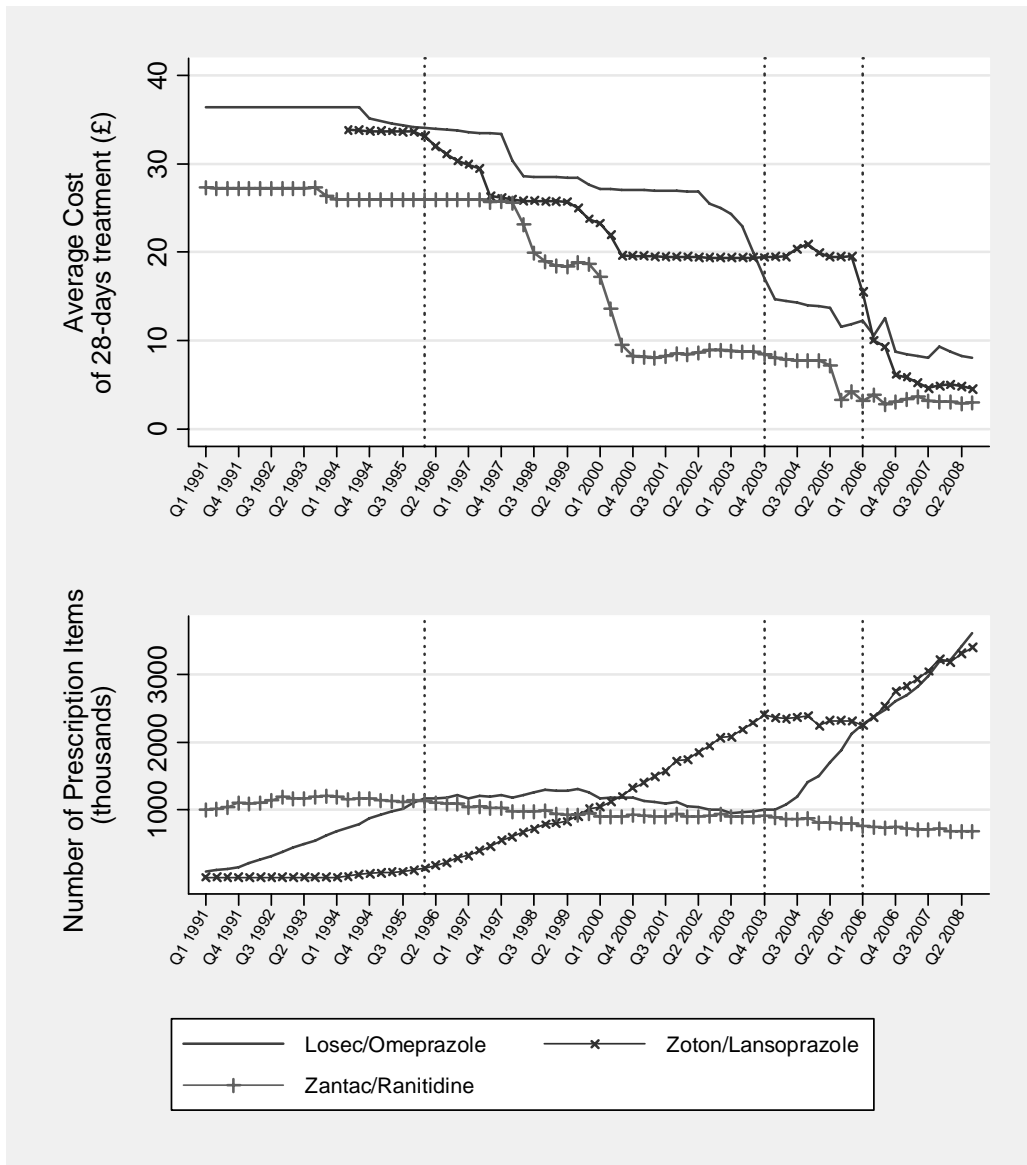


Source: OFT analysis of data provided by the NHS Information Centre

4.128. The OFT observes that in respect of the PPI formulations, the most significant price decreases occur after the entry of generic PPIs. Similarly, the entry of generic equivalents to Zantac also results in a significant decrease to the average price for Zantac/Ranitidine formulations. Significant Zantac/Ranitidine price decreases are also observed following PPI price changes (for example in 2000 when the price of Zoton declined, and in 2005 following significant decreases in the average price of Losec/Omeprazole in 2004). In contrast, Gaviscon prices remained broadly unchanged throughout the period.

4.129. Figure 4.6 below demonstrates how the sales volumes of the different formulations have been affected by the different events and the subsequent price changes:

**Figure 4.6: Prices and number of items prescribed for selected H2RAs and PPIs in England, Q1 1991 – Q3 2008**



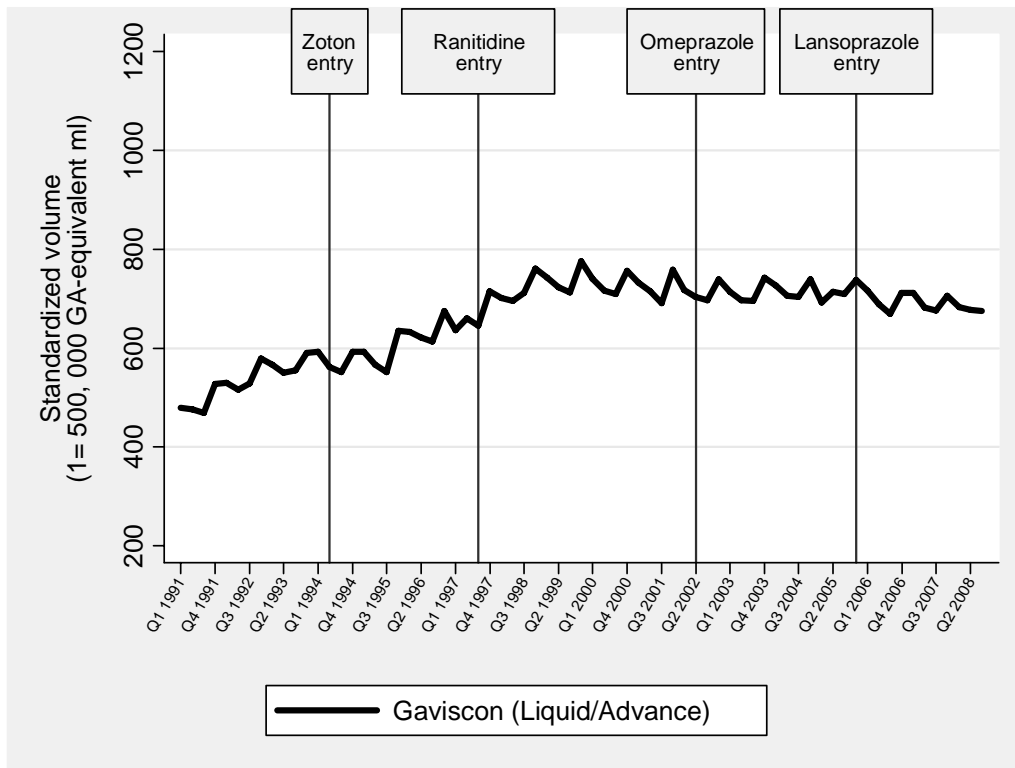
Source: OFT analysis of data provided by the NHS Information Centre



- 4.130. In Figure 4.6, the vertical dotted lines denote the significant changes in trends relevant to the sales volumes of the different products, and the price trends associated with them. It is apparent that the events relevant to PPIs have had a significant impact on the volume sold of different PPI formulations. For example, following its entry in Q2 1994 Zoton initially achieved modest sales volumes until it reduced its price in 1996/97. After this, sales of Zoton increased significantly at the expense of the significant sales growth that had until then been enjoyed by Losec. Similarly, the emergence of generic competition in respect of the Losec/Omeprazole formulation in Q2 2002, and the subsequent decrease in Losec/Omeprazole prices between then and 2004, arrested the sales growth of Zoton for some time and saw a return to growth for the Losec/Omeprazole formulation.
- 4.131. The impact of the price changes that have followed these PPI events is less pronounced on Zantac/Raniditine sales volumes. Rather, as outlined above, Zantac/Raniditine price decreases occurred in parallel with a number of the price decreases observed in respect of the leading PPI formulations. These decreases failed, however, to prevent a long-term decline in Zantac/Raniditine sales volumes.
- 4.132. As outlined above, Gaviscon prices remained broadly constant throughout the period (see Figure 4.5 above). In addition, despite the significant price decreases associated with each of the PPI and H2RA events described above, alginate sales volumes were largely unaffected (see figure 4.7 below).
- 4.133. The one event that did seemingly have an impact on Gaviscon sales was the generic entry in respect of Zoton/Lansoprazole. The average treatment cost for Zoton/Lansoprazole decreased by 69 per cent between Q4 2005 and Q4 2006 (see Figure 4.5 above). As a result, the average treatment costs of Zoton/Lasnoprazole fell from double those of Gaviscon prior to Q4 2005 to 36 per lower than those of Gaviscon by Q4 2006. As illustrated by Figure 4.7

below, this significant price change contributed to a very small decrease in alginate sales.<sup>463</sup>

**Figure 4.7: Volume sold of Gaviscon in England, Q1 1991 – Q3 2008**

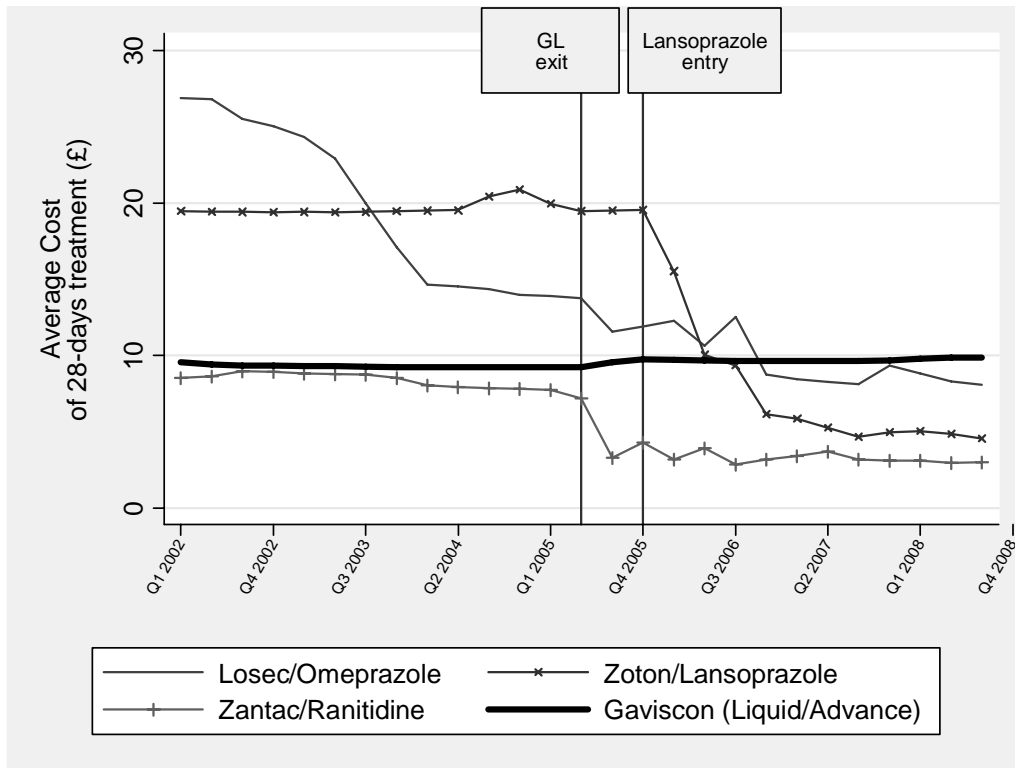


Source: OFT analysis of data provided by the NHS Information Centre

<sup>463</sup> In an internal presentation entitled 'UK NHS Changes' dated 23 August 2007, RB states that this event has resulted in a 2.7 per cent decline in GA sales and a 3.7 per cent decline in alginate sales (RB submission of 6 March 2009 in response to Q2 of OFT section 26 notice dated 14 January 2009, document 86). Despite the Zoton/Lansoprazole average treatment costs having reached 64 per cent of those of Gaviscon, RB considered that a 'plateau' had been reached whereby the alginates market has stabilised. The same document does not consider whether there would be merit in [,,,].

- 4.134. The lack of any significant impact on alginates prices and sales volumes contrasts starkly with the interaction between the different PPIs and between PPIs and H2RAs. This strongly suggests that there is no meaningful competitive interaction between PPIs/H2RAs and alginates and that the significant events relevant to PPIs/H2RAs did not constrain the sales of alginates.
- 4.135. The OFT has also considered whether the key event relevant to alginates, the Withdrawal, led to switching away from alginates to other treatments such as PPIs or H2RAs.
- 4.136. As described in Part 2J above, in June 2005 RB withdrew NHS packs of its leading alginate product, GL, from the prescription channel. In analysing the impact of the Withdrawal one must also note that later in 2005 generic equivalents to Zoton (Lansoprazole) were launched. In assessing the impact of the Withdrawal, it is noted that if PPIs and alginates compete with one another to a meaningful extent, both of these events would be expected to result in sales switching from alginates to PPIs, or in alginate prices decreasing to prevent such switching.
- 4.137. Figure 4.8 below sets out the pricing trends relevant to the leading formulations in the treatment area prior to and after the Withdrawal and launch of generic equivalents to Zoton (Lansoprazole):

**Figure 4.8: Average cost of treatment of selected H2RAs, PPIs, and alginates in England, Q1 2002 – Q3 2008**

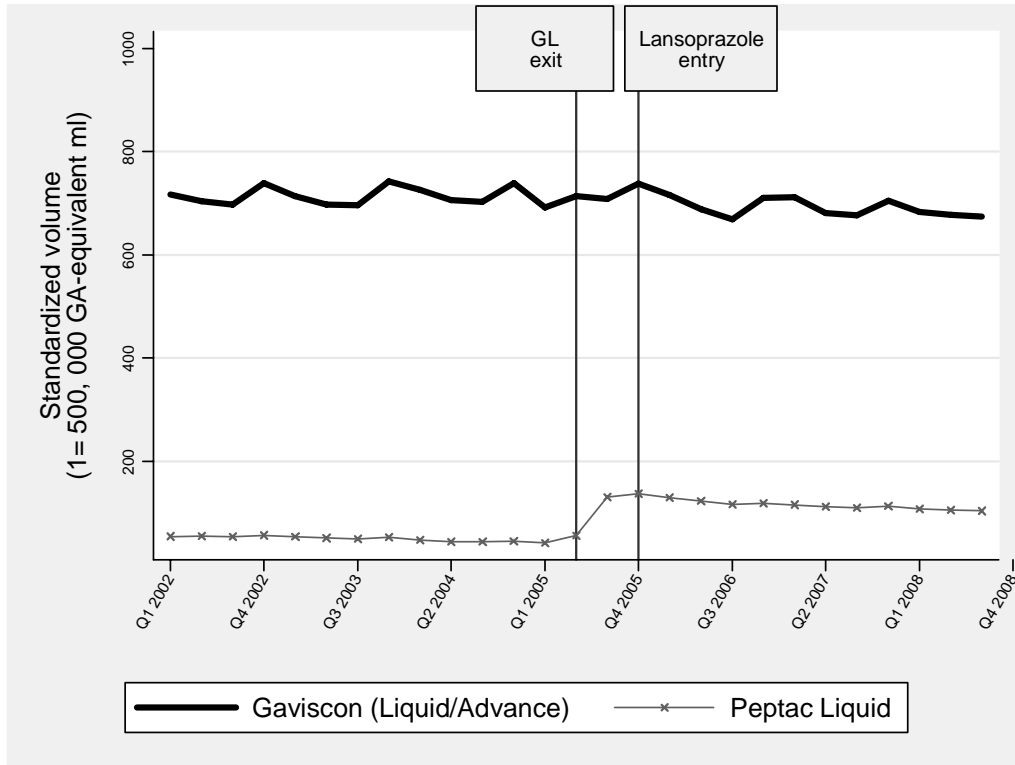


Source: OFT analysis of data provided by the NHS Information Centre

- 4.138. The OFT observes that the Withdrawal resulted in a slight increase in average Gaviscon treatment costs. As noted above, the subsequent generic entry of equivalents to Zoton (Lasoprazole) had no impact on Gaviscon prices.
- 4.139. Figure 4.9 below shows that the Withdrawal also had no significant impact on Gaviscon sales volumes (adjusted to take account of the differing concentrations between GA and GL, see paragraph 4.117 above) and that, to the extent that the Withdrawal induced switching away from Gaviscon, it was to the

rival alginate Peptac (the impact of generic entry in respect of Zoton/Lansoprazole was considered at paragraph 4.113 above).<sup>464</sup>

**Figure 4.9: Volumes sold of Gaviscon and Peptac in England, Q1 2002 – Q3 2008**



Source: OFT analysis of data provided by the NHS Information Centre

4.140. The withdrawal of the leading alginate, GL, does not therefore appear to have had an impact on the sales volumes of alginates or on Gaviscon pricing. This strongly suggest that PPIs and H2RAs do not represent a material competitive constraint on alginates sales as, if they did, one would expect the withdrawal of the leading

<sup>464</sup> The chart above takes into account the fact that GA is twice as concentrated as GL. To take this into account, the OFT divided the quantity dispensed (in ml) of GL by two to obtain the corresponding quantity of GA.

alginate to result in significant switching from alginates to PPIs/H2RAs and a significant decline in alginate volumes/prices.

4.141. Overall, it is apparent that the significant events that have affected PPIs/H2RAs have had little to no impact on the sales and pricing of alginates, and that the significant event relevant to alginates, the Withdrawal, has similarly not resulted in sales losses for alginates or in a change to Gaviscon's pricing. On the one occasion on which a PPI price decrease can be seen to impact upon alginate sales volumes, the significant magnitude of the price decrease and the very small impact on alginate volumes suggests that any constraint from PPIs towards alginates is very limited. This contrasts with the competitive interaction between different PPI formulations and between PPI formulations and the leading H2RA formulation.

4.142. The analysis of natural events therefore strongly suggests that any competitive interaction between PPIs/H2RAs and alginates is limited, and that the sales terms of alginates are not materially constrained by those of PPIs/H2RAs.

**vii) Conclusions on the relevant product market**

4.143. Having regard to the conceptual framework described at Part 4B above, the OFT finds that the qualitative and quantitative evidence that it has assessed shows that sales terms of alginates are not meaningfully constrained by those of PPIs and H2RAs. The OFT has not considered whether the sales terms of antacids constrain those of alginates as it considers that the assessment of dominance is not sensitive to this distinction (see part 5 below).

4.144. The OFT finds that the relevant product market is no wider than alginates and antacids and does not include H2RAs or PPIs because:

- alginates and anti-ulcerants have fundamentally different modes of action

- the current prescribing literature recommends the use of alginates for self-treatment (for example, when the patient seeks the pharmacist's advice and does not need to see the GP) or as part of a 'step-down' or 'step-off' approach (for the long-term management of dyspepsia). In contrast, PPIs are the recommended choice for GPs to treat both uninvestigated dyspepsia with alarm signs and symptoms and dyspepsia caused by GORD or ulcer. This is consistent with the reaction of several health authorities to the Withdrawal, which was to recommend that GPs switch prescriptions to another alginate (GA or Peptac, in most cases), and not to an H2RA or a PPI.
- RB's internal documents indicate that it considered Peptac to be its primary competitor in relation to Gaviscon. This is supported by the fact that [...]
- sales of alginates have remained broadly constant throughout the period from 1991 to 2008, in spite of the fact that several branded H2RAs and PPIs (including Zantac, Losec, and Zoton) lost patent protection, and their prices dramatically decreased. This is evidence that sales of alginates behaved to a large extent independently of H2RAs and PPIs, and that the latter failed to exert a material constraint on alginates
- the declining prices of PPIs and H2RAs have not exerted any downward pressure on alginates' prices, in contrast to the effect of generic PPI price changes on branded PPIs and of PPI price decreases on H2RAs, and
- the treatment cost and sales of alginates remained largely unaffected by significant market 'events' such as the entry of generic versions of popular H2RAs and PPIs, such as Zantac and Losec.

## **E. The interaction between the prescription and OTC sales channels**

### **i) Introduction**

4.145. As outlined above, antacids, alginates (including Gaviscon), H2RAs and (to a lesser extent) PPIs are also available OTC (they can be sold to the public without a prescription from a GP). This Section assesses whether sales terms of alginates in the prescription channel are constrained by the sales terms of alginates in the OTC channel, and the extent to which prices of products (and in particular, of alginates) in the OTC channel constrain prices of alginates in the prescription channel. In other words, it considers whether sales of alginates/antacids in the OTC channel are in the same relevant market as sales of alginates/antacids in the prescription channel.<sup>465</sup>

4.146. In a number of past merger cases in the pharmaceutical sector the Commission has found the OTC and prescription channels to be separate markets.<sup>466</sup> In *Bayer Healthcare/Roche (OTC business)*, for example, the Commission noted the following:

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<sup>465</sup> The OFT has not considered how the OTC prices of other treatments for GORD/dyspepsia impact upon the prescription channel prices of alginates. It can be assumed that, where there is no competitive interaction between alginates sales in the OTC and prescription channel, there would similarly be no interaction between other GORD/dyspepsia treatments sold in the OTC channel and alginates sold in the prescription channel.

<sup>466</sup> In 2000 the US Federal Trade Commission also identified a separate market for OTC H2RAs in *Glaxo Wellcome/SmithKline Beecham* (see [www.ftc.gov/os/2000/12/glaxoana.htm](http://www.ftc.gov/os/2000/12/glaxoana.htm)). In addition, the OFT and the Competition Commission have considered it appropriate to treat the supply of products through three different channels – prescription-only (POM), pharmacy-only (P), and general sale list (GSL) medicines – as distinct relevant markets. See the OFT's decision in relation to the anticipated acquisition by Boots of Alliance UniChem, published on 22 February 2006 (paragraphs 9-13), and the Monopolies and Mergers Commission's report on the proposed mergers between UniChem/Lloyds Chemists and GEHE AG/Lloyds Chemists, of July 1996 (in particular, chapter 4).



'The Commission has also in the past defined separate markets for OTC (as opposed to prescription) pharmaceuticals because medical indications (as well as side effects), legal framework, marketing and distributing tend to differ between these categories, even if the active ingredients are identical. OTC products may be advertised to the public at large. Doctors do not need to intervene in the purchase of these products. Consumers make their own choice and bear the costs of their purchase, generally leading to a higher price elasticity of demand. By contrast, prescription pharmaceuticals need to be prescribed by a doctor, whose intervention is thus essential in the choice of the product. Pricing for prescription products is influenced by the public health care system, who pays (part of) the purchase price via reimbursement. Marketing, therefore, is targeted at prescribers, that is, doctors and hospitals.'<sup>467</sup>

4.147. Some of these cases have related to situations where the relevant medicines are only available in one of the channels. However, in two of these cases the relevant products have been available in both the OTC and prescription channels, as is the case here.<sup>468</sup> The OFT notes that the reasoning outlined in all of these previous

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<sup>467</sup> See paragraph 13 of the Commission's decision in case COMP/M.3544 – *Bayer Healthcare/Roche (OTC business)*, of 19 November 2004. A similar point was also made in the following cases: COMP/M.1846 – *Glaxo Wellcome/SmithKline Beecham* (paragraph 14), of 8 May 2000; COMP/M.2922 – *Pfizer/Pharmacia* (paragraph 17), of 27 February 2003; COMP/M.3394 – *Johnson & Johnson/Johnson & Johnson MSD Europe* (paragraphs 14-15), of 29 March 2004; COMP/M.3751 – *Novartis/Hexal* (paragraph 3), of 27 May 2005; COMP/M.3853 – *Solvay/Fournier*, (paragraph 12), of 18 July 2005; COMP/M.4007 – *Reckitt Benckiser/Boots Healthcare International* (paragraph 10), of 6 January 2006; and COMP/M.4402 – *UCB/Schwarz Pharma* (paragraph 9), of 21 November 2006.

<sup>468</sup> The two cases that did involve products which were sold in both the OTC and prescription channels were *Novartis/Hexal* and *Solvay/Fournier*, where the products under consideration (among others) were H2RAs and laxatives, respectively.

cases – for example in relation to the differences between the legal framework, as well as between the pricing, purchasing and marketing mechanisms – is relevant to determining whether the two sales channels should be treated as separate markets in this specific case.

4.148. Furthermore, additional evidence – some of a more general nature, and some specific to the therapeutic area of dyspepsia and acid-related conditions – also indicates that in this case alginates dispensed in the prescription channel are in a distinct market from products available in the OTC channel.

**ii) Differences in purchasing and pricing mechanisms**

4.149. There are significant differences between the purchasing and pricing mechanisms observed in the prescription and OTC channels. The 'purchasers' (the person or body that pays for the medicine) and 'decision makers' (the person that chooses which medicine will be consumed) are different in the different channels.

4.150. In the prescription channel the purchaser of medicines is essentially the NHS, and the medicine that will be dispensed is selected by a GP. The patient neither selects the medicine nor pays for it.<sup>469</sup>

4.151. The price that the NHS pays for branded medicines dispensed in the prescription channel is set within the framework of the PPRS. As described in Part 2H.v)a) above, under the PPRS manufacturers of branded medicines set the initial price of their products, and these are then constrained insofar as each manufacturer is subject to portfolio-wide price and profit controls.

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<sup>469</sup> The OFT notes that certain patients will pay a prescription charge. However, that charge does not correspond to the price or value of the medicine being purchased.

4.152. After patent expiry an additional constraint faced by manufacturers of branded medicines in the NHS prescription channel is full generic competition (at least in cases where it is not impaired). When a GP's prescription form is written generically, pharmacists are then able to choose whether to dispense a branded medicine or its generic equivalent (see Part 2H.iv) above), and it is the pharmacist's ability to choose which of the therapeutically equivalent medicines to dispense that fosters strong price competition between suppliers. By way of example, the effects of competition from generic products on the prices of PPIs and H2RAs are shown in Figures 4.5 and 4.8, respectively.

4.153. The purchasing and pricing mechanisms are different in the OTC channel. Firstly, in the OTC channel consumers select their medicines on the basis of factors such as past experience with the product, their own judgement, brand recognition, stock availability, and by comparing prices of alternative treatment options. The consumer also pays the price of the chosen product and the government does not intervene in the pricing of OTC products.

4.154. The differing purchasing mechanisms and 'decision-makers' is also reflected in different marketing strategies. For example, in the prescription channel branded pharmaceutical suppliers seek to generate sales by focusing their marketing efforts towards the GP that selects the appropriate medicines ('detailing'). In the OTC channel, however, mass marketing campaigns are common (such as the 'dancing traffic cop' TV advertising employed for Gaviscon) as it is consumers who select their medicines and who must be targeted in order to generate sales.

**iii) The effect of OTC prices on pricing in the NHS prescription channel**

4.155. Since the price-setting mechanism and the person that chooses the medicine are different in the two channels, the price set in one channel would not be expected to materially constrain the price in the other. For example, a price reduction in the OTC channel

would not be expected to affect the decision-making process of GPs as to which medicine to prescribe,<sup>470</sup> or the prices set in the NHS channel (which are overseen by the PPRS).

4.156. This conclusion is confirmed by the following factors:

- Even if DH considered that the PPRS price of a branded product (say, Gaviscon) was too high relative to the OTC channel, there would not be any mechanism under the terms of the PPRS to request a price reduction for that product sold through the prescription channel.
- GPs are generally considered to have poor awareness of the NHS prices of different pharmaceutical products and, indeed, a survey referred to in the OFT's PPRS Market Study established that 'GP's ability to rank branded drugs in order of price proved no better than chance.'<sup>471</sup> It would therefore be reasonable to expect that GPs would also have very little knowledge of OTC prices. This means that changes in the relative prices between the prescription and OTC channels would not be expected to result in changes to GPs' prescribing practices.

4.157. The differences in the purchasing and pricing mechanisms described above have resulted in a significant difference between Gaviscon prices in the prescription channel and those in the OTC channel. For example, in 2008 the OTC retail price for GA was more than double the pharmacy reimbursement price in the NHS prescription channel (the PPRS price for GA was £5.40, while the equivalent OTC price (pro-rata) was £10.95). The extent of such

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<sup>470</sup> In fact, the decision of a GP about which medicine to dispense – to the extent that it is informed by price considerations – would rather be concerned with the price charged to the NHS and its respective Primary Care Trust.

<sup>471</sup> Box 2.3, page 23 of the OFT report on *The Pharmaceutical Price Regulation Scheme*, February 2007.

differences in respect of what are identical products indicates that (as one would expect given the differences in the purchasing and pricing mechanisms outlined above) there is no competitive interaction between the two channels.

4.158. The differences in purchasing mechanisms described above, as well as the lack of pricing constraints from the OTC channel towards the prescription channel, suggest that for alginate products the prescription channel is in a separate market from the OTC channel.

**iv) The effect of changes to OTC and NHS prescription channel pricing on purchasing volumes in each channel**

4.159. The above analysis of pricing and purchasing mechanisms suggests that a small but significant price reduction in the OTC channel would not be expected to constrain prices in the prescription channel. In respect of alginates, however, two other factors indicate that, even if a price reduction in the OTC channel could in theory encourage some patients to purchase Gaviscon over the counter rather than seek a prescription from GPs, this switch between channels would in any event be unlikely to take place in practice.

4.160. Firstly, according to NHS data examined by the OFT (see Part 4D.vi)a) above), approximately 95 per cent of prescriptions for alginates in England (both in value and volume terms) are exempt from the payment of a prescription fee (which was £7.10 in 2008/09). Second, RB's internal documents report that between [...] and [...] per cent of prescriptions for Gaviscon are 'repeat' prescriptions such that patients do not need to visit a GP each time they receive their treatment.<sup>472</sup> A number of Gaviscon

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<sup>472</sup> RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, documents 100, 105, 110 and 116.

patients in the prescription channel can therefore often obtain it without visiting their GP and free of charge.

4.161. These two factors imply that these patients have a limited incentive to switch to purchasing alginates in the OTC channel following a reduction in the OTC price of alginates, as such patients would not be expected purchase their medicine OTC when they could obtain it for free through the prescription channel. In turn, this lends further support to the conclusion that the prescription and OTC channels are separate markets in this case.

**v) Reckitt Benckiser's internal documents**

4.162. As set out below, RB's internal documents indicate that:

- RB's healthcare business in the UK is structured in [...] and
- when determining strategies relevant to the NHS segment, RB's considerations reveal [...].

4.163. In the covering letter to its submission dated 18 August 2009,<sup>473</sup> responding to an OFT section 26 Notice dated 28 July 2009, RB explained that it can provide no research or strategy documents regarding the extent to which sales of alginates in the prescription channel are affected by OTC prices, or the extent to which GPs encourage patients to buy alginates OTC as an alternative to obtaining them on prescription. RB said that the reason for this is that its [...], and this should not be interpreted as evidence that the OTC and prescription channels do not constrain each other. The OFT is of the view that RB's explanation is not supported by the documents and information that RB has itself provided.

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<sup>473</sup> Letter from RB dated 18 August 2009 in response to an OFT section 26 notice dated 28 July 2009 (OFT File Part 5, document 1).

4.164. Instead, the OFT considers that the evidence indicates that the prescription channel is not constrained by the OTC channel. This is illustrated by [...] <sup>474</sup> and by its commercial strategies.

4.165. In relation to RB's commercial strategy, the OFT has observed that a large number of internal RB documents (such as Brand Plans, Business Reviews, financial presentations and updates) are [...]. <sup>475</sup>

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<sup>474</sup> Appendix 3 to the covering letter to RB submission dated 18 August 2009, responding to an OFT section 26 notice dated 28 July 2009 (OFT file part 5, document 1).

<sup>475</sup> Such documents include inter alia: RB internal presentation entitled 'Situation Analysis', dated 2000 (RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, document 3); RB internal presentation entitled 'Gaviscon – Brand Planning', dated 2000 (RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, document 3); RB internal presentation entitled 'Gaviscon – NHS Volume Share', dated April 2000 (RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, document 5); RB internal undated presentation entitled 'Gaviscon Plans' (RB submission of 6 March 2009 in response to Q1(i) of OFT section 26 notice dated 14 January 2009, document 85); RB spreadsheet dated 24 March 2002 (RB submission of 6 March 2009 in response to Q1(i) of OFT section 26 notice dated 14 January 2009, document 120); RB undated internal presentation entitled 'Gaviscon – 2001 Business Review' (RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, document 13); RB undated business review document entitled 'UK Healthcare Plan 2001' (RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, document 15); RB internal presentation entitled '2003 Challenge' (RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, document 25); RB presentation dated 30 June 2003 entitled 'NHS Business Review and 2003 Balance to Go - National Conference, Redworth Hall' (RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, document 31); RB business review presentation dated 3 July 2003 (RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, document 33); RB business review presentation dated January 2004 (RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, document 50); RB presentation entitled 'The Future of Rx Gaviscon Around the World - Project White Tiger Launch Meeting' (RB submission of 6 March 2009 in response to Q4 of OFT section 26 notice dated 14 January 2009, document 55).

- 4.166. Furthermore, additional documents supplied by RB demonstrate that commercial decisions or business proposals in relation to activity in the [...]. This would not be expected to be the case if the two channels belonged to the same relevant market. For example, a report for RB dated 11 November 1998, entitled '*The Introduction of a Co-name for Alginate Antacids and its Potential Impact on Gaviscon Advance*' produced by Barlow Pharmaceutical Consultants, notes that 'we were not asked to consider the Gaviscon Brand OTC business.'<sup>476</sup> Also, an RB internal presentation dated February 2006 entitled 'Gaviscon Advance - GI Category Meeting' sets out a plan for RB to [...]. However, the slide headed 'Market Dynamics to be considered' [...].<sup>477</sup>
- 4.167. RB's internal documents also indicate that, when contemplating the Withdrawal, RB did not forecast significant switching from the NHS prescription channel to the OTC channel. Rather, as set out in detail in Part 6C.ii) below, RB expected the Withdrawal to result in patients/GPs switching to other alginate prescription packs.
- 4.168. RB's business decision making for the prescription and OTC channels further suggests that the two sales channels face different competitive conditions and that there is limited competitive interaction between them. This is in turn consistent with a conclusion that they can be considered as distinct markets in this case.

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<sup>476</sup> RB submission of 6 March 2009 in response to Q1(i) of OFT section 26 notice dated 14 January 2009, document 1.

<sup>477</sup> RB submission of 6 March 2009 in response to Q1(i) of OFT section 26 notice dated 14 January 2009, document 64.



**vi) Conclusion on the relevant sales channel**

4.169. The OFT finds that alginates/antacids dispensed in the prescription channel are in a separate market from alginates/antacids sold in the OTC channel. In particular, the OFT finds that:

- the purchasing and pricing mechanisms in the two channels are different, limiting any pricing constraint from the OTC channel to the prescription channel
- the prices observed in the OTC and prescription channels differ significantly and this suggests that there is no competitive interaction between the channels. This suggests that the prices in the OTC channel do not constrain those in the NHS prescription channel
- the vast majority of prescriptions for alginates are exempt from the payment of a prescription fee and are 'repeat' prescriptions. This in turn implies a significant number of prescription channel patients have limited incentives to switch to the OTC channel for the procurement of their alginates
- RB's healthcare business in the UK is organised [...], and the content of its internal documents suggest that it makes [...], which further suggests that each segment presents its own specific features.

**F. The relevant geographic market**

4.170. In previous cases in the pharmaceutical sector the relevant geographic market has been defined as national in scope. For example, the Commission reached this conclusion in *AstraZeneca* (see, in particular, paragraph 503), which is consistent with its

previous decisions.<sup>478</sup> The OFT also found the geographic market to be national in scope in *Genzyme*<sup>479</sup> and *Napp Pharmaceutical*.<sup>480</sup>

4.171. The definition of national markets is typically appropriate because of differences in the regulatory schemes for authorising and reimbursing medicines across countries, in the marketing strategies used by pharmaceutical companies, in doctors' prescribing practices and in prices. All of these factors apply in this case. The OFT therefore finds that the relevant geographic market is national (UK-wide) in this case.

## **G. Conclusions on the relevant market**

4.172. As set out above, what matters for the definition of the relevant product market is the extent to which the sales terms of different product types can be expected to materially constrain the conduct of a given undertaking in relation to its products.

4.173. As set out in Part 4E, the evidence considered by the OFT indicates that sales terms of alginates are not materially constrained by those of PPIs and H2RAs. In particular, the qualitative evidence considered by the OFT has established that alginates have differing therapeutic uses and modes of action to PPIs/H2RAs and that RB's internal documents indicate that it did not regard PPIs/H2RAs to be substitutable with alginates to any material extent. This assessment is consistent with the OFT's quantitative analysis which, in particular, finds that alginates' sales trends are largely independent of those for PPIs/H2RAs such that it

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<sup>478</sup> See, for example, Commission Decision IV/M.950, *Hoffmann-La Roche/Boehringer Mannheim* (1998) OJ L234/14, paragraphs 16 and 17.

<sup>479</sup> Decision No. CA98/3/03, *Genzyme Limited*, 27 March 2003, paragraphs 192 to 200.

<sup>480</sup> Decision No. CA98/2/2001, *Napp Pharmaceutical Holdings Limited*, 30 March 2002, paragraphs 89 to 93.

cannot be concluded that the sales terms of PPIs/H2RAs materially constrain those of alginates.

- 4.174. As set out in Part 4E, the evidence considered by the OFT indicates that the sales terms of alginates/antacids made in the prescription channel are not materially constrained by the sales terms of alginates in the OTC channel. The OFT finds that the pricing and purchasing mechanisms in the two channels differ to such an extent that it cannot be expected that sales terms in the OTC channel constrain those in the prescription channel. Further, the OFT finds that the prices observed in the two channels suggest that there is no significant competitive interaction between them. This is reflected in the internal decision making of RB.
- 4.175. As set out in Part 4F, the OFT considers the relevant geographic market to be the UK. In particular, it considers that the definition of a national market is appropriate because of the differences existing in (i) regulatory schemes for authorising and reimbursing medicines across countries; (ii) marketing strategies used by pharmaceutical companies; and (iii) doctors' prescribing practices and prices.
- 4.176. As such, the OFT finds that the relevant product market in this case is no wider than the supply of alginates and antacids by prescription in the UK.<sup>481</sup> RB has confirmed that it does not contest the OFT's finding in respect of the relevant market.

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<sup>481</sup> As outlined above, the OFT has not considered it necessary to determine whether antacids are in the same relevant markets as alginates, as it does not consider that such a distinction impacts upon its finding in relation to dominance (see Part 5B.i) below).

## 5 DOMINANCE

### A. Introduction

5.1. The OFT considers that, for the reasons set out in this Part, RB held a dominant market position in the relevant market (as defined in Part 4) at least between 2004 and 2008. In summary, the OFT finds that:

- RB's market share (by value) has been in excess of 80 per cent between 2004 and 2008 and its leading market position has not been threatened by the entry of competitors such as Pinewood.
- Barriers to expansion are significant in this market. Gaviscon is a widely recognised brand with an established customer base and competitors such as Pinewood have been unable to obtain a significant market share by convincing GPs to prescribe Peptac rather than Gaviscon. Indeed, no other manufacturer of alginates or antacids has achieved a market share over 10 per cent in the past 12 years, despite RB having withdrawn the leading product in the relevant market during this period.
- There are significant barriers to entry which make it difficult for potential entrants and current rivals to bring products to market and to then challenge RB's market position.
- Over the relevant period, the NHS has failed to exert countervailing buyer power vis-à-vis RB for the supply of Gaviscon products.

5.2. RB has not contested the OFT's finding that RB held a dominant position in the relevant market.<sup>482</sup>

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<sup>482</sup> RB SMFI, section 3.

5.3. This Part is structured as follows:

- Section B considers the extent of actual competition in the relevant market by reference to the market shares of RB and its competitors in the relevant market
- Section C considers potential competition, and in particular the existence, or otherwise, of significant entry barriers and the existence of other undertakings which might easily enter the market
- Section D considers whether the NHS, as the purchaser in the relevant market, can be regarded as having significant countervailing buyer power, and
- Section E explains the OFT's conclusions in relation to its finding that RB held a dominant position in the relevant market at least between 2004 and 2008.

## **B. Actual Competition**

### **i) Market shares**

#### **a) Introduction**

5.4. Market shares provide valuable insights into the structure of the relevant market as well as into the relative importance of the various undertakings active on it. As a result, they can be useful in assessing whether an undertaking is dominant. In *Hoffmann-La Roche* the Court of Justice ruled that 'very large market shares are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position'.<sup>483</sup> It also considered that the market shares in that case, which over the period 1972 to 1974 ranged from 87 per cent to 80.6 per cent, were of themselves

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<sup>483</sup> Case C-85/76 *Hoffmann-La Roche v Commission* [1979] ECR 461, paragraphs 39 and 41.

sufficient to prove dominance without any further analysis.<sup>484</sup> The importance of market shares as an indicator of dominance is especially relevant when the undertaking concerned has maintained a high market share over a long period of time and when its nearest competitors hold shares that are considerably lower.<sup>485</sup>

5.5. As noted in Part 4, the OFT considers that the relevant market in this case is no wider than the supply of alginates and antacids by prescription in the UK. The question of whether antacids are part of the relevant market can be left open because it is not material for the assessment of RB's dominance in this case. Accordingly, market shares presented in this Section include alginates and antacids sold in the prescription channel.

**b) Reckitt Benckiser's share of the relevant market**

5.6. The market shares by value of the various alginate brands prescribed in the UK from 2004 to 2008 are shown in Table 5.1 below. The corresponding market shares by volume are presented in Table 5.2.

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<sup>484</sup> Ibid, paragraphs 53 – 56.

<sup>485</sup> Case C062/86 *AKZO v Commission* [1991] ECR I-3359, paragraph 60.

**Table 5.1: Market shares by value of alginates and antacids in the (NHS) prescription channel, 2004 – 2008**

| a) Ingredient cost - £millions |       |       |       |       |       |
|--------------------------------|-------|-------|-------|-------|-------|
|                                | 2004  | 2005  | 2006  | 2007  | 2008  |
| Gaviscon (All formulations)    | 23.47 | 23.57 | 23.50 | 23.74 | 24.48 |
| Acidex + Peptac                | 1.05  | 2.09  | 2.73  | 2.59  | 2.52  |
| Gastrocote                     | 0.51  | 0.63  | 0.67  | 0.62  | 0.57  |
| Other products                 | 2.43  | 2.39  | 2.13  | 2.40  | 2.75  |
| TOTAL                          | 27.47 | 28.69 | 29.03 | 29.35 | 30.32 |

| b) Ingredient cost - % of total |      |      |      |      |      |
|---------------------------------|------|------|------|------|------|
|                                 | 2004 | 2005 | 2006 | 2007 | 2008 |
| Gaviscon (All formulations)     | 85%  | 82%  | 81%  | 81%  | 81%  |
| Acidex + Peptac                 | 4%   | 7%   | 9%   | 9%   | 8%   |
| Gastrocote                      | 2%   | 2%   | 2%   | 2%   | 2%   |
| Other products                  | 9%   | 8%   | 7%   | 8%   | 9%   |
| TOTAL                           | 100% | 100% | 100% | 100% | 100% |

Source: OFT analysis of data retrieved from the websites of the NHS Information Centres in England, Scotland, Wales and Northern Ireland.

**Table 5.2: Market shares by volume of alginates and antacids in the (NHS) prescription channel, 2004 – 2008**

| a) Items prescribed – millions   |      |      |      |      |      |
|----------------------------------|------|------|------|------|------|
|                                  | 2004 | 2005 | 2006 | 2007 | 2008 |
| Gaviscon (All formulations)      | 6.06 | 5.07 | 4.30 | 4.32 | 4.33 |
| Acidex + Peptac                  | 0.44 | 0.97 | 1.27 | 1.21 | 1.18 |
| Gastrocote                       | 0.14 | 0.17 | 0.19 | 0.17 | 0.15 |
| Other products                   | 0.79 | 0.75 | 0.65 | 0.60 | 0.56 |
| TOTAL                            | 7.43 | 6.96 | 6.40 | 6.30 | 6.23 |
| b) Items prescribed - % of total |      |      |      |      |      |
|                                  | 2004 | 2005 | 2006 | 2007 | 2008 |
| Gaviscon (All formulations)      | 82%  | 73%  | 67%  | 69%  | 70%  |
| Acidex + Peptac                  | 6%   | 14%  | 20%  | 19%  | 19%  |
| Gastrocote                       | 2%   | 3%   | 3%   | 3%   | 2%   |
| Other products                   | 11%  | 11%  | 10%  | 10%  | 9%   |
| TOTAL                            | 100% | 100% | 100% | 100% | 100% |

Source: OFT analysis of data retrieved from the websites of the NHS Information Centres in England, Scotland, Wales and Northern Ireland.

- 5.7. RB's share of the relevant market (by value) was 85 per cent in 2004 (the year before the Withdrawal) and remained above 80 per cent in subsequent years.
- 5.8. RB's market share in terms of items prescribed was 82 per cent in 2004. Its share dropped after the Withdrawal and its share was 67 per cent in 2006, though its share has subsequently increased to 70 per cent in 2008. As explained in paragraph 4.117 above, the higher concentration of GA meant that the Withdrawal had a greater impact on RB's volume market share than on its value market share. As noted at paragraph 4.110 above, the number of items prescribed is less suitable for assessing the competitive strength of different pharmaceutical products because of differences in pack or bottle sizes. The analysis of the market shares that follows therefore concentrates on the 'ingredient costs' (by value), rather than the 'items prescribed' (by volume).



- 5.9. Gaviscon's competitors have considerably lower market shares, with none establishing a UK market share by value of more than 10 per cent between 2004 and 2008 (the evolution of Peptac's share is discussed at paragraph 5.14 below).
- 5.10. The OFT has also considered market shares for England only, as this allows the OFT to assess the period from 1997 through to 2008 (see Table 5.3 below).<sup>486</sup> In England, Gaviscon's market share by value was 71 per cent in 1997 and steadily increased in the following years, reaching a maximum of approximately 83 per cent in 2004. From 2005 onwards (following the Withdrawal) Gaviscon experienced a slight decline, but its share remained high at 79 per cent in 2008.

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<sup>486</sup> Data was not available for the UK as a whole prior to 2004. We note that England NHS alginate sales account for around 80 per cent of the UK alginate spend (see paragraph 4.111 above).

**Table 5.3: Market shares by value of alginates and antacids in the (NHS) prescription channel, 1997 – 2008 (England only)**

| Year | Market Share by value (%)   |        |            |        |         |
|------|-----------------------------|--------|------------|--------|---------|
|      | Gaviscon (all formulations) | Peptac | Gastrocote | Acidex | Algicon |
| 1997 | 71                          | n/a    | 5.8        | n/a    | 1.6     |
| 1998 | 74                          | 0      | 5.1        | n/a    | 1.4     |
| 1999 | 76                          | 0.8    | 4.4        | n/a    | 1.3     |
| 2000 | 77                          | 2.4    | 3.8        | n/a    | 1.0     |
| 2001 | 77                          | 3.5    | 3.4        | 0      | 0.9     |
| 2002 | 79                          | 4.0    | 2.1        | 0      | 0.8     |
| 2003 | 81                          | 3.9    | 1.9        | 0      | 0.8     |
| 2004 | 83                          | 3.5    | 1.7        | 0      | 0.6     |
| 2005 | 81                          | 6.1    | 2.0        | 0.1    | 0.3     |
| 2006 | 79                          | 7.9    | 2.2        | 0.1    | 0       |
| 2007 | 79                          | 7.2    | 2.0        | 0.2    | 0       |
| 2008 | 79                          | 6.7    | 1.9        | 0.2    | 0       |

Source: OFT analysis of data provided by the NHS Information Centre. Note: Data for 2008 do not include the fourth quarter.

5.11. In conclusion, RB's consistently high share, which by value was over 80 per cent in the UK throughout the period from 2004 to 2008, strongly suggests that RB held a dominant position in the market for the supply of alginates and antacids by prescription in the UK. Indeed, as established above, market shares such as those held by RB in the relevant market indicate that RB would hold a dominant position in all but exceptional circumstances. This assessment is further supported by the fact the rival products' shares were significantly smaller and not capable of undermining RB's leading position in the relevant market.<sup>487</sup>

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<sup>487</sup> The OFT's findings in this regard are also supported by the General Court in *AstraZeneca*, which found that 'the Commission was entitled to take the view that AZ's possession of a particularly high market share and, in any event, a share which was

**c) Rival products have not managed to successfully challenge Gaviscon's dominant position over time**

- 5.12. As noted above, RB's market share in the UK has remained broadly unaltered, in the range 81 per cent to 85 per cent by value, between 2004 and 2008. During this period rival products have not managed to successfully challenge this position. This is illustrated by two events involving Peptac: (i) its launch on the market in 1998; and (ii) its attempts to compete with the Gaviscon portfolio following the Withdrawal in 2005.
- 5.13. As noted in Part 2, the patent for GL expired in 1997. Although a generic name for GL was not available at the time, Pinewood launched its own therapeutically equivalent branded generic product (Peptac) in 1998. Peptac was made available in the same dosage as GL and was cheaper than GL (Peptac's price was £1.94 for a 500 ml bottle in 1998, increasing to £2.16 from 1999, compared to £2.70 for GL in the same format). However, unlike GL, it was originally only available in aniseed flavour.<sup>488</sup>
- 5.14. Despite being therapeutically equivalent to but cheaper than GL, Peptac's success has been limited. By 2004, having been available for six years, Peptac had managed to achieve a market share by value of only four per cent. Even after the withdrawal of the leading product in the relevant market, GL, Peptac's market share by value did not reach 10 per cent. With a market share by value of more than 80 per cent in the same period, RB's position was not threatened by Peptac's entry despite the prices of NHS packs

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much higher than those of its competitors, was an entirely relevant indicator of its market power, which was out of all comparison to those of the other market players' (Case T-321/05 *AstraZeneca v Commission*, OJ C 221/33, judgment of 1 July 2010, paragraph 253).

<sup>488</sup> At the time of the launch of Peptac in 1998, Gaviscon Liquid was available in two flavours, aniseed and peppermint, although the latter was only introduced in Q4 1993 and was less successful than the original aniseed version.

of GL (until it was withdrawn) and GA remaining broadly constant.<sup>489</sup>

- 5.15. Pinewood's actions in 2005, following the Withdrawal, enabled it to increase its market share by a limited amount. Pinewood launched a new version of Peptac in peppermint flavour and reduced the price of Peptac from £2.16 to £1.95 per 500ml bottle, which compared with a price of £2.70 for GL NHS packs (500ml bottle) and GA (250ml bottle). As a result of some GPs switching to Peptac, Pinewood's share by value of the relevant market increased from four per cent in 2004 to seven per cent in 2005 and nine per cent in 2006 and 2007, before declining to eight per cent in 2008. Although Pinewood did gain share, this gain is small when considered in the context of the Withdrawal, where GL was therapeutically equivalent to Peptac and the leading product in the relevant market.
- 5.16. Peptac's relative success during this period did not affect RB's position to any significant extent. RB's market share by value of the relevant market only decreased from 85 per cent in 2004 to 81 per cent in 2008. Similarly, Pinewood's actions did not affect the pricing of GA after the Withdrawal, which stayed constant at £2.70 per 250ml bottle and £5.40 per 500ml bottle.

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<sup>489</sup> The OFT's view that the ability of RB to achieve this is an indicator of dominance is supported by the General Court in *AstraZeneca*, which states that 'the fact that AZ was able to maintain a much higher market share than those of its competitors while charging prices higher than those charged for other PPIs is a relevant factor showing that AZ's behaviour was not, to an appreciable extent, subject to competitive constraints from its competitors, its customers and, ultimately, consumers' (Case T-321/05 *AstraZeneca v Commission*, OJ C 221/33, judgment of 1 July 2010, paragraph 261). See also paragraph 266, which states that 'the ability of AZ to maintain higher prices than those of its competitors, while retaining a much higher market share, shows that it was able to exercise market power in respect of price, since neither competing producers, nor social security systems, which bore the cost of the medicines, nor indeed patients, were able to force AZ to bring its prices into line with those of competing products'.

- 5.17. It is apparent that RB foresaw that the withdrawal of its leading prescription channel product would not threaten its significant market share. RB's stated rationale for the Withdrawal was 'to maintain control of [the] UK alginates market rather than allow competitors to dictate the future of Gaviscon in the NHS franchise'.<sup>490</sup> Indeed, RB considered that although the Withdrawal would result in small market share losses initially, its market share would nevertheless remain very high and would 'stabilise at its new level'.<sup>491</sup>
- 5.18. RB's prediction about the impact on its market share of the Withdrawal was broadly accurate. This is illustrated by a presentation entitled 'Project White Tiger Review' for an RB meeting in March 2006, in which a graph showed that the total Gaviscon share of alginate prescriptions had fallen from a stable 95 per cent by value (and 92 per cent by volume) prior to the Withdrawal to a stable 85 per cent by value (70 per cent by volume) after August 2005.<sup>492</sup>
- 5.19. RB's high market share was therefore preserved despite Peptac's entry in 1998 and the launch of a second formulation and price reduction in 2005. Further, as RB foresaw, the withdrawal of its leading prescription channel product, GL, did not result in RB's market share by value falling significantly. This strongly suggests that RB was dominant in the relevant market.

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<sup>490</sup> Document entitled 'Project White Tiger Review' attached to an internal RB email dated 11 May 2006 (RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 425).

<sup>491</sup> RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 70.

<sup>492</sup> RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 404.

**ii) Barriers to expansion**

- 5.20. The very low market share of competitors in this market, and the fact that Peptac enjoyed limited success in the years following its launch in 1998 (in terms of sales and market share; see Table 5.1 above), despite being cheaper than GL, strongly suggests that existing competitors to Gaviscon face significant barriers to expansion.
- 5.21. In the pharmaceutical sector, the extent of any barriers to expansion will be influenced by whether or not the incumbent suppliers' products are patent protected and, where there is no longer patent protection, whether such products have been given a generic name.
- 5.22. Where leading branded products remain patent protected, or where no generic name exists, a competitor will need to convince GPs of the merits of their product versus the incumbents' products in order to achieve sales growth. In order to promote their products in competition with incumbent products, manufacturers therefore need to gain access to individual doctors, PCTs, pharmaceutical advisers and/or other clinicians responsible for advising GPs on prescribing practice, to convince them that their product should be prescribed rather than possible alternatives. This involves spending considerable sums on 'detailing' and other marketing activities. In the case of generic manufacturers, their products must be marketed with a brand name and such products are referred to as 'branded generics' (this scenario was described by RB as the 'branded generic threat', as opposed to the 'full generic threat', see paragraphs 2.80 to 2.84 above).
- 5.23. Where full generic competition exists, barriers to expansion would ordinarily be lower. Where an existing competitor supplies a product that is equivalent to a branded product whose patent has expired, it will not need to invest in GP detailing to seek to convince GPs that its product should be preferred. Rather, because pharmacies may receive a generically written prescription relevant

to the branded product and to the equivalent generic products, and because pharmacists can choose which product to then dispense, the competing supplier can generate significant sales provided that its product is priced competitively and pharmacists have an incentive to dispense it.

- 5.24. Before June 2005, GL was the leading product in the relevant market, and Pinewood Healthcare supplied an equivalent product (Peptac/Acidex). However, while NHS packs of GL were available, at no point was there a generic name for it. For this reason, the only way that Pinewood could generate sales of Peptac was to market it as a 'branded generic' and to promote it through 'detailing'. Pinewood could not rely on a pharmacist's ability to dispense its products on receipt of a prescription listing the applicable generic name.
- 5.25. Since July 2005, the only Gaviscon brand that has been available in NHS packs is GA, which is patent protected until 2016. To compete with GA, suppliers of competing products must invest in 'detailing' to persuade GPs to prescribe their medicines instead. Competitors such as Pinewood cannot rely on a pharmacist's ability to dispense its products on receipt of a prescription listing GA or a generic name for GA.
- 5.26. Because no generic name for a Gaviscon product was published in GPs' software until January 2009, GPs have therefore been required to type the brand name of a medicine in order to issue a prescription for a medicine in the relevant market. Indeed, RB itself noted that prior to the Withdrawal all sales of Gaviscon in the NHS prescription channel resulted from GPs first typing in the Gaviscon brand name into the IT systems.<sup>493</sup> The need for existing

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<sup>493</sup> See, for example, internal RB email dated 16 February 2005 (RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 70); a draft Product Launch Recommendation document for Project White Tiger, dated January 2005 (RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 55).

competitors to market their products as brands to generate prescriptions has therefore required them to overcome the incumbent advantage that RB enjoys having established Gaviscon as the most commonly prescribed product in the UK<sup>494</sup> and as a brand with significant recognition among patients and GPs.<sup>495</sup>

5.27. The need for Pinewood and other alginate manufacturers to invest significant sums in 'detailing' activities represents a significant barrier to expansion, particularly in view of the strength of the Gaviscon brand. This is particularly the case because it is incompatible with both the low cost/price model that generic companies operate and have expertise in,<sup>496</sup> and the fact that

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<sup>494</sup> RB slide presentation (undated) - RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 430.

<sup>495</sup> The contribution of an incumbent advantage and brand strength to a finding of dominance in the pharmaceutical sector is supported by the General Court's judgment in *AstraZeneca*. In that judgement, in respect of an analogous situation, the court found that 'AZ's privileged position stems precisely from an innovative breakthrough by it, which enabled it to develop a new market and to have the advantageous status of first mover advantage' (Case T-321/05 *AstraZeneca v Commission*, OJ C 221/33, judgment of 1 July 2010, paragraph 254) and went on to find that 'in view (i) of the specific features of the markets for pharmaceutical products, which are characterised by 'inertia' on the part of prescribing doctors, and (ii) of the difficulties encountered by pharmaceutical undertakings to enter a market... the [Commission] was entitled to take the view that first-mover status was an appreciable competitive advantage. That competitive advantage is also borne out by AZ's internal documents, which show that Losec enjoyed a solid brand image and reputation...' (paragraph 278).

<sup>496</sup> The implication of this is that, as a branded manufacturer which operates a business model of investing heavily in R&D and marketing, RB necessarily has superior resources over a generic manufacturer which operates a different business model in the context of the absence of a generic name. While this in itself does not confer on RB a position of dominance, the fact that such factors are relevant to, and would support, a finding of dominance is reflected by the General Court in *AstraZeneca*: '[T]he superiority in terms of the financial and human resources devoted by AZ to research and development and to its sales force is also a relevant factor for assessing the position of that undertaking relative to its competitors on the market. Although they are not sufficient in themselves to warrant the conclusion that AZ was in a dominant position during the relevant period,



generic medicines by definition offer no clinical advantage over the branded incumbent which the generic manufacturer can refer to when marketing to GPs.

- 5.28. In the case of Peptac, Pinewood has informed the OFT that the barriers to expansion associated with the absence of a generic name were such that it was necessary for it to contract a business partner with a marketing and distribution function. The consequence for Pinewood of being required to fund an agent to distribute, promote and market Peptac rather than being able to sell it directly to wholesalers was that it incurred additional costs of £1.13 per 500ml bottle sold.<sup>497</sup>
- 5.29. In its SMFI RB argues that Peptac's lack of success can be attributed to a material extent to the fact that it is inferior to Gaviscon.<sup>498</sup> RB states that, although Peptac is therapeutically equivalent to GL, there are 'material differences' between them, namely: raft strength, raft resilience, organoleptic profile (that is, taste and texture) and patient perception of quality. The OFT notes that both products meet the criteria of the BP ARFOS monograph, which includes a raft performance measure. Moreover, whatever the impact of the issues referred to by RB, it is apparent from the above analysis that competitors such as Pinewood face significant barriers to expansion in the relevant market.
- 5.30. Overall, it is apparent that significant barriers to expansion exist in this market. Existing competitors to RB face significant difficulties

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those findings none the less constitute a series of relevant indica which permit the inference that AZ had superior resources to those of its competitors such as to reinforce its market position in relation to them' (Case T-321/05 *AstraZeneca v Commission*, OJ C 221/33, judgment of 1 July 2010, paragraph 285-286).

<sup>497</sup> Pinewood submission dated 8 July 2009, in response to Q2-7 of OFT's section 26 notice dated 27 May 2009 (OFT file document F3.49.01).

<sup>498</sup> RB SMFI, paragraph 3.17.

in seeking to persuade GPs to prescribe their products instead of Gaviscon. Market share data indicates that none of RB's competitors have been able to achieve significant market shares, even despite RB's withdrawal of the leading product in the relevant market.

## **C. Potential competition**

### **i) Barriers to entry**

#### **a) Introduction**

5.31. The OFT has also considered the existence of barriers to entry. As set out in the OFT Guidelines on the assessment of market power,<sup>499</sup> the lower the barriers to entry, the more likely it is that potential competition will prevent undertakings within the market from profitably sustaining prices above competitive levels. An undertaking with a large market share in a market protected by significant entry barriers is likely to have market power.

5.32. The following analysis considers the barriers to entry faced by potential competitors seeking to develop a branded or generic product for this market.

#### **b) Introducing a new branded product**

5.33. The launch of a new pharmaceutical product is a costly and lengthy process. In the initial period of the R&D phase there are a number of stages including the identification of biological molecules associated with the disease in question<sup>500</sup> and the

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<sup>499</sup> OFT Guideline 415: *Assessment of Market Power*, paragraphs 5.2 and 5.4.

<sup>500</sup> Some of this research is conducted by private companies and some is undertaken within public sector institutions such as universities. Molecules, known as 'leads', which interact with the verified target(s) are then actively sought by developing new molecules and/or deriving them from existing treatments or natural remedies. The leads with the greatest potential to be developed into a safe and effective medicine are tested and the suitable candidates are taken forward to the next stage in the R&D phase. See *EC*

verification of these as potential therapeutic targets. During this time, the manufacturer usually begins to file 'primary patent' applications relating to the active molecules.

- 5.34. At the development stage of the R&D phase the lead compounds are tested for safety and efficacy in the laboratory and on animals ('pre-clinical' stage), then on humans ('clinical stage'). The clinical stage is comprised of three phases<sup>501</sup> and accounts for, on average, around 92 per cent of R&D costs.<sup>502</sup>
- 5.35. In the EU, medicinal products may only be launched on the market after they have obtained a National or Community Marketing Authorisation (MA). The MA process verifies the safety, quality and efficacy of the proposed medicine. The national MA process in the UK is carried out by the MHRA and takes approximately two years.
- 5.36. It can take between two and 10 years to complete the process of launching a new medicine, from filing an application for the first compound patent to the launch of the product, and the average time taken from patent application filing to product launch is 8.6 years.<sup>503</sup> As a result of these delays, there are various mechanisms

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*Pharmaceutical Sector Inquiry Report*, 8 July 2009, paragraphs 134 to 139, available at: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>.

<sup>501</sup> Phase I consists of studies on small groups of healthy humans to determine safety and side-effects. Phase II consists of studies on patients with the disease and also involve parallel tests using placebos. Phase III involves long-term trials using large patient groups. 'Secondary patent' applications may be made in Phase II of the development stage of R&D for aspects such as dosage forms, particular pharmaceutical formulations. Secondary patent applications may also be made for and also for new therapeutic applications which may be discovered in Phase III. See *EC Pharmaceutical Sector Inquiry Report*, 8 July 2009, paragraph 140.

<sup>502</sup> *EC Pharmaceutical Sector Inquiry Report*, 8 July 2009, paragraph 152.

<sup>503</sup> *EC Pharmaceutical Sector Inquiry Report*, 8 July 2009, paragraph 143.

available to manufacturers which enable them to benefit from additional patent-like protection, such as Supplementary Protection Certificates (SPCs)<sup>504</sup> and rules on data exclusivity.

- 5.37. The existence of lengthy and risky processes of R&D, clinical trials, development of production, obtaining a manufacturing licence and obtaining marketing authorisation is acknowledged by the CAT as 'represent[ing] a significant hurdle' for anyone contemplating entering the market.<sup>505</sup>
- 5.38. The difficulties in bringing a branded originator product to market are demonstrated by the experience of RB and by the lack of entry by competitors. RB's internal documents reveal that despite its experience in the area, it encountered significant difficulties in identifying a formulation that offered material and patentable innovations versus GL. As outlined further at paragraphs 2.164 to 2.166 above, in 2003/4 RB tried without success to develop a variant to GL that would not fall within the product monograph applicable to the original GL formulation.
- 5.39. Even where a manufacturer is able to successfully bring a new branded product to market, the barriers to expansion outlined in Section B (ii) above are such that that manufacturer may encounter significant difficulties in generating sales that represent anything more than a modest market share.

**c) Introducing a new generic product**

- 5.40. Provided that the relevant market includes a branded product whose patent has expired, the barriers to entry faced by those seeking to introduce a new generic product will typically be

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<sup>504</sup> Created by Council Regulation (EEC) No. 1768/92 of 18 June 1992, SPCs are a means by which the patent right for a medicine can be extended for a maximum of five years.

<sup>505</sup> Case No. 1016/1/1/03 *Genzyme Limited v OFT* [2004] CAT 4; paragraph 227.

considerably lower than those faced when seeking to introduce a new branded product.

- 5.41. Producers of generic medicines (whether branded or not) are able, subject to rules on data exclusivity,<sup>506</sup> to make an 'abridged application' for a MA without providing results of pre-clinical tests and clinical trials if it can be demonstrated that the generic product is 'essentially similar'<sup>507</sup> to the original product.
- 5.42. The EU regulatory framework on MAs was amended in 2004<sup>508</sup> and introduced a number of provisions to further improve the ability of generic medicines to obtain MAs, for example by permitting the authorisation of a generic product even if the original product is no longer authorised.<sup>509</sup>

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<sup>506</sup> Rules on data exclusivity (Directive 2001/83/EC) prevent MA bodies from processing abridged applications for generic medicines for a certain number of years after the first MA. Where the initial national authorisation application for a reference medicinal product was made in the UK before 30 October 2005, or a central authorisation application made before 20 November 2005, the product benefits from 10 years' protection. Where the initial national authorisation application for a reference medicinal product was made in the UK after 30 October 2005, or a central authorisation application made after 20 November 2005, new rules harmonised at EU level apply (Regulation 726/2004, and Directive 2004/27/EC amending Directive 2001/83/EC). Under the harmonised rules an abridged application for a generic product is possible eight years after the initial MA period although it is not possible to actually place that product on the market until 10 years after the original MA. In addition, if a new therapeutic indication with a significant clinical benefit as been approved for the reference product during the first eight years following the MA, the reference product will benefit from an additional year of marketing exclusivity.

<sup>507</sup> The meaning of the concept of 'essential similarity' was established by the Court of Justice in Case C-368/96 *R. v Licensing Authority Ex p. Generics (UK) Ltd* and is enshrined in Article 10(2)(b) of Directive 2004/27/EC.

<sup>508</sup> Regulation (EC) No. 726/2004 and Directive 2004/27/EC amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use.

<sup>509</sup> *EC Pharmaceutical Sector Inquiry Report*, 8 July 2009, paragraph 302.

- 5.43. As with new branded products, even where a manufacturer is able to successfully bring a generic product to market, the barriers to expansion outlined in Section B (ii) above are such that there may be significant difficulties in then generating sales levels that represent anything more than a modest market share.
- 5.44. Such are the barriers to entry (and expansion) in the relevant market that, despite GL having now been off-patent for over 12 years, only one generic manufacturer, Pinewood, has considered it worthwhile to introduce a generic equivalent to GL,<sup>510</sup> and has done so with limited success (see paragraphs 5.15 to 5.16, and 5.24 to 5.29 above). The OFT also notes that it is not possible to introduce a generic medicine that is equivalent to GA until 2016, when its patent expires.

**d) Regulatory restrictions**

- 5.45. As set out in Part 2 above, a factor which has had a significant impact on entry to the relevant market was the introduction of the MSLS.<sup>511</sup> It became no longer permitted for GPs to prescribe an almost unlimited range of medicines on their NHS prescriptions. Prescribing was restricted and several categories of drug were affected, including antacids.

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<sup>510</sup> The OFT notes RB's comment in its SMFI (Annex 4, paragraph 9), that a report prepared jointly by DH and ABPI entitled *PPRS: The Study into the Extent of Competition in the Supply of Branded Medicines to the NHS*, December 2002, identified some reasons why generic entry may not occur or may be slow in some markets. These factors include 'the nature of product: apart from a few companies, which specialise in the manufacture of oral liquids, generic companies concentrate on oral solid dosage forms, in particular tablets and generally avoid other presentations'. The OFT recognises that this factor may be applicable to the alginates market, although the OFT also notes that entry has occurred.

<sup>511</sup> See paragraph 2.111 above.

5.46. The impact of this is that many antacid suppliers became unable to access the prescription channel and compete with Gaviscon medicines in the relevant market.

**e) Conclusions on barriers to entry**

5.47. Overall, it is apparent that there are significant barriers to entry in the relevant market. First, to develop and introduce a new and innovative product in the market would require significant resource and have a limited prospect of success. Second, developing a generic equivalent to branded incumbent products also requires significant resources and is only possible where a leading branded incumbent product does not retain patent protection. Third, there are absolute regulatory restrictions on certain products (primarily antacids) being prescribed.

5.48. The significance of these barriers to entry has resulted in no significant market entry since Peptac's launch in 1998. These entry barriers must also be considered in the context of the significant barriers to expansion described in Section B (ii) above, which would be relevant to any supplier who was able to bring a new product to market.

**D. Countervailing buyer power**

5.49. In order to assess whether RB held a dominant position in the relevant market, it is also necessary to consider the extent to which the DH/NHS – as the 'single buyer' of pharmaceutical products in the prescription channel – exerted countervailing buyer power vis-à-vis RB.

5.50. The OFT Guideline *Assessment of Market Power* states that size is not sufficient for buyer power and that buyer power requires the

buyer to have choice.<sup>512</sup> Further, buyer power is most commonly found in industries where buyers and sellers negotiate.

5.51. In this case the OFT does not consider that the DH and NHS have sufficient negotiating strength to offset RB's market power, for the following reasons:<sup>513</sup>

- The overall objective of national pricing policies for medicines in the EU is to constrain public expenditure through the ex-factory price, reimbursement level and the frequency and conditions under which a medicine can be dispensed and used.<sup>514</sup> Its purpose is not to control the conduct of individual suppliers.
- In the UK the PPRS, which is negotiated between the DH and the ABPI, is the primary tool used by DH to control NHS branded medicine costs.<sup>515</sup> However, the PPRS does not provide DH with the ability to constrain the conduct of individual companies in the supply of specific products. Further, the focus of the PPRS profit and price controls is not only portfolio-wide for each scheme member, but is also negotiated

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<sup>512</sup> See *Assessment of Market Power* (OFT 415), paragraph 6.1, December 2004, available at: [www.of.gov.uk/OFTwork/publications/publication-categories/guidance/competition\\_act/oft415](http://www.of.gov.uk/OFTwork/publications/publication-categories/guidance/competition_act/oft415).

<sup>513</sup> The OFT's view that DH could not assert countervailing buyer power is supported in general by the findings of the General Court in *AstraZeneca*, which confirmed that the features of pharmaceuticals markets (which are unusual in comparison with other markets) would reinforce the market power of companies: '[T]he Commission is justified in finding ... that the health systems which characterise markets for pharmaceutical products tend to reinforce the market power of pharmaceutical companies, since costs of medicines are fully or largely covered by social security systems, which to a significant extent makes demand inelastic' (Case T-321/05 *AstraZeneca v Commission*, OJ C 221/33, judgment of 1 July 2010, paragraph 262).

<sup>514</sup> *EC Pharmaceutical Sector Inquiry Report*, 8 July 2009, paragraph 342.

<sup>515</sup> See Part 2H.v)a) above.



with and applied across all scheme members. Furthermore, notwithstanding any initial assessment of cost-effectiveness by NICE, the initial price for an individual medicine is not constrained by the PPRS over-and-above the portfolio-wide profit cap. The PPRS does not therefore enable the NHS to constrain the pricing and conduct of manufacturers in respect of individual products.<sup>516</sup>

- Although the NHS is described above as 'the single buyer' the NHS is not in fact a single, large corporate entity. Its operation is devolved to numerous executive or advisory bodies or agencies, including local PCOs/PCTs which have responsibility for containing costs.<sup>517</sup> None of these bodies have any specific powers to require a pharmaceutical company to alter its pricing practices.<sup>518</sup>

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<sup>516</sup> The OFT's view that the PPRS does not exercise any significant constraint on RB's ability to 'act independently' is supported by the CAT in *Genzyme*. The CAT noted that '[the PPRS] is not designed to control the prices of individual drugs'<sup>516</sup> and goes on to cite two passages from its own judgment in *Napp*, in which it said 'As regards the issue of dominance, the effects of the PPRS are at most remote and indirect ... In our view nothing in the PPRS affects Napp's autonomous conduct in such a way as to deprive Napp of its dominant position.' *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] CAT 1 [2002] CompAR [13], paragraphs 164 and 168 (Cited in Case No. 1016/1/1/03 *Genzyme Limited v OFT* [2004] CAT 4; paragraph 262 – 263).

<sup>517</sup> NHS bodies in England are not part of DH but have a close relationship to it as a result of the laws under which they are set up. For example, the NHS Chief Executive is one of the top leaders within DH. NHS Strategic Health Authorities (SHAs) are directly accountable to DH and the NHS Chief Executive has a direct management line to SHA Chief Executives within the NHS in England. Almost all NHS funding is directly allocated by DH to Primary Care Trusts (PCTs). PCTs are free-standing NHS organisations with their own boards, staff and budgets. They are responsible for 80 per cent of the total NHS budget. PCTs are monitored by their local SHA and are ultimately accountable to the Secretary of State for Health ([www.dh.gov.uk](http://www.dh.gov.uk)).

<sup>518</sup> This point was observed by the CAT in *Genzyme* (Case No. 1016/1/1/03 *Genzyme Limited v OFT* [2004] CAT 4; paragraph 246 – 247). Note that, although the CAT is

- Although PCOs/PCTs use various initiatives and incentives in order to influence prescribing, none of these devolved bodies themselves act as the decision-maker with respect to the medicines that are ultimately prescribed, the decision-maker being the prescribing clinician (for example, GP). This further undermines their ability to individually exercise buyer power.<sup>519</sup>
- As set out in paragraphs 2.128 and 2.129 above and paragraphs 6.103 to 6.111 below, DH does not consider that it has any power to object to or to prevent product withdrawals specifically.<sup>520</sup>

5.52. In the current case the NHS has theoretically had the ability to exercise choice between Gaviscon and Peptac since 1998. However, the fact that (i) the treatment cost of Gaviscon has remained broadly constant between 1991 and 2008 (see Figure 2.2 above) and (ii) that Gaviscon's value market share has

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referring to specific pricing practices carried out in that case, the key point may be applied more generally.

<sup>519</sup> The CAT notes in *Genzyme* that 'despite the large superstructure of strategic, executive and advisory bodies ... the clinical decision to prescribe [a medicine] for a patient suffering from [a disease] is taken locally by the responsible clinician... Thus, in practice, once the prescribing decision is taken by the clinician, the NHS ... has little option but to fund the product.' (Case No. 1016/1/1/03 *Genzyme Limited v OFT* [2004] CAT 4; paragraph 248 – 249). In the current case the responsible clinician is a GP, who retains prescribing independence even when a particular prescribing decision is being recommended by his or her PCT. In addition, the OFT notes that, to the extent that PCOs can influence GP prescribing (see Parts 2H.iii) above and Part 6C.iv) below) those initiatives which incentivise GPs to issue open scripts are effective only where it is possible for open scripts relevant to the branded product in question which, due to the Withdrawal, was not the case in relation to Gaviscon products until January 2009 when the generic name was implemented in GPs' prescribing software.

<sup>520</sup> In addition, as set out in the same sections, DH did not have any power to blacklist GA under the Medicines Selected List Scheme in the event that it disapproved of the Withdrawal.

remained above 80 per cent between 2004 and 2008 (and above 70 per cent since 1997 on the basis of data for England), despite Peptac being available at a significantly cheaper price than Gaviscon, demonstrates that in reality the NHS has failed to exert countervailing buyer power vis-à-vis RB for the supply of Gaviscon products.

## **E. Conclusions on dominance**

5.53. The evidence considered by the OFT in this Part demonstrates that RB, through its range of Gaviscon products, held a dominant in the relevant market at least between 2004 and 2008. In particular, this finding is supported by the following:

- RB's market share by value has been in excess of 80 per cent between 2004 and 2008 and RB's share has remained stable and high over an extended period of time. In particular, it has not decreased to any significant extent following the Withdrawal and the significant price reduction in respect of Peptac.
- Despite the emergence of a product (Peptac) that is therapeutically equivalent to GL, and that was priced below GL, RB was successful in maintaining its significant share of the market without lowering the price of Gaviscon products.
- Barriers to expansion are significant in this market. Gaviscon is a widely recognised brand with an established customer base. Competitors such as Pinewood have been unable to obtain a significant market share by convincing GPs to prescribe their brands rather than Gaviscon. Indeed, no other manufacturer of alginates or antacids has achieved a market share over 10 per cent in the past 12 years, despite RB having withdrawn the leading product in the relevant market during this period.

- There are significant barriers to entry which make it difficult for potential entrants and current rivals to bring products to market and to then challenge RB's market position.
- Over the relevant period, the NHS has failed to exert countervailing buyer power vis-à-vis RB for the supply of Gaviscon products.

5.54. Finally, the CAT in *Genzyme* notes that 'the very state of affairs which forms the subject matter of the present case itself indicates the ability of Genzyme to disregard the wishes of its customers and consumers.'<sup>521</sup> In this case, as set out in Part 6 below, RB was able to withdraw the leading and most popular product in the relevant market without losing significant market share. This also suggests that RB was in a position to 'disregard the wishes of its consumers and users, which is the hallmark of dominance'.<sup>522</sup>

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<sup>521</sup> *Genzyme Limited v Office of Fair Trading* [2004] CAT 4; paragraph 257.

<sup>522</sup> *Ibid*; paragraph 255. RB has argued in its SMFI (paragraph 3.18) that, as a matter of factual accuracy, RB cannot be said to have disregarded the wishes of its consumers because it considered the Withdrawal to be risky. The OFT considers that its statement that RB was in a position to disregard the wishes of its consumers is not materially factually inaccurate because RB carried out the Withdrawal despite i) being aware that both GA and Peptac were significantly less popular than GL; and ii) being of the view that the Withdrawal would be unpopular and that RB would consequently lose market share. The extent of risk or uncertainty involved does not undermine this finding because RB considered that, taking account of all available information and the various risks that existed, RB's forecast as to the expected outcome of the Withdrawal was that it would be unpopular with patients/GPs and that it would lose market share as a result.

## 6 ABUSE

### A. Introduction

6.1. The OFT finds that, for the reasons set out in this Part, RB's conduct, the Withdrawal, represents an abuse of its dominant position. In particular:

- The OFT finds that the Withdrawal was motivated by a desire to hinder the development of full generic competition in the relevant market. Moreover, the OFT finds that the Withdrawal would have been commercially irrational were it not for the anticipated benefits to RB of hindering the development of full generic competition. The Withdrawal cannot therefore be regarded as 'normal competition' or 'competition on the merits'.
- The OFT finds that, at the time of the Withdrawal, it was reasonable to expect that the Withdrawal would restrict competition, hindering the development of the full generic competition that would have been expected to emerge had GL NHS packs been retained. The OFT therefore considers that the Withdrawal tended to restrict competition or was capable of having that effect.

6.2. This Part is structured as follows:

- Section B presents the OFT's analysis of whether or not RB's conduct represents 'normal competition' or 'competition on the merits'.
- Section C presents the OFT's analysis of whether or not RB's conduct tended to restrict competition or was capable of restricting competition.
- Section D sets out the OFT's conclusion as to whether RB's conduct amounts to an abuse of a dominant position.

## **B. Normal Competition**

### **i) Introduction**

- 6.3. As set out at Part 3F above, in order to determine whether a dominant company's conduct can be regarded as 'normal competition' or 'competition on the merits', it is necessary to consider the rationale for the conduct, including whether the conduct was intended to restrict competition, and whether such conduct was rational and made commercial sense were it not for the potential to realise gains associated with restricting competition. This Section therefore assesses RB's rationale for the Withdrawal.
- 6.4. In sub-section (ii) below the OFT has assessed RB's rationale for the Withdrawal by reference to RB's contemporaneous internal documents. RB's internal documents indicate that:
- the rationale for the Withdrawal was to protect RB's prescription sales of Gaviscon by hindering the development of full generic competition, and
  - the Withdrawal of GL NHS packs was commercially irrational were it not for the anticipated gains to RB of hindering the development of full generic competition.
- 6.5. In sub-section (iii) the OFT has considered the explanations that RB presented to the OFT in its section 26 responses, and those that it presented to industry stakeholders at the time of the Withdrawal, by reference to its contemporaneous internal documents.
- 6.6. In sub-section (iv) the OFT has considered DH's involvement in the Withdrawal process.
- 6.7. In its response to the section 26 Notice issued by the OFT on 14 January 2009, RB stated that the Withdrawal was 'both rational

and justifiable'.<sup>523</sup> By signing the ERA, RB has admitted that the Withdrawal was not 'normal competition' or 'competition on the merits' (see paragraph 2.26 above).

**ii) The rationale for the Withdrawal**

**a) Introduction**

6.8. This sub-section considers RB's rationale for and intention behind the Withdrawal, by reference to its own internal documents. RB's contemporaneous internal documents indicate that the decision to withdraw GL NHS packs was driven by a desire to restrict effective competition to its Gaviscon portfolio in the prescription channel, following the publication of a generic name corresponding to GL. In particular, RB's internal documents reveal that it considered that after the Withdrawal many GPs and patients would switch to its patent protected product, GA, which would not face full generic competition on publication of a generic name corresponding to GL.

6.9. The Withdrawal should be considered in the context of the events that preceded the Withdrawal. In the period between 2000 and 2004, there was uncertainty within RB as to the date on which a generic name corresponding to GL would be published and RB considered ways in which it could delay that process (see Part 2I above). During this period, RB considered a number of options as strategies that could be implemented to best protect its prescription channel Gaviscon portfolio from competition following the publication of a generic name corresponding to GL.<sup>524</sup>

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<sup>523</sup> Letter from RB dated 6 March 2009 in response to the OFT's section 26 notice dated 14 January 2009.

<sup>524</sup> Such options included ensuring that a new product monograph corresponding to GL included an alginate specification that only RB could match (see, for example, internal RB slide presentation dated August 2000 – RB submission dated 6 March 2009 in response to Q1(i) of OFT section 26 Notice dated 14 January 2009, document 51 and internal RB

- 6.10. One of these options, the withdrawal of GL, was initially rejected on the basis that doing so would risk market share losses. Rather, until 2005, RB was focused on developing a new version of GL (as part of project Atlas) that would be outside of the scope of the new monograph for the existing formulation of GL, and would, therefore, not face full generic competition on publication of the monograph and associated generic name.
- 6.11. By February 2005 RB had abandoned project Atlas having failed to successfully develop a suitable new formulation of GL.<sup>525</sup> At that time, RB considered that its 'Generics Defence' included two options. The first of these was to 'fight generic competition using [...]'.<sup>526</sup> The second option was to 'withdraw Gaviscon Liquid and force a choice between Gaviscon Advance and competitors' and to 'implement BEFORE a generic name is granted'.<sup>527</sup>
- 6.12. RB chose to pursue the Withdrawal and the name given to this strategy was project 'White Tiger'.<sup>528</sup> RB defined the first phase of project White Tiger, implemented in June 2005, as 'the proactive withdrawal of GL from the NHS in advance of the anticipated

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email dated 4 September 2000 – RB submission dated 6 March 2009 in response to Q1(i) of OFT section 26 Notice dated 14 January 2009, document 57) and [...] (internal RB email dated 13 May 2004 – RB submission of 6 March 2009 in response to Q1(iii) of OFT section 26 Notice of 14 January 2009, document 28).

<sup>525</sup> See RB submission of 6 March 2009, in response to Q1(vi) of the OFT's section 26 notice dated 14 January 2009, document 158.

<sup>526</sup> See paragraph [...] above.

<sup>527</sup> RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 454. See also Q1 (iii), document 77.

<sup>528</sup> The idea of withdrawing GL NHS packs from the prescription channel in order to switch the NHS business to GA appears to have been put forward in May 2004. RB submission of 6 March 2009, in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 28.



publication of a generic monograph and hence the creation of a generic name'.<sup>529</sup>

6.13. In sub-section (b) below the OFT has considered RB's rationale for the Withdrawal as set out in RB's contemporaneous internal documents. In sub-section (c) the OFT has considered the financial implications of the Withdrawal as set out in RB's contemporaneous internal documents, with a view to determining whether the Withdrawal was commercially rational in the absence of any anticipated gains derived from restricting competition..

**b) The rationale as set out in RB's contemporaneous internal documents**

6.14. This sub-section outlines the rationale for and intention behind RB's decision to carry out the Withdrawal, as set out in its contemporaneous internal documents. RB's internal documents reveal an intention to use the Withdrawal as a means of ensuring that GPs would be unable to issue open prescriptions relevant to off-patent liquid Gaviscon products available in prescription packs. Having done so, pharmacies would continue to receive closed Gaviscon prescriptions against which they would not be free to choose to dispense an equivalent generic medicine, and the development of full generic competition would be hindered.

6.15. To put this rationale in context, it is useful first to summarise those elements of the regulatory framework that are of most relevance to such a strategy. As set out in Part 2G above:

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<sup>529</sup> RB submission of 6 March 2009, in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 425. See also Q1 (iii) document 454. Similarly, in document 77 of the same response project White Tiger was defined as:

'Proactive withdrawal of Gaviscon Liquid from the NHS on June 4<sup>th</sup> 2005

- To force the issue of trade-up and move as much business as possible into our patent-protected formulation

- In advance of the anticipated granting of the Gaviscon generic name'.

- Where no generic name exists for a particular product, GPs issue a prescription for a given branded product. When a pharmacist receives a prescription for a branded medicine, it is obliged to dispense the named medicine and cannot choose to dispense an alternative medicine that it regards as being equivalent.
- The publication of a generic name enables a GP to prescribe using that generic name, and the recipient pharmacy can then choose to dispense any product (branded or generic) that is relevant to that generic name. It is this choice between products that fosters effective price competition between originator and generic manufacturers.

6.16. In determining RB's response to the then anticipated publication of a generic name corresponding to GL, it is also relevant to recall that RB was aware that all of its NHS channel sales were generated by GPs who searched for products under the 'Gaviscon' name.<sup>530</sup> Having typed 'Gaviscon' into their IT system and identified both GA and GL, GPs could choose which of those products to prescribe for their patient. RB was also aware that having identified a suitable branded product, GPs are encouraged to then use their 'G' button to identify the applicable generic name (where one exists), and to provide patients with an open script that includes that name against which a recipient pharmacist could then choose to dispense any applicable product.<sup>531</sup>

6.17. RB was aware that for as long as there was no generic name corresponding to GL, GPs who selected GL could not use their 'G' button to then provide open prescriptions. RB recognised that the inability to identify generic equivalents to GL had assisted greatly

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<sup>530</sup> See paragraph 2.171 above.

<sup>531</sup> RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 425.

in limiting market share losses to therapeutically equivalent products such as Peptac:

'For the past 8 years RB has managed to resist the genericisation of GL past the expiry of its patent in 1997 ...

When GPs press G on their computer no generic name is brought up. This has enabled sales team to keep losses of Rx to Peptac and other generic competitors to below 5 percent of the total alginate scripts.<sup>532</sup>

6.18. As outlined at paragraphs 2.161 to 2.194 above, RB's contemporaneous internal presentations suggest that its decision to carry out the Withdrawal was driven by the need to pre-empt the publication of a generic name corresponding to GL, and to ensure that the NHS Gaviscon portfolio was not exposed to the full generic competition associated with the widespread issuing of open prescriptions.<sup>533</sup>

6.19. RB's contemporaneous internal documents explain the rationale of the Withdrawal as being ultimately to prevent GPs from using their 'G' button to identify products such as Peptac:

'If we do not do White Tiger [the Withdrawal], when they [GPs] type 'Gaviscon' and press the 'G' key, the script will print for Raft Forming Alginate Suspension. It is then the

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<sup>532</sup> New Launch Recommendation Paper for White Tiger dated January 2005, RB submission of 6 March 2009, in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 55.

<sup>533</sup> RB also referred to resulting benefits and noted that the Withdrawal would enable RB to (i) retain a viable base from which RB could invest in the future growth of GA and (ii) preserve much of the specialised workforce that it deployed in the NHS channel. The OFT does not consider that either of these benefits should be regarded as 'pro-competitive' efficiency gains. (RB SMFI, paragraphs 2.18 to 2.18(b) and 4.1(a), see paragraphs 6.36 to 6.39 below).

pharmacist's choice to fill it with Gaviscon, Peptac or indeed any reimbursable product which meets the BPC monograph specification.

'If we do implement White Tiger, when they type in 'Gaviscon', the list will bring up the GA SKUs. If the GP then presses the 'G' button, the script will print for the generic description of GA, which until the patent expires in 2016 will only be able to be filled with GA.'<sup>534</sup>

'This would mean that when a generic name was finally published, our remaining GA business would still have no generic equivalent and therefore we would still not suffer from generic substitution of Peptac for Gaviscon.'<sup>535</sup>

- 6.20. RB's internal documents demonstrate that its strategy was driven by the concern that, had GL NHS packs been retained, large numbers of GP's would have continued to identify it on their IT system and then prescribe it generically such that RB's 'entire Gaviscon NHS franchise will be under threat'.<sup>536</sup> By carrying out the Withdrawal, RB considered that pharmacies would not receive open prescriptions against which they could choose to dispense a Gaviscon product or a generic equivalent, such that it would be in a position to 'maintain control of [its] own destiny' and 'not allow

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<sup>534</sup> Internal RB email dated 16 February 2005 (RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 70).

<sup>535</sup> New Launch Recommendation Paper dated January 2005 - RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 55.

<sup>536</sup> RB submission of 6 March 2009, in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 55.

the competition to dictate the future of one of RB's global power-brands'.<sup>537</sup>

- 6.21. It is apparent that the significance of the anticipated generic name was the decisive factor in RB's decision to implement the Withdrawal. The 'strategic rationale' for project White Tiger was outlined in a contemporaneous internal RB document that was entitled 'project justification'. The relevant justifications were headed 'the significance of the generic name' and 'the publication of the monograph' and no other factors were presented as being relevant to the recommendation to proceed with the Withdrawal.<sup>538</sup>
- 6.22. Internal RB documents from after the Withdrawal also make it clear that the objective of the Withdrawal was to remove the potential for GPs to identify easily the generic name for Gaviscon products available in prescription packs. For example, a 'White Tiger Review' document sent on 11 May 2006 (almost a year after the Withdrawal) reflects on how the Withdrawal, and the associated impact on GP prescribing, was necessary to protect prescription channel Gaviscon sales from the share losses associated with full generic competition:<sup>539</sup>

'Publication of a Product Monograph for alginates will open up Gaviscon NHS Liquid business to true generic competition. When the GP types Gaviscon and presses the

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<sup>537</sup> RB submission of 6 March 2009, in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 55. A similar statement is made in document 425 of the same response, where RB refers to the rationale of the Withdrawal as being 'to maintain control of the (UK) alginates market rather than allow competitors to dictate the future of Gaviscon in the NHS franchise'.

<sup>538</sup> RB submission of 6 March 2009, in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 55.

<sup>539</sup> RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 425.

'Ctrl + G' key, a generic name will be printed on the script. It will then be up to the pharmacist to fill the script with any form of generic Alginate which meets the generic descriptor, usually done based on profit maximisation for the pharmacy. Given this scenario, protection of our business was critical in order to prevent loss of [...] of RB's NHS business in Gaviscon Liquid.'

- 6.23. RB considered that, to ensure that it did not concede market share to competitors such as Pinewood when a generic name was published, it was necessary to ensure that the Withdrawal took place before that name was published. This preoccupation with ensuring that the Withdrawal took place in advance of the publication of the generic name is repeated in a number of RB's internal documents. Indeed, RB does not dispute that the timing of the Withdrawal was influenced by the expectation of the publication of a monograph corresponding to GL in September 2005<sup>540</sup> and recognises that this is confirmed by a number of its internal documents, some of which are considered below (see also paragraphs 2.198 to 2.206 above).
- 6.24. A particular concern for RB was that if GL NHS packs remained in GPs' IT systems after a generic name corresponding to GL was published, repeat prescriptions would be shifted to scripts written generically as soon as a generic name was published.<sup>541</sup> An email chain dated 14 December 2004 summarises RB's concern:

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<sup>540</sup> Letter from RB dated 6 March 2009 in response to the OFT's section 26 notice dated 14 January 2009.

<sup>541</sup> RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 454, p19. See also New Product Launch Recommendation Paper dated January 2005 - RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 55.

'After successfully stalling for 8 years, we are finally expecting the granting of the gaviscon generic name. This will be via the publication of the monograph by the BPC. Our best guess is that this will occur between September and December 2005. This will mean that from this date, generic prescribing and substitution of Gaviscon NHS will be possible. This will put at risk the estimated £10.5m of business that we have tied up in Gaviscon Liquid. [...] the proposed strategy which has been presented to and broadly accepted (although obviously not finalised) by the exec team, is that we do the following: From at latest June 2005 [...] withdraw gaviscon liquid from NHS sale.'<sup>542</sup>

- 6.25. As set out at paragraphs 2.161 to 2.194, the significance of the timing was known by RB Directors. An RB director approved the notification to DH of the Withdrawal on the basis of the need to ensure that it was executed sufficiently in advance of the earliest anticipated date of the publication of the product monograph, having been advised that 'delaying White Tiger 1/2/3 months risks not being able to do it at all'.<sup>543</sup>
- 6.26. Similarly, an internal RB email dated 28 July 2005 confirms that RB Directors were aware that the Withdrawal needed to take place before the publication of a generic name to successfully 'pre-empt' the threat of full generic competition.<sup>544</sup>
- 6.27. As set out at paragraph 2.183, RB also considered it necessary to withdraw and de-list GL NHS packs sufficiently in advance of the

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<sup>542</sup> RB submission of 6 March 2009, in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 34.

<sup>543</sup> Internal RB email dated 5 April 2005. RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 154.

<sup>544</sup> RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 375.

introduction of a generic name in order to present the Withdrawal credibly to DH. Having determined that DH 'take[s] a very dim view of what they see as efforts to manipulate the patent system, which they consider has the effect of defrauding the NHS by reducing levels of generic prescribing', RB considered it necessary to withdraw and de-list GL NHS packs well in advance of the publication of the generic name so as to 'provide a convincing rationale for doing so that is of benefit to the NHS'.<sup>545</sup>

6.28. RB's contemporaneous internal documents (as set out in Part 2, Section I) also indicate that over a number of years a primary focus of RB was to identify ways of delaying or inhibiting the publication of a generic name corresponding to GL, and that the Withdrawal therefore took place in the context of a longstanding desire to delay or hinder the development of full generic competition to GL. RB's contemporaneous internal documents include numerous statements outlining its intention to delay the introduction by the BNF/BPC of a generic name corresponding to GL and the documents contain, inter alia, the following statements:

'We should remind ourselves what our objective is here ... to delay for as long as possible, the introduction of a generic name and subsequent black listing for Gaviscon while we cannibalise our NHS franchise with Gaviscon Advance.'<sup>546</sup>

'The objective of either a raw material or product monograph application to the BPC is to delay the granting of a generic

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<sup>545</sup> RB submission dated 6 March 2009 in response to Q1 (iii) of OFT section 26 Notice dated 14 January 2009, document 55.

<sup>546</sup> RB submission of 6 March 2009 in response to Q1 (i) of OFT section 26 notice dated 14 January 2009, document 15.



name for Liquid Gaviscon by either the BNF or the BPC for as long as possible.'<sup>547</sup>

'Our objectives are:

to delay the publication of the monograph for as long as is possible.'<sup>548</sup>

'We must now do everything in our power to slow down the [Gaviscon] liquid monograph'<sup>549</sup>

6.29. Considering the evidence in the round, it is apparent from RB's contemporaneous internal documents that RB carried out the Withdrawal as a means of pre-empting the introduction of generic prescribing in respect of GL and thereby hindering the development of full generic competition in the relevant market. RB's internal documents suggest that the desire to impair effective competition was the key factor in RB's decision to carry out the Withdrawal. This, in particular, is evidenced by the documents that formed the basis for RB senior management's approval of the strategy.

**c) The impact of the Withdrawal on RB's financial performance**

6.30. RB's contemporaneous internal documents reveal that, were it not for the prospect of using the Withdrawal to pre-empt effective competition to its Gaviscon portfolio, the Withdrawal would have been loss-making and therefore not a commercially rational strategy. As set out below, RB's internal documents reveal that on implementing the Withdrawal, it expected to suffer market share

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<sup>547</sup> RB submission of 6 March 2009 in response to Q1 (ii) of the OFT's section 26 notice dated 14 January 2009, document 22.

<sup>548</sup> RB submission of 6 March 2009 in response to Q1 (ii) of the OFT's section 26 notice dated 14 January 2009, document 171.

<sup>549</sup> RB submission of 6 March 2009 in response to Q1 (ii) the OFT's section 26 notice dated 14 January 2009, document 288.

losses to competitors such as Peptac. These share losses were expected to result in decreases to RB's revenue and profitability. Such losses were only rational for RB to incur because it foresaw that it would derive subsequent benefits from having hindered the development of full generic competition.

6.31. As outlined above at paragraphs 2.42 and 2.162, prior to its withdrawal GL was RB's leading prescription alginate-based product. It accounted for 45 per cent<sup>550</sup> of its prescription channel sales (by value) compared to GA's share of 38 per cent.<sup>551</sup> Indeed, the situation was very similar to that which existed in 2003 when, as outlined above, RB had concluded that [...],<sup>552</sup> and the resulting 'halt' in switching from GL to GA was such that, even as a means of protecting the Gaviscon portfolio from full generic competition, the Withdrawal was unattractive.<sup>553</sup> On this basis alone, RB's decision to carry out the Withdrawal appears out of the ordinary and difficult to rationalise in the absence of any potential to realise gains from hindering the development of full generic competition.

6.32. In 2005, RB considered that [...] was likely to mean that the Withdrawal would result in some GPs and PCTs identifying products such as Peptac as the appropriate alternative to GL, such that on carrying out the Withdrawal the Gaviscon share of the

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<sup>550</sup> RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 99.

<sup>551</sup> RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 454.

<sup>552</sup> RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 14.

<sup>553</sup> RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 6. See also Q1 (iii) documents 7 and 8.

prescription market would fall overall.<sup>554</sup> As set out at paragraphs 2.186 to 2.194 above, RB's working assumption was that share losses of around [...] per cent would be incurred through a [...] per cent loss of repeat prescriptions<sup>555</sup> and it was on this basis that an RB director approved the Withdrawal.<sup>556</sup> The same figures were also communicated to members of the RB Board.<sup>557</sup>

6.33. In line with the [...] market share losses that RB anticipated, the documents referred to below demonstrate that RB was also expecting the Withdrawal to lead to a decrease of its revenues and profitability when compared to RB's budgeted performance for 2005<sup>558</sup> and the performance that it forecasted had it retained GL

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<sup>554</sup> The share losses that RB anticipated as a consequence of the Withdrawal varied during the course of the discussions prior to the Withdrawal itself. The envisaged value share losses ranged from a [...] loss to Peptac (although this was in the context of a paper designed to reassure RB sales staff; see internal RB email and QA paper dated 20 May 2005 - RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 267) to a worst case scenario that would see a [...] per cent loss of cash turnover (see internal RB email dated 3 March 2005 - RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 151).

<sup>555</sup> RB's share loss forecasts were determined as a proportion of alginate sales in the prescription channel.

<sup>556</sup> RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 154.

<sup>557</sup> An internal RB email dated 11 May 2006, noted that 'the one-off loss of [...] percent of repeat GL Rxs in 2004 is correct to reflect the WT financials presented to [an RB director] as this reflects a loss of business of £[...]mn against 2004.' See RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 425.

<sup>558</sup> RB's 2005 budget was based on the assumption that no generic name would be published in 2005 and therefore provides a useful benchmark to determining whether, other things being equal (in other words, absent the threat of the generic name and the subsequent full generic competition), it would have been profitable and rational for RB to have carried out the Withdrawal.

NHS packs. Documents that outline RB's revenue and profit expectations are described in Part 6C.ii) below and at paragraphs 2.186 to 2.194 above.

6.34. During the development of project White Tiger, and in advance of the Withdrawal, RB's working assumption was that the Withdrawal would result in a £[...]m decrease in annual net revenue and a £[...]m decrease to annual operating profit versus the budgeted performance for 2005.<sup>559</sup> It was on the basis of these forecasts that an RB director approved project White Tiger and the Withdrawal.<sup>560</sup> Significantly, therefore, the decision to carry out the Withdrawal was based on the understanding that the Withdrawal would, other things being equal (in other words, there continuing to be no generic name), result in a decrease in RB's profitability that would render the strategy commercially irrational in the absence of benefits derived from hindering the development of full generic competition.

6.35. There was uncertainty as to the actual impact that the Withdrawal would have on RB's performance and various possible outcomes were therefore mooted in RB's internal documents.<sup>561</sup> For example,

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<sup>559</sup> RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 430. See also Q1 (iii), documents 38, 69, 82, 92, 95, 98, 101, 144, 148, 151, 168, 201, 355; and Q2, documents 5, 35 and 36.

<sup>560</sup> Internal RB email dated 4 April 2005 - RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 154. See also document 412 of the same section 26 notice response in which an RB director approves the project.

<sup>561</sup> See, *inter alia*, internal RB email dated 13 December 2004 (RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 34); Slides attached to internal RB email dated 2 March 2005 (RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 77). Only one individual suggested that the Withdrawal could make economic sense were it not for the threat of full generic competition. She could not 'quite believe I'm saying this' and noted that the forecast gains were as a consequence

the White Tiger 'project champion' considered that the impact on cash turnover could vary greatly, but considered that even the 'best case' would see an [...] per cent decrease in cash turnover, while in the 'worst case' scenario a [...] per cent decrease in cash turnover would be realised.<sup>562</sup> Significantly, none of these scenarios indicate that RB expected the Withdrawal to result in an increase in RB's revenues or profitability, further suggesting that RB's decision to carry out the Withdrawal was only rational given the potential to hinder the development of full generic competition in the relevant market.<sup>563</sup>

- 6.36. It is apparent from RB's internal documents that RB did not foresee pro-competitive gains as a result of the Withdrawal. While the OFT notes that at the time of the Withdrawal, RB expected the Withdrawal to (i) provide a viable base from which RB could invest in research and development relevant to the future growth of GA and (ii) enable RB to preserve much of the specialised workforce that it deployed in the NHS channel (see paragraph 6.18 above). However, the OFT does not consider that either of these benefits should be regarded as pro-competitive efficiency gains.<sup>564</sup> In

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of [...] for which the recommended dose is higher. Her estimates were not referred to anywhere else in the 454 documents provided in response to Q1(iii) of the section 26 notice dated 14 January 2009, and did not form the basis of the approval of project White Tiger (internal RB email dated 31 March 2005 - RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 143).

<sup>562</sup> Internal RB email dated 4 March 2005 - RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 151.

<sup>563</sup> Paragraphs 2.224 to 2.228 refer to evidence that confirms that RB's expectation of share and performance decline remained at the date of the Withdrawal, and represented the benchmark against which the 'success' of project White Tiger would then be assessed.

<sup>564</sup> For example, efficiency cost savings that could be achieved irrespective of whether or not effective competition was inhibited.

particular, these expected benefits cannot be said to result from the Withdrawal as a self standing action, as the Withdrawal alone had no potential to provide for a greater ability to invest in market research in respect in GA, or to retain a specialised workforce in the NHS channel. Rather, the benefits that RB foresaw related to the expectation that the Withdrawal would assist RB to protect its Gaviscon NHS portfolio from full generic competition and maintain higher profitability and revenue that would, over the longer term, provide the basis for investment in research and development and its specialised work force (see paragraphs 6.14 to 6.29 above). The expected benefits referred to by RB are therefore a consequence of the restriction of competition that RB foresaw on carrying out the Withdrawal, and cannot be regarded as pro-competitive efficiency gains.

- 6.37. It is also apparent from RB's internal forecasts that RB did not foresee pro-competitive gains in the longer term that would have made the Withdrawal a rational strategy in the absence of anticipated gains derived from restricting competition.<sup>565</sup> This is illustrated by the projections outlined above, and in an email from an RB director which noted the expectation that the share losses that would be suffered immediately after the Withdrawal would be sustained, and that 'once the hit is taken, that's it and the business will stabilise at its new level'.<sup>566</sup>

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<sup>566</sup> Internal RB email dated 16 February 2005 - RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 70, page 2; see also Q2, document 4 and Q2, document 6. See also internal RB email dated 4 March 2005 - RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 151, and the references to the envisaged market shares losses taking place on an 'ongoing basis'.

- 6.38. In the 454 documents<sup>567</sup> provided in response to the OFT's request for contemporaneous documents relevant to the Withdrawal, RB did not at any point seek to estimate or quantify any efficiency savings that would see the Withdrawal generate improvements in profitability, revenues or market share in the longer term, or that would enable it to grow revenues and market share more effectively in the medium and long term. Indeed, the information communicated to an RB director, and which informed that Director's approval of the Withdrawal, made no reference to the value and/or likelihood of longer term benefits (other than those linked to hindering the development of full generic competition).<sup>568</sup>
- 6.39. Similarly, when assessing the success of project White Tiger in 2006, RB devoted no attention to considering whether any efficiency gains had been realised and whether they may eventually justify the share, revenue and profitability decline suffered by RB after the Withdrawal. Rather, RB assessed the share losses suffered and concluded that the Withdrawal was justified only as it had enabled RB to earn greater returns than it expected to realise had it retained GL NHS packs and been faced with full generic competition.<sup>569</sup>
- 6.40. RB did however invest resource in assessing the extent to which the performance of its NHS Gaviscon business had benefited from the Withdrawal versus a situation under which GL NHS packs had

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<sup>567</sup> Contained in RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009.

<sup>568</sup> Internal RB email dated 4 April 2005 - RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 154.

<sup>569</sup> RB submission of 6 March 2009 in response to Q2 of the OFT's section 26 notice dated 14 January 2009, document 24.

remained available as a prescription medicine and where full generic competition had been allowed to emerge.<sup>570</sup>

6.41. As further set out in Section D below, whereas RB forecasted that the Withdrawal would enable it to preserve a significant market share at prevailing price levels, it expected the retention of GL NHS packs to result in [...] revenue, profit and market share losses and the need to offer [...] price discounts to compete effectively with generic suppliers.<sup>571</sup> The key distinction between the scenarios presented by RB was the extent to which open prescriptions would be written against which pharmacies would be able to choose whether to dispense a prescription pack of a Gaviscon product or an equivalent generic product (see Section D below). Indeed, RB forecasted that the Withdrawal would ensure that open scripts could not be issued for Gaviscon products, and the resulting benefits to RB provide the only basis on which the decision to carry out the Withdrawal was itself expected to be profitable, and therefore rational, for RB. The following graph, which was presented internally within RB, illustrates the lower revenues and profits that RB expected initially on carrying out the Withdrawal when compared to retaining it,<sup>572</sup> and the subsequent recoupment (in terms of higher revenues and profits) that it expected to enjoy after the publication of the generic name, having

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<sup>570</sup> RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 430, page 21.

<sup>571</sup> RB submission of 6 March 2009, in response to Q3 of the OFT's section 26 notice dated 14 January 2009, document 36.

<sup>572</sup> Profitability and revenue forecasts included in the RB submission of 6 March 2009, in response to Q3 of the OFT's section 26 notice dated 14 January 2009, document 36. In the graphs below, NR refers to Net Revenue and COP refers to Company Operating Profit. Project Eric refers to the option of retaining NHS packs of GL.



hindered the development of full generic competition by implementing the Withdrawal.<sup>573</sup>

[...]

6.42. Considered in the round, RB's contemporaneous internal documents therefore demonstrate that RB's decision to carry out the Withdrawal was, at that time, irrational but for the benefits that RB expected to derive from hindering the development of full generic competition. This analysis suggests that, other things being equal, RB's decision to carry out the Withdrawal was expected to result in share, revenue and profitability decreases that would be sustained. This analysis supports the findings at sub-section C (i) (b) above in that it suggests that the purpose of the Withdrawal was to hinder the development of full generic competition, as it would have made no economic sense if this were not the case.<sup>574</sup>

**iii) RB's explanations of its conduct**

**a) Introduction**

6.43. RB has stated to the OFT that the following reasons formed part of its rationale for the Withdrawal:<sup>575</sup>

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<sup>573</sup> Ibid.

<sup>574</sup> On page 5 of RB's submission dated 6 March 2009, RB itself acknowledges that it changed the timing of the Withdrawal in response to the anticipated timing of the publication of the corresponding generic name. This itself implies that the decision to carry out the Withdrawal in June 2005 was irrational were it not for the benefits that RB expected to derive from restricting competition.

<sup>575</sup> Letter from RB dated 6 March 2009 in response to the OFT's section 26 notice dated 14 January 2009.

- it had always been the intention of RB to convert sales of GL to the NHS into sales of GA, but that switching from GL to GA had been slower than RB had hoped
- the 'ongoing' intention to convert NHS sales of GL to sales of its 'superior' GA product was part of a 'normal lifecycle management strategy'. and
- the 2004 introduction of GA tablets permitted RB to offer a complete portfolio of GA products to GPs.

6.44. At the time of the Withdrawal, RB advanced various statements to stakeholders in support of its decision to carry out the Withdrawal. These explanations included RB's argument that the completion of the GA portfolio prompted the Withdrawal, which as outlined above is also an argument that RB has presented to the OFT. At paragraph 4.3 of its SMFI, RB states that it 'has **not** sought to rely on these matters per se as showing that the Withdrawal was normal competition'. For completeness, this sub-section nevertheless considers each of the arguments presented to stakeholders as well as the background to their inception.

6.45. The merits of these arguments are considered in sub-sections (b) to (d) below.

**b) RB's intention to convert sales of GL to GA**

6.46. In explaining the rationale for the Withdrawal, RB stated that it had always been its intention to convert sales of GL to GA in the prescription channel and that this formed part of the rationale for the Withdrawal.

6.47. The OFT recognises that following the launch of GA, RB had an ongoing intention to 'cannibalise' sales from GL to GA. However, the OFT notes that it is RB's ongoing assessment of the desirability of carrying out the Withdrawal that is of relevance to an assessment of whether the Withdrawal was 'normal competition' or 'competition on the merits', and not its ongoing intention to encourage prescription of GA. In this regard the OFT

observes that (i) RB had previously considered that withdrawing NHS packs of GL was commercially unattractive; and (ii) were it not for the competitive threat associated with the publication of the generic name, RB had no plans to withdraw NHS packs of GL in the foreseeable future.

6.48. As outlined in paragraph 6.9 above, in the period 2000 to 2004 there was uncertainty within RB as to the date on which a generic name corresponding to GL would be published. During this period, RB considered a number of options as strategies that could be implemented to protect its prescription channel Gaviscon portfolio following the publication of a generic name, one of which was the withdrawal of NHS packs of GL.

6.49. One of the factors that contributed to the decision not to go through with the withdrawal of NHS packs of GL in 2003 was the significant resistance that was expected to it from a number of patients/GPs.<sup>576</sup> In an internal RB email dated 10 July 2003 explaining why GA could not necessarily act as a replacement for the withdrawn and de-listed GL NHS packs, it was noted that:

'One of the main reasons for not just using Advance for this replacement strategy is that 4 years of experience have taught us how much resistance there is in switching to Advance. There are significant numbers of die hard Gaviscon Liquid script writers.'<sup>577</sup>

6.50. In relation to GL, RB reflected that having been available for 35 years 'GPs and patients know it and love it' and for this reason only 23 per cent of prescriptions had been 'cannibalised' to GA

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<sup>576</sup> See paragraph 2.162 and footnote 206 above.

<sup>577</sup> Internal RB email dated 10 July 2003 – RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 14.

despite the latter having been available for eight years.<sup>578</sup> Indeed, in 2005 GL remained the most prescribed medicine brand in the UK.<sup>579</sup>

6.51. This situation was reflected in the 'grinding halt' to switching from GL to GA noted by an RB senior manager.<sup>580</sup> Indeed, by 2003 the value market shares of GL and GA were quite stable at 41 per cent and 28 per cent respectively and this contributed to the conclusion that it was not going to be possible to protect the £9m of GL revenue from the threat of a generic name by 'upgrading into GA'.<sup>581</sup>

6.52. In 2003, RB was therefore of the view that even in the face of the generic threat to its GL business, the withdrawal of GL would be undesirable and could be expected to result in a high risk of significant losses to equivalent products such as Peptac. RB was aware of [...] and that the withdrawal of GL was likely to result in share loss to products such as Peptac.

6.53. As set out paragraphs 2.161 to 2.167, as an alternative to GL's withdrawal, RB therefore opted to pursue project 'Atlas', and to

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<sup>578</sup> RB slide presentation (undated)- RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 430. Earlier RB documents suggested slightly different 'cannibalisation' figures (e.g. internal RB email of 3 May 2005 suggests 40 per cent (Q1(iii), document 246). The OFT thinks it is reasonable to take the latest figure as most accurate as it would have been calculated using the latest data.

<sup>579</sup> RB slide presentation (undated)- RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 430.

<sup>580</sup> Internal RB email dated 7 July 2003 – RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 6.

<sup>581</sup> Internal RB email dated 10 July 2003 – RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 14.

seek to develop a replacement for GL that would be outside the scope of any new monograph for the existing GL formulation.

6.54. RB's internal documents do not suggest that the withdrawal and de-listing of GL NHS packs had simply been brought forward from a preferred date by which time RB expected it to make commercial sense, but instead make reference to GL's continued popularity and the fact that switching from GL to GA had been exhausted. In fact, had GL NHS packs not been withdrawn in advance of the generic name as a means of hindering the development of full generic competition, the OFT notes that RB's forecasts were based on the assumption that RB would retain GL NHS packs until at least 2010 (see Part 6C.ii) below).

6.55. Overall, it is apparent that having initially launched GA as a replacement product for GL, sales of GA proved disappointing such that RB did not deem it commercially desirable to replace GL with GA by withdrawing the former. Having been available for more than six years, by 2003/4, RB concluded that even as a means of protecting its portfolio from full generic competition the withdrawal of GL was commercially unattractive, and the plan to replace GA with GL appeared to have been abandoned. Indeed, were it not for the opportunity to pre-empt the publication of the generic name, it is apparent that RB was forecasting that it would retain GL until at least 2010.

**c) Conversion as part of a normal lifecycle-management strategy**

6.56. RB has argued that RB's ongoing intention to convert sales of GL to GA was part of a 'normal lifecycle management strategy', and that this formed part of the rationale for the Withdrawal.

6.57. For the reasons outlined below, the OFT considers that, while an intention to convert sales of GL to GA may be consistent with a 'normal lifecycle management strategy', achieving that strategy by the Withdrawal cannot itself be regarded as part of a 'normal lifecycle management strategy'.

6.58. While there is no accepted definition of a 'normal lifecycle management strategy' in the pharmaceutical sector, the OFT considers that in this context a 'normal lifecycle management strategy' would involve a pharmaceutical manufacturer choosing to replace an existing product with one that incorporates innovations that are valued by clinicians and patients alike, such that it can make commercial sense (irrespective of any gains from hindering the development of full generic competition) to withdraw the original product for which there may then be no (or only limited) residual demand.

6.59. It is apparent from RB's internal documents that RB considered that the Withdrawal was not a 'normal lifecycle management strategy'. Rather, its internal discussions refer to the Withdrawal as being an 'industry first'.<sup>582</sup> For example, the following statement featured in a slide headed 'White Tiger Background – Unique and High Risk / Gain Opportunity', included within a presentation attached to an internal RB email dated 26 May 2006, entitled 'White Tiger presentation for exec':<sup>583</sup>

'No model in place as no other brand / company has done or able to do this. All products have monographs from birth'.

6.60. Similarly, in a document entitled 'Project White Tiger Review', which was attached to an internal RB email dated 11 May 2006, the Withdrawal was referred to as:

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<sup>582</sup> RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 430, slide 56338, page 78.

<sup>583</sup> RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 430, slide 56301, page 17. See also slide 56319, page 50, which expresses similar sentiments.

'a unique and high risk strategy to shift business to Gaviscon Advance, our patent protected formula, which no other brand has attempted before'.<sup>584</sup>

- 6.61. An email dated 23 February 2005 from RB's 'Crisis Management PR agency' to RB explains that the Withdrawal was perhaps 'unique' as, crucially, the Withdrawal was not being made in the context of its replacement with a new improved version of it and instead RB was to encourage switching to GA, a product that it had marketed since 1997:

'Our understanding is that removal from the NHS lists of an apparently effective market leading product which is trusted by GP's and patients alike is a very unusual, if not unique, course of action... Given that GA has been on the market since 1997 RB cannot claim that the switch is simply to a new improved version, and indeed if that were the case one assumes that the withdrawal of liquid would have been phased'<sup>585</sup>

- 6.62. In the OFT's view, the Withdrawal differs significantly from 'normal lifecycle management strategy' given that, prior to its withdrawal, GL was the leading alginate brand and, following its withdrawal, GL was not replaced with a new improved medicine that was preferred by patients/GPs. Instead, at the time of the Withdrawal there remained significant demand for GL. Further, on carrying out the Withdrawal, RB encouraged GPs instead to prescribe GA, a product that had been available for seven years

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<sup>584</sup> Internal RB email and spreadsheets dated 11 May 2006 – RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 425, p 3.

<sup>585</sup> RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 74.

and that remained significantly less popular with GPs than the withdrawn and de-listed GL.

- 6.63. RB was aware that it was withdrawing an existing product that the majority of patients/GPs still preferred and that was valued. In an internal RB email entitled 'White Tiger presentation for exec', it was acknowledged that:<sup>586</sup>

'[...] percent GPs have not upgraded to Gav Advance after 8 years of effort

White Tiger effectively removes that choice which will lead to some resentment/anger'

- 6.64. The documents described above demonstrate that neither RB nor its advisors were of the view that the decision to carry out the Withdrawal was in any way 'normal' or typical of the pharmaceutical industry. Rather, the decision to withdraw RB's leading product was described by RB as being 'unique', 'high risk' and as an 'industry first'. Further, given the significant demand for GL that existed at the time of the Withdrawal, and the fact that the Withdrawal was irrational were it not for benefits that were expected to be derived from restricting competition (see Part 6Bii)b) above), the OFT does not consider that the Withdrawal forms part of a 'normal lifecycle management strategy'.

**d) RB's representations to stakeholders**

- 6.65. As outlined at Part 2J.iii), around the time of the Withdrawal RB presented various explanations to stakeholders as to why it had decided to withdraw and de-list GL NHS packs. The explanations were as follows:

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<sup>586</sup> Slide presentation from RB submission of 6 March 2009 in response to Q1 (iii) of the OFT's section 26 notice dated 14 January 2009, document 430, slide 56301, page 17.



- the Withdrawal reflected the completion of its GA portfolio having launched GA tablets (this argument was subsequently presented to the OFT as an explanation of the Withdrawal)
- as the superior second generation product, RB wanted GA to be the sole preserve of GPs and the NHS
- by making each set of products only available in a particular channel, the Withdrawal would help to eliminate the apparently fraudulent dispensing of OTC GL packs against prescriptions<sup>587</sup>
- GA was lower in sodium than GL, and therefore had safety advantages in relation to, for example, patients with hypertension, and
- the Withdrawal would assist prescribers as, under the current system, it was often difficult for a GP to ascertain whether new patients had previously tried GL or GA, and therefore to know whether prescribing either product may be an appropriate first step before moving to more expensive options such as PPIs.

6.66. In its SMFI, RB stated that it has 'not sought to rely on any of these matters per se as showing that the Withdrawal was normal competition'<sup>588</sup> and states that such representations were legitimate presentational points.<sup>589</sup> For completeness, this sub-section nevertheless considers each of the arguments presented to stakeholders as well as the background to their inception.

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<sup>587</sup> RB submission dated 6 March 2009, in response to Q 1 (iii) of OFT section 26 Notice dated 14 January 2009, document 34.

<sup>588</sup> RB SMFI, paragraph 4.3.

<sup>589</sup> See, for example, RB SMFI Annex 2 paragraph 6.

- 6.67. The OFT considers that, individually or when taken together, the explanations fail to rationalise RB's decision to carry out the Withdrawal. In particular, the OFT finds that:
- RB's contemporaneous internal documents suggest that the explanations RB presented to external stakeholders did not inform RB's decision to carry out the Withdrawal
  - RB's contemporaneous internal documents suggest that these factors were not expected to generate significant benefits, such that the decision to carry out the Withdrawal was irrational were it not for benefits derived from hindering the development of full generic competition (see Part 6Bii)b) above)
  - RB's contemporaneous internal documents suggest that the external explanations were adopted as a means of diverting the focus from the actual driver of the Withdrawal, namely the desire to hinder the development of full generic competition, and
  - the individual explanations that RB presented to stakeholders appear to be counterintuitive, flawed or of limited importance, such that they cannot individually or together reasonably be expected to have contributed to the decision to carry out the Withdrawal.
- 6.68. Part 6Bii) above describes the rationale of the Withdrawal that is presented in RB's contemporaneous internal documents. Those documents suggest that the Withdrawal and its timing was motivated by a desire to pre-empt and hinder the development of generic competition, as a means of protecting the Gaviscon portfolio. Those documents, including those which form the basis of senior management and director approval of the Withdrawal, do not mention the explanations described at paragraph 6.65 above.
- 6.69. Further, in the documents described at paragraphs 2.184 to 2.194 and 6.30 to 6.42 above, in which the financial implications of the

Withdrawal are assessed, no mention is made of the factors that RB presented publicly. To the extent that there would be benefits to RB in relation to these factors, the OFT would have expected such documents to devote significant attention to determining their value and in particular whether they were significant enough to offset the significant share, revenue and profitability decreases that RB forecasted would result from the Withdrawal. It can only be concluded that the factors presented externally were either (i) not expected to generate benefits of a significant magnitude such that RB did not consider that it was necessary to take account of them in its forecasts, or (ii) incorporated and valued in RB's forecasts but, despite their inclusion, RB nevertheless forecasted that the Withdrawal would result in sustained share, revenue and profit decreases. On that basis, it is apparent that these factors do not impact upon the finding at Part 6Bii) above that RB's decision to carry out the Withdrawal was irrational were it not for the anticipated benefits associated with hindering the development of full generic competition.

- 6.70. The documents presented at Part 2J.iii) above indicate that although the decision to carry out the Withdrawal was driven by a desire to pre-empt the publication of a generic name and to hinder the development of full generic competition, RB and its PR advisors were of the view that it was not sustainable to present the generic name driver of the Withdrawal publicly. The documents presented above suggest that the explanations that RB presented externally were in fact used as means of diverting the focus from the generic name motivation and to limiting the anticipated adverse response to the Withdrawal.
- 6.71. RB's concern that the generic name motivation should not be publicly known is revealed in various documents. For example, it is apparent from paragraph 2.183 that RB considered it necessary to withdraw and de-list GL NHS packs well in advance of the publication of the generic name corresponding to GL in order to limit the prospect of alerting DH to the actual rationale of the Withdrawal. Further, the importance to RB of the generic name

rationale not being publicly known is also illustrated in its assessments of the success of the Withdrawal. In an internal slide presentation which appears to date from early 2006 (in a slide entitled 'White Tiger Implementation Update') one of RB's measures of success was as follows:

'No mention of generic name as motivator for withdrawal'<sup>590</sup>

- 6.72. RB's internal documents therefore imply that the explanations that RB presented publicly were not significant in RB's decision to carry out the Withdrawal. RB's Directors/senior management did not approve the Withdrawal on the basis of them, RB did not seek to value the benefits associated with them, and RB's internal documents indicate that they were constructed as a means of justifying the Withdrawal publicly in the knowledge that the actual rationale would not be acceptable to stakeholders. This assessment is supported by an assessment of the merits of the individual explanations which, as set out below, cannot individually or collectively be considered as reasonable explanations of a decision to carry out the Withdrawal.

**RB's completion of a full range of GA products as part of the rationale for the Withdrawal**

- 6.73. In a letter dated 6 March 2009 in response to a section 26 Notice from OFT dated 14 January 2009, RB stated that:<sup>591</sup>

'At the same time as the withdrawal of the 500ml presentation of Gaviscon Liquid, RB introduced a 250ml presentation of Gaviscon Advance. In 2004, Gaviscon

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<sup>590</sup> Internal RB slide presentation – (2005 – exact date uncertain) - RB submission dated 6 March 2009 in response to Q1(i) of OFT section 26 Notice dated 14 January 2009, document 267, page 2.

<sup>591</sup> Cover letter to RB submission dated 6 March 2009 in response OFT section 26 Notice dated 14 January 2009.

Advance tablets had been introduced for NHS prescription. The availability of a superior product in a full range of preparations and sizes for NHS prescribers, as well as the ongoing intention to achieve conversion of Gaviscon Liquid prescriptions into Gaviscon Advance prescriptions as part of a normal lifecycle management strategy formed part of the rationale for the withdrawal of Gaviscon Liquid by RB.'

- 6.74. In its letter of 11 April 2005 to DH formally announcing the date of the Withdrawal, RB explained its rationale as follows:<sup>592</sup>

'As we now have a complete range of presentations and flavours available within the Gaviscon Advance® range, we have decided to rationalise the Gaviscon® brand completely to make a clear separation between the OTC and NHS businesses.

We plan to remove Gaviscon® Liquid 500ml from distribution from NHS sale from 4th June 2005, leaving doctors the simple choice of prescribing either Gaviscon Advance® liquid or tablets to meet the clinical needs of prescription patients on Alginate therapy.'

- 6.75. In its SMFI, RB has clarified that its point 'was never that the availability of a full range of GA products dictated the timing of the Withdrawal'. Rather, in its SMFI, RB stated 'the availability of a full suite of GA products was of benefit to prescribers and patients and allowed GA to be presented as the exclusive Gaviscon product for the NHS prescription channel'.<sup>593</sup>

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<sup>592</sup> Letter dated 11 April 2005 from Britannia (on behalf of RB) to DH – RB submission dated 12 December 2008 in response to OFT section 26 Notice of 28 November 2008, OFT file part 2, document 9.56.

<sup>593</sup> RB SMFI, Annex 2, paragraph 2.

- 6.76. The OFT's view is that the completion of a full range of GA products, by launching a tablet form of GA, is not a credible justification for the Withdrawal.
- 6.77. First, such a strategy would mean that having brought to market a product variant to its less popular brand, GA, RB chose to withdraw from the market its more popular brand, GL.<sup>594</sup>
- 6.78. Second, at the time of the Withdrawal, tablet sales were much lower than liquid sales such that changes to tablet formulations appear incapable of explaining the withdrawal of RB's leading liquid brand. As set out at Table 2.1 above, before the Withdrawal, GA tablet sales accounted for only 0.3 per cent of Gaviscon NHS sales (by value) while Gaviscon Original tablet sales accounted for only 8.3 per cent.
- 6.79. Furthermore, as set out in Part 6Bii)b) above, even having completed the range of GA products, RB was well aware that the popularity of GL was such that the Withdrawal would see RB sustain market share losses and a decrease in its turnover and profitability.

**RB wanted GA to be the sole preserve of the NHS**

- 6.80. RB also advanced a separate, though related, argument that the Withdrawal was executed to provide GPs with exclusive access to GA. The argument was made by RB's PR agency in a section of its discussion document (see paragraphs 2.196 to 2.197 above)

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<sup>594</sup> In advance of the withdrawal, in Q1 2005, GA accounted for only 35.2 per cent of Gaviscon sales (by value) in the prescription channel, whereas GL account for 49 per cent of sales (by value) (see Table 2.1 above).

entitled 'Positioning/Initial Key Messages'. It noted:<sup>595</sup>

'This change [the Withdrawal] means that the most advanced, effective product in the Gaviscon range will be available exclusively to the NHS – where it belongs; while the old established product continues to be available OTC.'

6.81. In an internal RB email exchange dated 15 February 2005 on the same subject, it was noted that this 'story' would be presented to a number of key stakeholders:<sup>596</sup>

'Communication plan/PR

As outlined in the launch paper, the basis of our story is that we are undertaking a strategic realignment to ensure that the NHS has the exclusive benefit of the most up-to-date alginate formulation, at no additional cost per dose. We will be promoting this message to all key target audiences as outlined in the attached communications grid.'

6.82. The OFT's view is that this argument cannot be regarded as a credible justification for the Withdrawal. First, the OFT notes that to make GA the sole preserve of the NHS, it is necessary to withdraw GA from the OTC channel, but not necessary to withdraw and de-list NHS packs of GL.

6.83. Second, it seems highly unlikely that GPs would have generally welcomed the fact that GA would be available exclusively for them

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<sup>595</sup> Discussion document dated 22 February 2005 – RB submission dated 6 March 2009 in response to Q1 (iii) of OFT section 26 Notice dated 14 January 2009, document 74. See also slide presentation in Q1 (iii), document 263, page 17 and Q&A in Q1 (iii), document 272, page 5.

<sup>596</sup> RB submission dated 6 March 2009 in response to Q2 of OFT section 26 Notice dated 14 January 2009, document 3.

to prescribe, and that GL would be exclusively available OTC, when more of them had indicated a preference to prescribe GL. Indeed, as outlined at paragraph 2.185 above, RB had itself foreseen that GPs may react angrily to the Withdrawal.

- 6.84. Similarly, notwithstanding RB's view that GA may be a superior product to GL, RB was aware that there was [...] and also a significant loyalty to GL among GPs.<sup>597</sup> One would expect that it is the requirements of a company's customers that would ordinarily drive a company's decision on which product to withdraw or retain, and RB was aware that the majority of patients/GPs did not wish to have exclusive access to GA at the expense of access to GL.
- 6.85. It is apparent from RB's contemporaneous internal documents that providing GPs with exclusive access to GA was not regarded by RB as a material factor in the decision to carry out the Withdrawal, and was presented to stakeholders such as DH simply as a way of helping to divert attention away from the actual rationale of hindering the development of full generic competition. For example, in an internal RB email exchange on 16 February 2005 in response to the question 'why do we need to withdraw Gaviscon Advance 150, 300, 600?' is the following reply:<sup>598</sup>

'Because to make the story to the DOH credible (ie strategic alignment of brands), we need to phase out Gaviscon Advance OTC within 12 months. NB that there will be no 2005 P&L impact as we will advise the DOH we have legally binding commercial supply contracts which will prevent us withdrawing before 2006.'

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<sup>597</sup> See paragraph 2.162 and footnote 206 above.

<sup>598</sup> Internal RB email exchanges dated 15 and 16 February 2005 – RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 70.



6.86. This justification is further undermined by the fact that, although stakeholders were to be told that GA would be the exclusive preserve of GPs, RB's plan was that it would in fact be subsequently retained within the OTC sector albeit under the new brand name 'Gaviscon Extra Strength'. For example, an internal RB email dated 4 April 2005 notes:<sup>599</sup>

'One key point we do need to firm up is what we say about OTC. As we discussed in the mtg, it is of major importance that we are able to tell GPs that the Gaviscon Advance brand will be theirs and theirs alone in the relatively near future, whilst avoiding issues among our Pharmacy customers. As I understand it the current plan is that we will re-badge OTC Advance to Extra Strength within 12 months – I have therefore reflected this timeline (although not the full plan) in the statement'

6.87. Despite RB's statements to DH and others to the contrary, RB did not ultimately withdraw the GA formulation from the OTC channel to make it the 'sole preserve' of GPs in the prescription channel. RB has stated that its plan to do so was changed 'when RB realised that this would be unnecessary for implementing the switch in the NHS prescription channel, and unprofitable'.<sup>600</sup>

#### **Fraudulent dispensing of OTC packs**

6.88. RB's internal 'key messages' literature referred to an argument that, because GA and GL were sold in both the OTC and

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<sup>599</sup> Internal RB email dated 4 April 2005 from [...] to RB staff – RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 notice of 14 January 2009, document 148. See also internal RB email dated 8 April 2005, RB submission dated 6 March 2009 in response to Q1 (iii) of OFT section 26 Notice dated 14 January 2009, document 175; and RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 70.

<sup>600</sup> RB SMFI, Annex 2, paragraph 4.

prescription channels, this was giving rise to the fraudulent dispensing of OTC packs against NHS prescriptions whereby pharmacists would erroneously claim that they had dispensed a more expensive OTC pack against an NHS prescription. This point was presented in RB's PR agency's 'Positioning/Initial Key Messages' (see paragraphs 2.196 to 2.197 above) as follows:<sup>601</sup>

'The clear positioning of Gaviscon Advance in the NHS only, and Gaviscon Liquid in OTC also ensures that there can be no opportunity for fraud in prescription fulfilment. There have been cases in the past where, with medicines available both as pharmaceutical supplies and OTC, pharmacists could charge the NHS for 'additional' product by supplying prescriptions from OTC supplies.'

- 6.89. The OFT considers that the actions of RB in relation to GA are such that this argument cannot explain RB's decision to carry out the Withdrawal. As a product that was available in both channels, RB's concerns around fraudulent dispensing applied also to GA. As outlined above, RB has however retained the GA formulation in both channels. It is therefore difficult to understand why, in the case of GL NHS packs, it was necessary to withdraw and de-list the product as a means of preventing fraudulent dispensing.
- 6.90. Further, in the internal documents provided by RB in which the Withdrawal is considered, the concern is mentioned only as a possible external justification. The documents make no reference to RB having sought to measure the detriment caused by this problem, or having considered whether it would merit the withdrawal of its leading NHS Gaviscon product in the prescription channel.

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<sup>601</sup> Discussion document dated 22 February 2005 – RB submission dated 6 March 2009 in response to Q1 (iii) of OFT section 26 Notice dated 14 January 2009, document 74.

6.91. Finally, prescribing data indicates that the prescription of OTC GL continued or even increased following the Withdrawal (see paragraphs 2.36 and 2.37 above).

**GA is lower in sodium and therefore has safety advantages**

6.92. To seek to persuade stakeholders that the Withdrawal was favourable, RB sought to stress the benefits of GA versus GL. Accordingly, a key part of the messages to stakeholders was that GA had considerably less sodium than GL. For example, in the March 2005 Q&A for GPs and Pharmacists, the following is noted:

'What are the benefits of Gaviscon Advance over Gaviscon?

... Gaviscon Advance contains 63% less sodium than Gaviscon Original.'<sup>602</sup>

6.93. It is apparent that any such safety advantage in terms of GA would not justify the Withdrawal from the NHS prescription channel. In this regard, the OFT notes the following:

- For at least the previous seven years, the majority of GPs had considered that, notwithstanding the fact that GA may have sodium related safety advantages when compared to GL, GL was their preferred product.
- It is apparent that GL was and is perfectly safe for the vast majority of patients, as otherwise it would have been withdrawn from the market altogether.
- GPs themselves were perfectly competent to identify the small group of patients for whom a high-sodium product would not be suitable and prescribe accordingly.

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<sup>602</sup> RB internal document entitled 'White Tiger Q&A' dated 17 March 2005 – RB submission dated 6 March 2009 in response Q1 (iii) of OFT section 26 Notice dated 14 January 2009, document 109.

- 6.94. Moreover, internal RB documents suggest that for a small minority of patients GA would be unsuitable because of its potassium content, in the same way as GL's sodium content might make it unsuitable for others.<sup>603</sup>
- 6.95. Further, the potential of such arguments to justify the Withdrawal is further undermined by the fact that RB was considering [...].<sup>604</sup> RB was proposing to use [...] as a way of competing with Peptac for those scripts not written for GA, and was apparently rather less concerned with the safety issues that were presented as being significant to its decision to carry out the Withdrawal.
- 6.96. Furthermore, the OFT would have assumed that, had RB retained significant concerns over the sodium levels of GL relative to GA, it would have also withdrawn it from the OTC channel. Indeed, one would assume that it is more appropriate to deny GL to the less informed OTC consumer, who may be unaware of a safety concern, than to deny the same choice to a GP who is qualified to appraise a medicine's relative performance and safety.

**GPs could be certain that patients would not have taken GA before**

- 6.97. In the 'Overall White Tiger Message' document discussed at paragraph 2.215 above, the following reason is given as an element of the rationale for withdrawing and de-listing GL NHS

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<sup>603</sup> Internal RB email dated 26 August 2003 – RB submission dated 6 March 2009 in response to Q1(vi) of OFT section 26 Notice dated 14 January 2009, document 38, which states: 'One word of caution on the proposed sodium/potassium bicarbonate mix is that it is not just patients on dialysis who would be affected, but potentially patients taking antihypersensitive drugs such as ACE inhibitors. Some databases and prescribing advisers already suggest that patients on ACEs should not take Gav Advance because of its potassium content.'

<sup>604</sup> See the presentation entitled '[...]' in the RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 379. See also document 411 of the same response, and the reference [...].

packs from the prescription channel and GA from the OTC channel:<sup>605</sup>

'Gaviscon's unique positioning as a successful brand both OTC and NHS has created some significant challenges for the NHS.

Firstly, when making an Rx decision for a GORD patient, it is often difficult for a GP to ascertain whether the patient has previously tried Gaviscon [GL] or Gaviscon Advance, and therefore to know whether this may be an appropriate first step before moving to more expensive options such as PPIs.'

- 6.98. First, the OFT notes that in order to prevent this issue from arising, it is necessary to have only one of GA or GL in the OTC channel, but not to withdraw and delist GL NHS packs from the prescription channel. However, RB has withdrawn and de-listed GL NHS packs from the prescription channel and retained both GA and GL in the OTC channel.
- 6.99. Second, there is no indication elsewhere in RB's documents that this was an issue for GPs and the NHS before the Withdrawal.
- 6.100. Third, it is apparent that RB's overall strategy would have exacerbated this problem rather than help to solve it. As outlined above, at the time of the Withdrawal RB was apparently planning to 're-badge' GA as Gaviscon Extra Strength in the OTC channel. This would have meant that when a patient visited a GP, patients would have been even less clear as to whether they had tried GA, having been sold it under a different brand name.

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<sup>605</sup> Internal RB email exchanges dated 15 and 16 February 2005 – RB submission dated 6 March 2009 in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 69.

- 6.101. Considered in the round, the OFT has concluded that the explanations that RB presented to stakeholders are not capable of rationalising RB's decision to carry out the Withdrawal. First, it is apparent from RB's internal documents that they were not the driver of RB's decision to carry out the Withdrawal. Second, each of the arguments appears to be either flawed or to be of such minor importance that they cannot individually or collectively explain RB's decision to carry out the Withdrawal.
- 6.102. Further, as noted in Part 6Bii)c) above, RB's own forecasts suggest that the Withdrawal would result in a decrease in share, revenue and profits, such that any benefits it associated with these explanations were apparently insufficient to make the Withdrawal profitable of itself. This further suggests that the decision to carry out the Withdrawal only made commercial sense as a means of hindering the development of full generic competition to Gaviscon products in the prescription channel, and the purpose of the Withdrawal was to hinder the development of full generic competition.

**iv) The role of the Department of Health in the withdrawal and de-listing of GL NHS packs**

- 6.103. As outlined in paragraph 2.127 above, a manufacturer may wish to withdraw a product from the market for a number of reasons such as changes in medical practice, commercial decisions or problems in obtaining active ingredients. Under Best Practice Guidelines agreed between DH and the ABPI, companies should provide DH with advance notification of such a discontinuation for the purpose of enabling the NHS to begin contingency planning to ensure security of supply and to minimise the impact of the withdrawal on patients. DH has no powers to prevent any discontinuations that are notified to it. However, DH may seek to persuade the company to take mitigating action if the planned

withdrawal is likely to have a negative impact on the NHS or patients, for example due to reduced supply or increased cost.<sup>606</sup>

6.104. As noted above at paragraph 2.219, on 11 April 2005 Britannia Pharmaceuticals (on behalf of RB) wrote to DH to inform it of the intention to discontinue GL NHS packs:

'As we now have a complete range of presentations and flavours available within the Gaviscon Advance® range, we have decided to rationalise the Gaviscon® brand completely to make a clear separation between the OTC and NHS businesses. [...] This rationalisation will be less confusing for both doctors and patients and will clearly differentiate the OTC and Rx brand.

'All existing patients on Gaviscon® tablets or liquid will be able to be switched to Gaviscon Advance® products easily and we will be carrying out and [sic] educational and informational programme to assist all concerned.

'Costs to the NHS will be neutral as Gaviscon Advance® is priced pro rata to Gaviscon Liquid, dose for dose. At the same time we will also launch a 250ml bottle of Gaviscon Advance® (in both flavour variants) which we intend to price at £2.70, equivalent to one month's supply of current Gaviscon Liquid® 500ml. We would kindly like you to approve our launch price proposal. [...]

'As we will be operating to a planned schedule, I would be grateful if we could receive your approval by the end of April.'<sup>607</sup>

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<sup>606</sup> Letter dated 3 July 2009 from DH to OFT (OFT file part 3, document 47.01).

<sup>607</sup> Letter dated 11 April 2005 from Britannia Pharmaceuticals to DH (RB submission of 12 December 2008 in response to OFT section 26 notice dated 28 November 2008, OFT file part 2, document 9.56).

6.105. In response to RB's notification about the Withdrawal, DH responded as follows:

'I can confirm that our records have been updated with respect to the discontinuation of Gaviscon Liquid 500ml and your proposed price of Gaviscon Advance 250ml (£2.70) which is acceptable to the Department.'<sup>608</sup>

6.106. This exchange of correspondence confirms that it was only necessary for RB (via Britannia Pharmaceuticals) to seek approval from DH for the price of the new 250ml bottle of GA. The Withdrawal was simply a matter about which DH was notified.

6.107. This exchange in correspondence is also consistent with the advice provided to RB by a 'PPRS consultant', who advised RB that the Withdrawal notification would receive limited scrutiny from DH in that it 'should go through without touching the sides'.<sup>609</sup>

6.108. DH has since confirmed to the OFT that its examination of the Withdrawal would indeed have been 'minimal', and that its role

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<sup>608</sup> Letter dated 25 April 2005 from DH to Britannia Pharmaceuticals Limited - RB submission of 12 December 2008 in response to OFT section 26 notice dated 28 November 2008, document 57.

<sup>609</sup> RB slide presentation entitled 'White Tiger Update, Slough March 2005' (RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 95). The OFT notes that that consultant is described elsewhere by RB as 'the leading industry consultant on DOH/PPRS management' (RB submission dated 6 March 2009 in response to Q1(iii) of OFT section 26 Notice dated 14 January 2009, document 348). It is therefore reasonable to assume that such a statement carries some authority. See also the New Product Development Brief for Project Atlas of March 2004 (RB submission dated 6 March 2009 in response to Q1(vi) of OFT section 26 Notice dated 14 January 2009, document 91) which indicates, that RB did not expect DH to present a significant impediment to the Withdrawal of GL NHS packs and their replacement with another product: 'The only proactive communication of the switch would be to the DoH/PPRS where we would complete one of their official product withdrawal/replacement forms indicating our reason for the switch being due to the development of an improved product with new prescriber and patient benefits.'



'was essentially to ensure that the pricing of the products (GA and GL) was such that the dosage price would not increase for the NHS'.<sup>610</sup> In a letter to the OFT dated 3 July 2009,<sup>611</sup> Luisa Stewart (Assistant Director – Pricing, Supply and Prescriptions, DH) states that 'there are no circumstances in which [DH has] powers to refuse a company's product withdrawal or replacement.'

6.109. Notwithstanding DH's views as to its powers to reject a product withdrawal and the issues that it will consider on receipt of a product withdrawal notification, in its SMFI<sup>612</sup> RB states that at the time of the Withdrawal it identified a risk that DH had the power to 'blacklist' GA under the MSLS, which would have prevented prescriptions being written for GA.

6.110. Notwithstanding that this risk was noted by RB in its internal documents, the OFT does not consider that DH had the capacity to blacklist GA in response to the Withdrawal, or that DH ever gave serious consideration to doing so. In particular, the OFT notes that while it is correct that DH has the power to add products to the MSLS in some circumstances, it is rare for DH to do this and the circumstances in which it is able to do so are very specific and are not applicable to the Withdrawal.<sup>613</sup> Further, in addition to the statements by DH cited above that no such power exists in

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<sup>610</sup> Note of meeting between OFT and DH on 9 June 2009 (OFT file part 3, document 33A).

<sup>611</sup> OFT File Part 3, document 47.01.

<sup>612</sup> RB SMFI, Annex 3 paragraphs 1 to 3.

<sup>613</sup> In its SMFI, RB states that Gaviscon Granules and Gaviscon 250 tablets have been blacklisted in the past (see RB SMFI, Annex 3 paragraph 3). However, the inference to be drawn from the source cited by RB (The National Health Service (General Medical Services) Amendment (No 2) Regulations 1993 (SI 1993 No.2421)) is that this occurred at least as long ago as 1993. In addition, RB does not provide any further information or evidence relating to the reasons why these products were blacklisted and in what way those events are analogous to the Withdrawal.

relation to product discontinuations, the criterion used by DH for adding products to the MSLS demonstrates that it could not blacklist any product for non-clinical reasons such as disapproval about a product withdrawal. As set out in Part 2H.iii)c) above, that criterion is:

'... on expert advice, they had no clinical or therapeutic advantage over other, cheaper, drugs in the following categories ... indigestion remedies.'<sup>614</sup>

6.111. Given DH's lack of powers to prevent product withdrawals and the clinical nature of the criteria for blacklisting products, the OFT concludes that the Withdrawal was the result of RB's actions, and not in any way driven by the actions of DH.

**v) Conclusions**

6.112. As set out in Part 3 above, to determine whether a dominant company's conduct can be regarded as 'normal competition' or 'competition on the merits', the OFT may consider whether its objective was to impair competition and/or whether the conduct was irrational and made no commercial sense in the absence of the potential to realise gains associated with restricting competition. This Section therefore assessed RB's rationale for the Withdrawal.

6.113. RB's contemporaneous internal documents demonstrate that the driver of its decision to carry out the Withdrawal was a desire to hinder the development of full generic competition by ensuring that GPs were unable to use the 'G' button on their software systems to identify a generic name corresponding to a Gaviscon product available in prescription packs and to then issue open prescriptions in respect of such products. This rationale is referred to in numerous internal documents that relate to project White Tiger, and forms the basis of the relevant communications to the relevant

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<sup>614</sup> Drug Tariff, Part XVIIIIC – Criteria notified under the Transparency Directive.

senior managers and Directors within RB. Further, this rationale forms the basis of RB's subsequent assessments of the success of project White Tiger.

- 6.114. RB's contemporaneous internal documents also demonstrate that were it not for the gains that RB expected to derive from hindering the development of full generic competition, it would have been commercially irrational to carry out the Withdrawal. RB's documents reveal that it expected the Withdrawal to result in market share, revenue and profitability decreases, and that the Withdrawal was only profitable to RB insofar as it enabled RB to hinder the development of the full generic competition that it otherwise expected to ensue on publication of the generic name corresponding to GL.
- 6.115. The OFT finds that the explanations that RB has presented to it and to stakeholders do not suggest that the Withdrawal was rational in the absence of an anti-competitive intent.
- 6.116. First, while it had always been RB's intention to convert sales of GL to GA, RB's internal documents demonstrate that (i) RB had previously considered that withdrawing NHS packs of GL was commercially unattractive; and (ii) were it not for the competitive threat associated with the anticipated publication of the generic name, RB had no plans to withdraw NHS packs of GL in the foreseeable future. This reinforces the assessment that at the time the Withdrawal took place, it was expected to be loss making and irrational in the absence of the anticipated benefits associated with hindering the development of full competition.
- 6.117. Further, the OFT does not consider that the Withdrawal was part of a 'normal lifecycle management strategy'. RB's internal documents reveal that it considered the Withdrawal to be a 'first' and 'unique' and also reveal an anti-competitive rationale that cannot be considered consistent with the concept of 'normal product lifecycle management strategy'.

6.118. The factors that RB referred to in its representations to stakeholders also fail to explain RB's decision to carry out the Withdrawal. In particular, the OFT finds that (i) these factors were not referred to in the contemporaneous internal documents that informed RB's decision to carry out the Withdrawal; (ii) RB's own assessments of the financial implications of the Withdrawal imply that any benefits associated with these factors were not sufficient to suggest that the Withdrawal was commercially rational in the absence of an anticompetitive intention; and (iii) the explanations were themselves counterintuitive or of such minor importance that they cannot individually or collectively be regarded as plausibly forming the basis of RB's decision to carry out the Withdrawal.

6.119. The OFT therefore finds that RB's decision to carry out the Withdrawal was motivated by a desire to hinder the development of full generic competition to its Gaviscon portfolio in the relevant market. It is apparent that were it not for the potential to do so, and to secure the resulting gains, the Withdrawal would not have been commercially rational. The OFT therefore finds that the Withdrawal cannot be regarded as 'normal competition' or as 'competition on the merits'.

## **C. Effect on Competition**

### **i) Introduction**

6.120. In this Section the OFT sets out its analysis of the effects of the Withdrawal on competition.

6.121. As set out in detail below, the OFT finds that the Withdrawal tended to restrict competition or was capable of having that effect. This finding is evidenced by:

- RB's own forecasts at the time of the Withdrawal, which anticipated that the Withdrawal would assist RB in protecting its portfolio from full generic competition and enable it to

preserve a high market share and to continue to sell its products at the prevailing price levels

- Pinewood's expectations, which suggested that had GL NHS packs been retained, following the publication of a generic name Pinewood would have faced lower barriers to expansion and price competition in the relevant market would have been more effective, and
- The OFT's assessment that, at the time of the Withdrawal, it was reasonable to expect that the Withdrawal would hinder the development of full generic competition.

6.122. Further, the OFT considers that the developments in the relevant market observed since the Withdrawal are not inconsistent with a finding that the Withdrawal tended to restrict competition or was capable of having that effect.

6.123. Prior to receiving the SO, RB stated that 'nothing in its behaviour has prevented or delayed Pinewood, the manufacturers of Peptac, from promoting and growing its share'.<sup>615</sup> RB has since admitted that its conduct tended to restrict the competitive process, but has not made any admission that its conduct has had material adverse effects on competition or consumers.<sup>616</sup>

**ii) RB's forecasts**

6.124. As part of its assessment of whether or not to carry out the Withdrawal, RB forecasted the cash flows that it would expect to realise if GL NHS packs were retained. Under this scenario, RB expected that the Gaviscon portfolio would be exposed to full generic competition whereby pharmacists would be able to choose

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<sup>615</sup> Cover letter to RB submission of 6 March 2009, in response to the OFT's section 26 notice dated 14 January 2009.

<sup>616</sup> RB SMFI, paragraph 4.5.

whether to dispense GL or equivalent generic medicines such as Peptac and that this 'will open up [the] Gaviscon NHS Liquid business to true generic competition' (see also Part 6B.ii) above).<sup>617</sup>

6.125. RB anticipated that a [...] proportion of the scripts that had previously been written for GL would instead be written as open scripts that referred to the new generic name corresponding to GL. On receipt of these open scripts pharmacists would be free to dispense any available product that corresponded to the generic name and the underlying monograph. RB forecasted that the proportion of scripts that would be open would be as follows:<sup>618</sup>

|                                            | 2005 | 2006  | 2007  | 2008  | 2009  |
|--------------------------------------------|------|-------|-------|-------|-------|
| Share of prescriptions written generically | 0    | [...] | [...] | [...] | [...] |

6.126. Given that pharmacists presented with open scripts would be free to choose between therapeutically equivalent products, and that pharmacists are financially incentivised (though higher margins) to dispense cheaper generic products where available (see paragraph 2.115 above), RB forecasted that to retain some business in respect of these open scripts it would need to offer [...] that would

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<sup>617</sup> RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 425.

<sup>618</sup> RB submission of 6 March 2009, in response to Q3 of the OFT's section 26 notice dated 14 January 2009, document 36.

include the following discounts in respect of the open scripts for which it faced competition:<sup>619</sup>

|                                           | 2005 | 2006  | 2007  | 2008  | 2009  |
|-------------------------------------------|------|-------|-------|-------|-------|
| RB's discount in relation to open scripts | 0    | [...] | [...] | [...] | [...] |

6.127. RB was planning to use [...], and was expecting otherwise to lose [...] share to competitors supplying a generic equivalent to GL to other pharmacies. As a proportion of the open scripts issued by GPs, RB expected its competitors to achieve the following level of sales:<sup>620</sup>

|                                                | 2005 | 2006  | 2007  | 2008  | 2009  |
|------------------------------------------------|------|-------|-------|-------|-------|
| Proportion of open scripts lost to competitors | n/a  | [...] | [...] | [...] | [...] |

6.128. For each product dispensed against a generic prescription, pharmacies would be reimbursed at the Drug Tariff price rather than the PPRS price. While prior to the Withdrawal the Drug Tariff price for Peptac (£2.17 per 500ml) was already materially lower than the PPRS price for GL (£2.70 per 500ml), RB envisaged that the widespread provision of open scripts, and the resulting pharmacy choice, would in any case result in [...] decreases in the applicable Drug Tariff price and in RB's price for Gaviscon. For example, as of 2003 RB was predicting that publication of a

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<sup>619</sup> Ibid.

<sup>620</sup> Ibid.

generic name would result in a [...] per cent decrease to the Drug Tariff list price paid by the NHS (before clawback) and a [...] per cent decrease to the price paid by pharmacies. In a subsequent document, while RB was less convinced of a decrease to the Drug Tariff list price, it was envisaging decreases in the 'street price' of between [...] and [...] per cent.<sup>621</sup> RB also refers to the potential for full generic competition to GL to 'drop the price of Gaviscon to an expected [...] % of [the] current price'.<sup>622</sup>

6.129. RB anticipated that these share losses and price decreases would result in a [...] decrease in its Gaviscon net revenues in the NHS channel, such that its 2009 net revenues would be [...] of those generated in 2005.<sup>623</sup>

|                          | 2005   | 2006   | 2007   | 2008   | 2009   |
|--------------------------|--------|--------|--------|--------|--------|
| RB forecast net revenues | £[...] | £[...] | £[...] | £[...] | £[...] |

6.130. It can be inferred from RB's forecasts that it was anticipating that generic competitors such as Pinewood would achieve [...] market shares if GL NHS packs were retained. RB forecasted that by 2009 it would lose £[...] million of the £[...] million sales that would

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<sup>621</sup> RB submission of 6 March 2009, in response to Q3 of the OFT's section 26 notice dated 14 January 2009, documents 20, 27, 28 and 32.

<sup>622</sup> RB submission of 6 March 2009, in response to Q3 of the OFT's section 26 notice dated 14 January 2009, document 35. RB forecasted the impact of full generic competition on Gaviscon prices in a number of other internal documents. For example, in document 1 of the response to Q1(iii) of the same notice'.

<sup>623</sup> RB submission of 6 March 2009, in response to Q3 of the OFT's section 26 notice dated 14 January 2009, document 36.



have otherwise have been generated in respect of GL.<sup>624</sup> The RB turnover losses forecasted by RB imply that, by 2009, RB envisaged that the volume market share of companies supplying generic equivalents to GL (including Pinewood) would have been around [...] per cent.<sup>625</sup> The 'generic' share of the relevant market was therefore expected to increased by a factor of [...] had GL NHS packs been retained.

6.131. RB's forecasts therefore suggest that, had GL NHS packs been retained, RB anticipated that full generic competition would have resulted in the NHS paying [...] less for alginates. RB's projections indicate that it expected that the competitive position of generic competitors would have been [...] enhanced, with the generic market share increasing [...] between 2005 and 2009.

6.132. As outlined at Part 6B.ii) above, RB anticipated that by carrying out the Withdrawal it would be able to ensure that a significant proportion of GPs would prescribe GA instead of GL. Pharmacies that received prescriptions for the GA formulation (which is patent protected and does not face generic competition) would have no choice but to dispense GA. RB considered that even after the

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<sup>624</sup> RB submission of 6 March 2009, in response to Q3 of the OFT's section 26 notice dated 14 January 2009, document 36.

<sup>625</sup> This market share figure has been estimated as follows:

- RB was expecting to lose [...] per cent of its GL sales (£[...] million/£[...] million).
- Prior to the Withdrawal, the GL share of the relevant market was 51.8 per cent. By 2009, RB anticipated that it would have lost [...] per cent of this share ([...] per cent), leaving a remaining GL share of [...] per cent.
- The lost share for GL would have been won by Pinewood and any other suppliers of generic equivalents to GL. Their combined market share would have been around [...] per cent, that is, their pre-existing share (5.9 per cent) plus the share won from GL ([...] per cent).

publication of a generic name corresponding to GL, the Withdrawal would therefore ensure that RB 'would still not suffer from generic substitution of Peptac for Gaviscon'.<sup>626</sup>

6.133. RB's forecasts are based on the assumption that pharmacies would continue to receive closed scripts, whereby pharmacies that received prescriptions relevant to Gaviscon prescription packs would have no choice of which product to dispense and RB would not need to offer [...] discounts to pharmacies in order to generate sales.<sup>627</sup>

6.134. RB anticipated that, after the Withdrawal, a [...] proportion of those patients who had been prescribed GL would instead be prescribed GA.<sup>628</sup> Accordingly, RB considered that its share of the market would suffer [...] decreases, and its overall Gaviscon prescription channel net revenues would remain relatively stable despite the withdrawal and de-listing of GL NHS packs:<sup>629</sup>

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<sup>626</sup> New Launch Recommendation Paper dated January 2005 - RB submission of 6 March 2009, in response to Q1(iii) of the OFT's section 26 notice dated 14 January 2009, document 55.

<sup>627</sup> RB submission of 6 March 2009, in response to Q3 of the OFT's section 26 notice dated 14 January 2009, document 36. In contrast to project ERIC forecast described above, the forecasts relevant to the Withdrawal do not refer to the [...]

<sup>628</sup> RB expected that around [...] per cent of GL prescriptions would be switched to GA following the withdrawal (specifically, RB anticipated that it would lose [...] per cent of repeat prescriptions, which accounted for [...] per cent of all GL prescriptions). See RB submission of 6 March 2009, in response to Q3 of the OFT's section 26 notice dated 14 January 2009, document 39.

<sup>629</sup> RB submission of 6 March 2009, in response to Q3 of the OFT's section 26 notice dated 14 January 2009, document 36.

|                               | 2005  | 2006  | 2007  | 2008  | 2009  |
|-------------------------------|-------|-------|-------|-------|-------|
| RB forecast net revenues (£m) | [...] | [...] | [...] | [...] | [...] |

6.135. RB's net revenue forecasts reflect an expectation that, as a result of the Withdrawal, GPs would not write prescriptions that would provide pharmacies with a choice of products to dispense, and that the majority of GPs would write prescriptions for GA. Without this choice RB anticipated that it would not need to [...] and consequently would not need to [...] to pharmacies. The average Gaviscon reimbursement price (or average NIC) would therefore remain at around the level observed prior to the Withdrawal and prior to the publication of the generic name corresponding to GL.

6.136. RB considered that by ensuring that pharmacists could not receive open scripts in relation to its products, its share of the relevant market would remain much higher than had it retained GL NHS packs. RB forecasted that its market share by volume would decline by around [...] per cent following the Withdrawal.<sup>630</sup>

6.137. In summary, RB forecast that by carrying out the Withdrawal it could hinder the development of full generic competition. RB expected this to enable it to preserve a significant market share, and to enable to it to sustain the price levels observed prior to the Withdrawal.

6.138. The OFT has established above that, if GL NHS packs had remained available after the publication of a corresponding generic

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<sup>630</sup> RB submission of 6 March 2009, in response to Q3 of the OFT's section 26 notice dated 14 January 2009, document 34. RB envisaged that it would lose [...] per cent of its GL sales. Given that the GL market share was 51.8 per cent prior to the Withdrawal, this implies that RB expected its overall share to decrease by around [...].

name, RB expected that GPs would issue a [...] proportion of open scripts and the resulting dispensing choice afforded to pharmacists would give rise to price competition and lower prices for GL and therapeutically equivalent products. A comparison of the resulting impact on RB's net revenue (NR) and operating profit (COP) is illustrated by the graph below, which is an extract from an RB presentation:<sup>631</sup>

[...]

6.139. On the basis of RB's own forecasts of how retaining or withdrawing GL NHS packs would affect its net revenues, and the assumptions RB made about pricing and share losses, it is possible to infer that had GL NHS packs been retained, RB expected the NHS to realise [...] savings. For example, RB envisaged that it would ultimately need to offer discount of [...] per cent in order to incentivise pharmacies to dispense GL. Further RB forecast that [...] per cent of prescriptions for the GL formulation would specify the generic name. These prescriptions would have been subject to reimbursement under the much lower Drug Tariff price, rather than the PPRS price applicable to branded prescriptions.

6.140. RB also expected the Withdrawal to enable it to preserve a higher share of the market than would have been possible had GL NHS packs been retained. While RB expected the retention of GL NHS packs to ultimately result in volume market share losses of [...] per cent, it expected the Withdrawal to result in volume share losses of only [...] per cent.

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<sup>631</sup> RB submission of 6 March 2009, in response to Q3 of the OFT's section 26 notice dated 14 January 2009, document 36.

**iii) Pinewood's expectations**

6.141. This sub-section considers Pinewood's estimate of the market shares and pricing that it would have expected under conditions of full generic competition.

6.142. When launching Acidex/Peptac, Pinewood expected to 'capture around 30 per cent of Gavison's sales' in the first year of generic entry.<sup>632</sup> This compares to RB's expectation that it would ultimately lose around [...] per cent of its GL prescription sales had it retained NHS packs of GL, and that generic competitors such as Pinewood would achieve a market share of approximately [...] per cent by 2009 (see paragraph 6.130 above).

6.143. Pinewood also anticipated that under conditions of full generic competition, it would be in a position to offer a lower price for Peptac/Acidex. Pinewood explained that because of the lack of a generic name corresponding to GL and GPs' resulting inability to provide open scripts, it 'had to work with a partner which had a marketing distribution function that Pinewood lacked in order to promote a 'branded generic' (i.e. Peptac)'.<sup>633</sup> Had GL NHS packs been retained following the publication of a generic name, Pinewood explains that 'the price of Peptac would not have had to reflect the costs of advertising and promoting a 'branded generic''.<sup>634</sup>

6.144. The potential price decrease that may have been delivered by full generic competition is further indicated by Pinewood's internal

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<sup>632</sup> Pinewood submission dated 8 July 2009 in response to Q2 of OFT section 26 Notice dated 27 May 2009, page 2 (OFT file part 3, document 49.01).

<sup>633</sup> Pinewood submission dated 8 July 2009 in response to Q4 of OFT section 26 Notice dated 27 May 2009, page 4 (OFT file part 3, document 49.01).

<sup>634</sup> Pinewood submission dated 8 July 2009 in response to Q4 of OFT section 26 Notice dated 27 May 2009, page 6 (OFT file part 3, document 49.01).

discussions concerning possible list prices for its generic products. For example, after launching Peptac/Acidex Pinewood considered a range of possible prices to different categories of customers of between £1.20 and £2.55 (compared with the price of £2.16 prior to the Withdrawal).<sup>635</sup> The range of feasible prices for Peptac/Acidex suggests that had GL NHS packs been retained, increasingly intense generic competition would have had the potential to force down the Drug Tariff price of GL and equivalent medicines significantly. [...]

6.145. In its SMFI, RB argues that Pinewood's estimates are of limited value as they are not supported by contemporaneous documents and its estimates represent only 'vague assertions' that fail to recognise the particular characteristic of the market.<sup>636</sup> The OFT considers that, as the leading competitor to RB in the relevant market, Pinewood's estimates are relevant to an assessment of whether the Withdrawal tended to restrict competition or was capable of having that effect. The OFT also considers that, although Pinewood's estimates are not supported by contemporaneous internal documents, it is noteworthy that their forecasts are [...].

6.146. Pinewood's expectations suggest that, had GL NHS packs been retained following the publication of a generic name, it expected to face lower barriers to expansion, and price competition in the relevant market would have been more effective.

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<sup>635</sup> A letter from Dr Alan J. Smith to Pinewood dated 4 January 2000, Pinewood submission dated 10 June 2009 in response to Q1 of OFT section 26 Notice dated 27 May 2009 (OFT file part 3, document 35.12).

<sup>636</sup> RB SMFI, Annex 4, paragraphs 8 to 11.

**iv) The OFT's assessment**

- 6.147. Had GL NHS packs been retained, following the introduction of a generic name for it in GPs prescribing software GPs would have been able to search for Gaviscon products, identify NHS packs of GL, and then use the 'Ctrl G' function to issue open scripts by reference to them. At the time of the Withdrawal, NHS packs of GL had a market share (by value) of 40 per cent and it was therefore reasonable to expect that the introduction of a generic name corresponding to GL would have resulted in a significant volume of open prescriptions being written by reference to GL. Pharmacies that received such open prescriptions would have been able to choose whether to dispense GL or equivalent generic medicines, and it was reasonable to expect that such choice would have provided for full generic competition between suppliers. As a consequence, it was reasonable to expect that competitors such as Pinewood would have been able to generate significant sales volumes by offering attractive pricing terms to pharmacies such that they dispensed Acidex/Peptac against open scripts, and without incurring marketing spend aimed at convincing PCOs/GPs to prescribe their products.
- 6.148. At the time of the Withdrawal, it was reasonable to expect that, if NHS packs of GL were withdrawn, GPs that searched for NHS packs of a liquid Gaviscon product would find only GA, against which only closed prescriptions could then be issued. It was therefore reasonable to expect that, as a result of the Withdrawal, significantly fewer open prescriptions would be written than would have otherwise been the case following the publication of the generic name corresponding to GL, and therefore there would be significantly less scope for pharmacies to choose between competing suppliers. As a consequence, it was reasonable to expect that suppliers would have less incentive to compete on price to persuade pharmacies to dispense their medicines, and that competitors such as Pinewood would continue to incur higher marketing expenditure to persuade (i) PCOs to recommend to GPs

that they prescribe Peptac/Acidex, and (ii) GPs to prescribe Peptac/Acidex.

- 6.149. It would therefore have been reasonable to expect that, had GL NHS packs been retained, full generic competition would have begun to replace branded generic competition following the introduction of the generic name corresponding to GL in GPs prescribing software, and therefore that the Withdrawal would restrict competition from that date. While the timing of the introduction of the generic name in GPs prescribing software was uncertain, there was no reason to believe, at the time of the Withdrawal, that it would not in due course take place.<sup>637</sup>
- 6.150. The OFT considers that, at the time of the Withdrawal, no market developments could reasonably have been foreseen that would have prevented the Withdrawal from having the potential to restrict competition following the introduction of the generic name corresponding to GL. One market development that has been noted (see paragraphs 2.108 to 2.110 above, and paragraphs 6.157 to 6.161 below) is the increased use of prescribing tools such as ScriptSwitch and practice formularies. At the time of the Withdrawal these prescribing tools were in limited use and there would have been considerable uncertainty as to the extent to, and way in, which they would be used in the relevant market in future. Whatever impact they may have had in practice, or may have in the future,<sup>638</sup> this uncertainty is such that, at the time of the Withdrawal, the potential for increased use of ScriptSwitch and/or

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<sup>637</sup> RB expected the generic name corresponding to GL to take effect in early 2006. This estimate did not take account of the need for the name to be published in the BNF and then implemented in GPs' prescribing software before it would take effect. The generic name corresponding to GL was published in the BNF in 2008 and adopted in GPs' software in January 2009 (see paragraphs 2.158 to 2.159 above).

<sup>638</sup> See paragraph 6.157 below.



practice formularies in the relevant market cannot mean that the Withdrawal was not capable of restricting competition.

6.151. It would have been reasonable to expect the Withdrawal to have restrictive effects until 2016, when the patent for GA is due to expire. In 2016, it will be possible for generic entrants to market medicines that are therapeutically equivalent to GA and, providing a generic name for GA exists and GA remains available in NHS packs, it will then be possible for GPs to issue open scripts by reference to it.

6.152. At the time of the Withdrawal, it was therefore reasonable to expect that (until 2016) the Withdrawal tended to restrict competition or was capable of having that effect. In particular, it was reasonable to expect the Withdrawal to result in GPs prescribing significantly fewer open scripts by reference to liquid Gaviscon NHS packs and that this would (i) hinder the development of the increased price competition that is typically associated with full generic competition; and (ii) result in existing and potential competitors having to incur higher detailing and/or marketing costs to win market share than would have otherwise been the case.

**v) Conclusions on the effects that it was reasonable to expect at the time of the Withdrawal**

6.153. The forecasts provided by RB suggest that it expected the Withdrawal to restrict competition and to assist RB in preserving its high market share while continuing to charge prices at their prevailing levels.

6.154. Pinewood's expectations suggested that had GL NHS packs been retained, following the publication of a generic name corresponding to GL Pinewood would have faced lower barriers to expansion and price competition in the relevant market would have been more effective.

6.155. The OFT's assessment is that at the time of the Withdrawal, it was reasonable to expect that the effect of the Withdrawal would be to hinder the development of full generic competition in the market for the supply of alginates and antacids by prescription in the UK. This assessment is consistent with the expectations of RB and Pinewood at the time of the Withdrawal.

6.156. On this basis, the OFT considers that the Withdrawal tended to restrict competition or was capable of having that effect. RB has admitted that the Withdrawal tended to restrict the competitive process.<sup>639</sup>

**vi) Market developments since the Withdrawal**

6.157. The Withdrawal took place in June 2005 and it is now possible to observe developments in the relevant market since that time. The key developments are as follows:

- Following the Withdrawal, the majority of the NHS GL market share switched to GA. GA retained a market share by value of 58 per cent, while GL OTC packs retained a market share by value of five per cent.
- RB has been able to maintain a leading position in the market, with a market share (by value) of over 80 per cent. Following the Withdrawal, Pinewood's market share increased slightly but remained below 10 per cent (by value).
- GA remains patent protected and only closed prescriptions can be issued by reference to it. The prevalence of closed GA prescriptions in the relevant market is such that pharmacists still generally have no choice between medicines on receipt of prescriptions relevant to Gaviscon products.

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<sup>639</sup> RB SMFI, paragraph 4.5

- Prescribing tools such as ScriptSwitch and practice formularies have become more commonly used. ScriptSwitch is now used by 58 per cent of GP practices<sup>640</sup> and RB has stated that the use of practice formularies is now 'widespread'.<sup>641</sup>
- There has been limited price competition for alginate products. Average treatment costs for alginates have remained at the level observed prior to the Withdrawal.

6.158. The OFT considers that these developments are not inconsistent with the finding that the Withdrawal tended to restrict competition or was capable of having that effect.

**vii) Conclusions on the effects of the Withdrawal on competition**

6.159. It is apparent from RB's internal documents that, prior to the Withdrawal, RB expected the Withdrawal to hinder the development of full generic competition. Pinewood's expectations also suggest that, had GL NHS packs been retained, following the publication of a generic name corresponding to GL it would have faced lower barriers to expansion and price competition in the relevant market would have been more effective. Further, the OFT considers that, at the time of the Withdrawal, it would have been reasonable to expect that the Withdrawal would restrict competition and lead to higher prices for the NHS and higher costs for RB's existing and potential competitors than would have otherwise been the case.

6.160. The OFT therefore concludes that RB's conduct tended to restrict competition or was capable of having that effect. RB has admitted that its conduct tended to restrict the competitive process.

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<sup>640</sup> See [www.scriptswitch.co.uk](http://www.scriptswitch.co.uk).

<sup>641</sup> As set out above, the OFT is not required, and has not sought, to assess or quantify the actual effects on competition. The OFT therefore reaches no findings on the influence of ScriptSwitch and practice formularies in the relevant market.

6.161. The OFT considers that the market developments observed since the Withdrawal are not inconsistent with its finding that the Withdrawal tended to restrict competition or was capable of having that effect.

#### **D. Conclusion**

6.162. The OFT finds that the Withdrawal amounts to an abuse of a dominant position. The OFT finds that the Withdrawal was not 'normal competition' or 'competition on the merits' and that it tended to restrict competition or was capable of having that effect.

6.163. The OFT finds that the Withdrawal cannot be regarded as 'normal competition' or 'competition on the merits' as the objective of the Withdrawal was to hinder the development of full generic competition and the Withdrawal was irrational in the absence of the benefits that RB expected to derive from hindering the development of full generic competition. This finding is informed by the following:

- In relation to the Withdrawal, RB's internal documents indicate that that decision, and its timing, was made by reference to the need to ensure that it took place prior to the publication of a generic name corresponding to GL. In so doing, RB considered that it would be able to persuade many GPs and patients to switch to its patent protected product, GA, which would not face generic competition on publication of a generic name corresponding to GL.
- RB's internal documents reveal that, were it not for the prospect of using the Withdrawal to pre-empt effective competition to its Gaviscon portfolio, the Withdrawal was expected to be loss-making and not therefore a commercially rational strategy. RB's documents reveal that had it not carried out the Withdrawal as a means of pre-empting the publication

of a generic name corresponding to GL, it was proposing to retain GL NHS packs for the foreseeable future.

- RB's internal documents indicate that, over a number of years, a primary focus of RB has been to identify ways of delaying or impairing the publication of a generic name corresponding to GL, thereby hindering the development of full generic competition to GL.
- The explanations of the Withdrawal that RB has presented (to the OFT and to stakeholders) do not alter this conclusion. In particular, RB's argument that it was always intended to convert sales of GL to GA does not alter the assessment that at the time the Withdrawal took place, the Withdrawal was expected to be loss making and irrational in the absence of benefits that it expected to derive from hindering the development of full generic competition.
- Furthermore, RB's argument that the Withdrawal was the outcome of a 'normal product lifecycle management' is not supported by RB's own internal documents or by any objective assessment of its approach.
- The OFT has also found that RB's representations to stakeholders were either counterintuitive or of such minor significance that they cannot individually or collectively reasonably explain RB's decision to carry out the Withdrawal. Further, it is apparent from RB's internal documents that the factors referred to externally did not inform its decision to carry out the Withdrawal, and that that decision was irrational in the absence of the benefits that it expected to derive from hindering the development of full generic competition.

6.164. The OFT finds that the Withdrawal tended to restrict competition or was capable of having that effect. This conclusion is informed by the following findings:

- RB expected that the effect of the Withdrawal would be to hinder the development of full generic competition in the relevant market by ensuring that pharmacists were denied a choice of product on receipt of prescriptions relevant to Gaviscon products.
- RB expected the Withdrawal to enable it to preserve its very high market share and to maintain its list and realised prices at the levels observed prior to the Withdrawal and prior to the publication of a generic name corresponding to GL. Had GL NHS packs been retained, RB anticipated that it would have lost [...] market share and would have needed to [...] to preserve some sales in respect of a [...] volume of open scripts. RB's forecasts indicate that the Withdrawal was expected to result in the NHS paying [...] more for products in the relevant market than would have been the case had GL NHS packs been retained.
- At the time of the Withdrawal, it would have reasonable to expect the Withdrawal to significantly limit GPs' provision of open scripts and that this would hinder the development of full generic competition in the relevant market.
- The market developments observed since the Withdrawal are not inconsistent with the OFT's finding that the Withdrawal tended to restrict competition or was capable of having that effect.

6.165. The OFT reaches its conclusions having in mind the need to be satisfied on the balance of probabilities that the infringement took place. In any event, however, the OFT finds that the evidence it has assessed is strong and compelling evidence of abuse.

## **7 EFFECT ON TRADE**

### **A. Effect on trade within the United Kingdom**

7.1. As noted in Part 4F above, the OFT finds the relevant geographic market to be national (UK-wide) in this case. The OFT therefore finds that RB's conduct affects trade within the United Kingdom.

### **B. Effect on trade between Member States**

7.2. The OFT also finds that RB's conduct may affect trade between Member States since the requisite elements set out above in Part 3G are fulfilled for this jurisdictional test to be satisfied.

7.3. RB's conduct is at least capable of affecting 'trade between Member States'.<sup>642</sup> The main competitor affected by RB's alleged abuse is Pinewood (see paragraph 2.11 above) which is based in Ireland. Consequently, even though the alleged abuse only covers the UK, the patterns of trade between Member States (such as between the UK and Ireland) are at the very least potentially affected and therefore, RB's alleged conduct may affect trade between Member States.

7.4. In addition, RB's conduct has an influence on trade patterns. By making it more difficult for an Irish competitor to penetrate the UK market for antacid and alginate medicines supplied on prescription, RB's conduct has altered the normal flow of trade or caused the market to develop differently from the way it would have developed absent the alleged conduct.<sup>643</sup>

7.5. Finally, the effect on trade of RB's conduct is appreciable. The very presence of an undertaking, such as RB, which is dominant in

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<sup>642</sup> See paragraphs 3.62 to 3.66 above.

<sup>643</sup> See paragraph 3.64 above.

a national market, is likely to hinder penetration of that market by a competitor, such as Pinewood, and accordingly any abuse which increases the difficulty of market entry is considered to have an appreciable effect on inter-State trade.<sup>644</sup> Consequently, the OFT finds that RB's conduct may have an appreciable effect on trade between Member States and therefore that RB's conduct also infringed Article 102 TFEU.<sup>645</sup>

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<sup>644</sup> See paragraph 3.66 above.

<sup>645</sup> See Part 3C above.



## **8 THE OFT'S ACTION**

### **A. Introduction**

- 8.1. This part of the Decision sets out the enforcement action that the OFT is taking and its reasons for taking that action.

### **B. Decision**

- 8.2. On the basis of the evidence and the reasons set out in Part 6 above, the OFT finds that RB has infringed the Chapter II prohibition and Article 102 of the TFEU. The OFT finds that, by carrying out the Withdrawal, RB abused its dominant position in the market for the supply of alginates and antacids by prescription in the UK (the 'Infringement').

### **C. Directions**

- 8.3. Section 33(1) of the Act provides that if the OFT has made a decision that conduct infringes the Chapter II prohibition, it may give to such person or persons as it considers appropriate such directions as it considers appropriate to bring the infringement to an end.
- 8.4. The OFT considered whether any direction(s) would be appropriate in this case, but has not identified any direction that would effectively remedy any effects of the Infringement.
- 8.5. In the SO, the OFT proposed to direct RB to reintroduce and re-list NHS packs of GL. However, Pinewood, Teva and DH submitted that the OFT should not direct RB to reintroduce NHS packs of GL as doing so would be of little benefit to competition or consumers. In particular, it was observed that the majority of GPs/patients have not prescribed/consumed GL NHS packs for six years, and that GP and patient inertia made large-scale switching back to GL highly unlikely. Given the limited benefits that these parties anticipated from re-introducing NHS packs of GL, the OFT

considers that it would be disproportionate to require RB to re-introduce NHS packs of GL.

## **D. Penalties**

### **i) General points**

#### **a) Introduction**

8.6. Section 36(2) of the Act provides that on making a decision that the conduct in question has infringed the Chapter II prohibition, the OFT may require the undertaking concerned to pay it a penalty in respect of the infringement.

#### **b) Statutory cap on penalties**

8.7. Pursuant to section 36(8) of the Act, no penalty which has been fixed by the OFT may exceed 10 per cent of the turnover of the undertaking calculated in accordance with the provisions of the Competition Act 1998 (Determination of Turnover for Penalties) (Amendment) Order 2000 (SI 2000/309) (the '2000 Order'), as amended by the Competition Act 1998 (Determination of Turnover for Penalties) (Amendment) Order 2004 (SI 2004/1259) (the '2004 Order').<sup>646</sup>

#### **c) The OFT's margin of appreciation in determining the appropriate amount of a penalty**

8.8. Provided the penalties it imposes in a particular case are within the range of penalties permitted by section 36(8) of the Act and the 2000 Order (as amended by the 2004 Order) and the OFT has had regard to the Penalty Guidance under section 38 of the Act, the OFT has a margin of appreciation when determining the appropriate amount of a penalty under the Act.<sup>647</sup> Moreover, each

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<sup>646</sup> Section 36(8) of the Act.

<sup>647</sup> *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2005] CAT 13, at [168]. See also *Umbro Holdings Limited and Others v Office of Fair Trading* [2005] CAT 22, at [101] and [102].

case is specific to its own facts and circumstances and it cannot be assumed that the level of penalty appropriate for a particular party in one case (or the manner in which the Penalty Guidance has been applied) will necessarily be the same in respect of another party in another case.<sup>648</sup> Finally, the OFT does not consider that it is in any event bound by its decisions in relation to the calculation of penalties in previous cases. Rather, the OFT considers that, subject to the above, it is free to apply its policy as appropriate having regard to all relevant circumstances and its overall policy objectives on financial penalties, as set out in the Penalty Guidance.

**d) Conduct of minor significance**

8.9. Section 40(3) of the Act provides that a person is immune from the effect of section 36(2) of the Act if his conduct is conduct of minor significance. Conduct of minor significance is defined, pursuant to section 40(1) of the Act and Regulation 4 of the Competition Act 1998 (Small Agreements and Conduct of Minor Significance) Regulations 2000 (SI 2000/262), as conduct by an undertaking the applicable turnover of which for the business year ending in the calendar year preceding the one during which the infringement occurred does not exceed £50 million.

8.10. As RB's applicable turnover exceeded £50 million its conduct is not of minor significance and, accordingly, RB does not benefit from immunity from financial penalties.

**e) Intention/negligence**

8.11. The OFT may impose a penalty on an undertaking which has infringed the Chapter II prohibition only if it is satisfied that the

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<sup>648</sup> See, for example, *Kier Group plc and others v Office of Fair Trading* [2011] CAT 3, at [116] where the CAT noted that 'other than in matters of legal principle there is limited precedent value in other decisions relating to penalties, where the maxim that each case stands on its own facts is particularly pertinent'.

infringement has been committed intentionally or negligently.<sup>649</sup>  
The OFT is not required to decide whether the infringement was committed intentionally or negligently, as long as it is satisfied that the infringement was either intentional or negligent.<sup>650</sup>

8.12. The CAT has stated that:

'An infringement is committed intentionally for the purposes of the Act if the undertaking must have been aware that its conduct was of such a nature as to encourage a restriction or distortion of competition. An infringement is committed negligently for the purposes of section 36(3) if the undertaking ought to have known that its conduct would result in a restriction or distortion of competition.'<sup>651</sup>

8.13. The circumstances in which the OFT might find that an infringement has been committed intentionally include the following:

- the agreement or conduct has as its object the restriction of competition
- the undertaking in question is aware that its actions will be, or are reasonably likely to be, restrictive of competition but still wants, or is prepared, to carry them out, or
- the undertaking could not have been unaware that its agreement or conduct would have the effect of restricting

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<sup>649</sup> Section 36(3) of the Act.

<sup>650</sup> *Napp Pharmaceutical Holdings Limited and Subsidiaries v Director General of Fair Trading* [2002] CAT 1, at [453] to [455]. See also, for example, *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2005] CAT 13, at [221].

<sup>651</sup> See *Napp Pharmaceutical Holdings Limited and Subsidiaries v Director General of Fair Trading* [2002] CAT 1, at [452] to [458].

competition, even if it did not know that it would infringe Article 101 (formerly Article 81 EC), Article 102 TFEU, the Chapter I and/or Chapter II prohibition.<sup>652</sup>

- 8.14. Ignorance or a mistake of the law is irrelevant to the assessment of intent (or negligence),<sup>653</sup> and the OFT is not obliged to show that an undertaking knew that its conduct infringed the Act.<sup>654</sup>
- 8.15. In establishing whether or not an infringement is committed intentionally, the OFT may consider internal documents generated by the undertaking in question. It may be inferred that an infringement has been committed intentionally where consequences giving rise to an infringement are plainly foreseeable from the pursuit of a particular policy by an undertaking.<sup>655</sup>
- 8.16. The OFT is likely to find that an infringement of Article 101 TFEU, Article 102 TFEU, the Chapter I and/or Chapter II prohibition has been committed negligently where an undertaking ought to have known that its agreement or conduct would result in a restriction or distortion of competition.<sup>656</sup>

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<sup>652</sup> See OFT 407, *Enforcement* (December 2004), paragraph 5.9.

<sup>653</sup> *Ibid*, paragraph 5.10.

<sup>654</sup> *Napp Pharmaceutical Holdings Limited and Subsidiaries v Director General of Fair Trading* [2002] CAT 1, paragraph 456.

<sup>655</sup> See OFT 407, *Enforcement* (December 2004), paragraph 5.11. See also *Napp Pharmaceutical Holdings Limited and Subsidiaries v Director General of Fair Trading* [2002] CAT 1, paragraph 456 and *Aberdeen Journals Limited v Office of Fair Trading* [2003] CAT 11, paragraphs 485 - 488.

<sup>656</sup> See OFT 407, *Enforcement* (December 2004), paragraph 5.12. See also *Napp Pharmaceutical Holdings Limited and Subsidiaries v Director General of Fair Trading* [2002] CAT 1, at paragraph 457; and case 27/76 *United Brands Co and United Brands Continental BV v Commission* [1978] 1 CMLR 429 at paragraphs 298 – 301, [1977] ECR 207.

8.17. In the present case, the OFT finds that RB was aware that its actions were reasonably likely to be restrictive of competition, but was still prepared to carry them out.<sup>657</sup> As set out in Part 6 above, the OFT finds that RB carried out the Withdrawal as a means of hindering the development of full generic competition, and that RB expected the Withdrawal to enable it protect its Gaviscon portfolio from the effects of full generic competition.

8.18. The OFT therefore finds that RB committed the Infringement intentionally.

8.19. To the extent that RB may genuinely have been unaware of the anti-competitive nature of its conduct, the OFT considers that it is apparent from the evidence set out above in Part 6C that RB at the very least ought to have known that the Withdrawal would result in a restriction or distortion of competition and that RB, therefore, at least negligently committed the Infringement.

**f) Turnover of the undertaking**

8.20. For the purpose of the penalty calculation, the OFT considers that the relevant turnover or total turnover as applicable, is the turnover of the undertaking that comprises the relevant single economic entity, as described in Part 3D above.

8.21. An undertaking may comprise several legal entities within the same corporate group. In this case, the OFT has based its penalty

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<sup>657</sup> See *Napp Pharmaceutical Holdings Limited and Subsidiaries v Director General of Fair Trading* [2002] CAT 1, at [456] where the CAT stated 'While in some cases the undertaking's intention will be confirmed by internal documents, in our judgment, and in the absence of any evidence to the contrary, the fact that certain consequences are plainly foreseeable is an element from which the requisite intention may be inferred. If, therefore, a dominant undertaking pursues a certain policy which in fact has, or would foreseeably have, an anti-competitive effect, it may be legitimate to infer that it is acting 'intentionally' for the purposes of section 36(3) [of the Act].'

calculations on the consolidated turnover of the legal entities to which the OFT has attributed liability for the Infringement.

**ii) Calculation of penalties**

**a) Introduction**

8.22. In accordance with section 38(8) of the Act, the OFT must have regard to the guidance on penalties issued under section 38(1) of the Act, for the time being in force, when setting the amount of the penalty. The guidance on penalties in force at the time of this Decision is the Penalty Guidance, which sets out five steps for determining the appropriate amount of a penalty.

8.23. In imposing a financial penalty in respect of the Infringement, the OFT has identified the legal person or persons whom it considers to have been party to the Infringement and therefore liable for the ensuing financial penalty. The addressees of this Decision are set out in paragraph 2.5 above.

**b) Step 1: calculation of the starting point**

8.24. The starting point for determining the level of a penalty is calculated having regard to the seriousness of the infringement and the relevant turnover of the undertaking.<sup>658</sup> The starting point may be any amount up to a maximum of 10 per cent of the undertaking's relevant turnover.<sup>659</sup>

8.25. The relevant turnover that is used to determine the starting point is the undertaking's turnover in the relevant product market and the relevant geographic market affected by the infringement in the undertaking's last business year.<sup>660</sup>

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<sup>658</sup> Penalty Guidance, paragraph 2.3.

<sup>659</sup> *Ibid*, paragraph 2.8.

<sup>660</sup> *Ibid*, paragraph 2.7.

- 8.26. At the time the ERA was concluded, the OFT's policy was to interpret the last business year as the business year preceding the date of the OFT's infringement decision, or, in the case of an early resolution agreement, the business year preceding the date of the early resolution agreement. However, in certain recent judgments of the Competition Appeal Tribunal in the *Construction* appeals,<sup>661</sup> the last business year is interpreted by the CAT to be the undertaking's business year preceding the date on which the infringement ended, and the OFT has applied this approach below. As set out further below (see paragraph 8.60 below), the OFT notes that on either interpretation of the last business year, the final penalty arrived at in this case is broadly similar.
- 8.27. The OFT has considered the relevant product market and geographic market affected by RB's conduct in Part 4 above. The OFT finds that the relevant product market in this case is no wider than the supply of alginates and antacids by prescription and the relevant geographic market is no wider than the UK. RB's relevant turnover in the relevant market in the last business year preceding the date on which the Infringement ended was £[...].<sup>662</sup>
- 8.28. The actual percentage which is applied to the relevant turnover at Step 1 of the penalty calculation depends upon the nature of the infringement. The more serious and widespread the infringement, the higher the starting point is likely to be.<sup>663</sup> When making this assessment, the OFT considers a number of factors, including the

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<sup>661</sup> *Kier Group plc and others v Office of Fair Trading* [2011] CAT 13, at 130 to 139. See also *Durkan Holdings Limited and others v Office of Fair Trading* [2011] CAT 6, at [145] to [159] and *GF Tomlinson Group Limited and GF Tomlinson Building Limited v Office of Fair Trading* [2011] CAT 7, at [82] to [113].

<sup>662</sup> Letter from RB to OFT dated 15 March 2010 (OFT file part 8, document 24.01). RB's relevant turnover is not affected by the inclusion or otherwise of antacid medicines in the relevant market.

<sup>663</sup> Penalty Guidance, paragraph 2.4.



nature of the product/services, the structure of the market, the market share of the undertaking involved in the infringement, the effect on competitors and third parties and direct or indirect damage caused to consumers.<sup>664</sup>

8.29. The OFT considers that the Withdrawal represents a serious infringement. In particular:

- As set out at Part 5 above, the OFT finds that RB has held a market share (by value) of over 80 per cent for a number of years. Existing competitors to RB face significant barriers to expansion, and new entrants to the market face significant barriers to entry and expansion.
- As set out at Part 5 above, the OFT finds that the objective of the Infringement was to hinder competition. The OFT finds that instead of meeting the threat of full generic competition by, for example, offering more favourable prices to its customers, RB implemented the Withdrawal as a means of hindering the development of full generic competition in the relevant market.
- As set out in Part 6B above, the OFT finds that the Withdrawal tended to restrict competition and/or was capable of having that effect. At the time of the Withdrawal, it was reasonable to expect that it would (i) hinder the development of the increased price competition that is typically associated with full generic competition; and (ii) result in Pinewood and potential entrants to the market having to incur higher detailing and/or marketing

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<sup>664</sup> *Ibid*, paragraph 2.5. See also *Kier Group plc and others v Office of Fair Trading* [2011] CAT 3, at [133]: 'It is clearly necessary to take into account the effects (actual or potential) of an infringement when considering its seriousness'. As explained in Part 3 above, the OFT is not required to, and has not sought to, quantify the actual effects on competition. Accordingly, in assessing the seriousness of the Infringement, the OFT has limited its consideration to the potential effects of the Infringement.

costs to win market share than would have otherwise been the case.

- It was reasonable to expect that the Withdrawal would not generate any material benefits to consumers or to the NHS in advance of its restrictive effects.

8.30. The OFT also notes that conduct of this type in the pharmaceutical sector has the potential to hinder the development of full generic competition, and that the effects of doing so can last for a considerable period and prevent significant price decreases. These factors reinforce the assessment that the Infringement was serious in nature.

8.31. Taking into account the above factors, the OFT concludes that a starting point of 7 per cent of RB's relevant turnover is appropriate for determining its penalty at Step 1.

8.32. RB's penalty after Step 1 is £[...].

**c) Step 2: adjustment for duration**

8.33. The starting point under Step 1 may be increased or, in exceptional circumstances decreased, to take into account the duration of the Infringement.<sup>665</sup>

8.34. The OFT finds that the Infringement took place in June 2005 such that the action of the Withdrawal had a duration of less than a year. Part years may be treated as full years for the purpose of calculating the number of years of the infringement.<sup>666</sup> The OFT has therefore made no increase or decrease for duration at Step 2 of the penalty calculation. As noted at paragraph 8.30 above and

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<sup>665</sup> Ibid, paragraph 2.10.

<sup>666</sup> Ibid, paragraph 2.10. See also *Apex and Asphalt and Paving Co Limited v Office of Fair trading* [2005] CAT 4 and *Double Quick Supplyline Limited and Precision Concepts Limited v Office of Fair Trading* [2007] CAT 13.

paragraph 8.42 below, however, the restrictive effects and financial gains associated with conduct such as the Withdrawal have the potential to occur over a significant period, and account is taken of this factor at Step 3.

8.35. RB's penalty after Step 2 remains £[...].

**d) Step 3: adjustment for other factors**

8.36. The penalty may be adjusted, as appropriate, after Step 2 of the penalty calculation, to achieve the twin objectives of the OFT's policy on financial penalties: to impose penalties on infringing undertakings which reflect the seriousness of the infringement; and to ensure that the threat of penalties will deter undertakings generally from engaging in anti-competitive practices.<sup>667</sup> Adjustments to the financial penalty at Step 3 may result in either an increase or a decrease in the financial penalty.<sup>668</sup>

8.37. In considering whether any adjustment to the penalty is required for the purposes of deterrence, the OFT considers both the need specifically to deter the infringing undertaking from engaging in such behaviour in future ('specific deterrence') and also the need more generally to ensure that other undertakings are deterred from engaging in similar behaviour ('general deterrence').

8.38. In considering whether the financial penalty calculated at the end of Step 2 is sufficient, the OFT may have regard to a range of considerations. These may include the undertaking's size and financial position (by reference to indicators such as total turnover profits, dividends and margins)<sup>669</sup> and the OFT's estimate of any

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<sup>667</sup> Paragraph 1.4 of the Penalty Guidance.

<sup>668</sup> *Ibid*, paragraph 2.12.

<sup>669</sup> See, for example, *Kier Group plc and others v Office of Fair Trading* [2011] CAT 3, at [170] to [172].

potential economic or financial benefits made by the infringing undertaking(s) from the infringements.<sup>670</sup>

- 8.39. RB's penalty after Step 2 has to be considered in the context of Reckitt Benckiser Group plc's total worldwide turnover of £7,753 million and Reckitt Benckiser (UK) Limited's turnover of £601 million in the year ending December 2009. RB's penalty after Step 2 is approximately [...] per cent of Reckitt Benckiser Group plc's total worldwide turnover and approximately [...] per cent of Reckitt Benckiser (UK) Limited's turnover. The OFT considers that these to figures represent an extremely small proportion of the respective turnover of RB worldwide and in the UK given the nature of the infringement.
- 8.40. Additionally, Reckitt Benckiser Group plc's worldwide operating profits for the year ending December 2009 were £1,891 million and Reckitt Benckiser (UK) Limited's operating profits for the year ending December 2009 were £329 million. RB's penalty after Step 2 is approximately [...] per cent of Reckitt Benckiser Group plc's worldwide operating profits and [...] per cent of Reckitt Benckiser (UK) Limited's operating profits. The OFT considers that these figures represent a very small proportion of those respective profit measures given the nature of the infringement.
- 8.41. Having regard to those figures and given the nature of the infringement, the OFT considers that the financial penalty reached after step 2 would not provide a sufficient deterrent to RB or other dominant companies contemplating similar conduct.
- 8.42. Furthermore, the OFT considers that the penalty calculation must also recognise the significant financial gains that dominant companies such as RB can potentially realise by engaging in conduct that hinders the development of full generic competition. In particular:

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<sup>670</sup> Penalty Guidance, paragraph 2.11.

- This type of conduct will often be capable of restrictive effects that last for some time and that it may not be possible to remedy. On this basis, this type of conduct would be expected to generate financial gains for dominant companies over a considerable period. In this case the OFT has found that it was reasonable to expect the Withdrawal's restrictive effects to last for a period of at least seven years (see paragraph 6.152 above).
- Full generic competition can provide for significant price reductions, and these reductions can be prevented by conduct that hinders the development of full generic competition.<sup>671</sup> On this basis, such conduct would be expected to generate significant financial gains for dominant companies.

8.43. In this regard, the OFT notes that at the time of the Withdrawal RB expected to realise [...] financial gains as a consequence of the Withdrawal.<sup>672</sup> Notwithstanding that the OFT has not sought to quantify the actual effects of the Withdrawal, or any associated financial gains for RB, the OFT considers that the expected gain is a relevant factor when determining the appropriate penalty.

8.44. To reflect these considerations, and to ensure that both RB and other dominant undertakings are sufficiently deterred from engaging in similar conduct in future, the OFT considers that it is necessary to increase RB's penalty significantly at Step 3.

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<sup>671</sup> As set out in Part 6C, the OFT has not made findings as to the extent of the Withdrawal's effects in the relevant market.

<sup>672</sup> See paragraph 6.138 above. RB had forecast that within 4 years of the generic name for GL being published, the Withdrawal would provide for [...] in additional Net Revenue, and [...] in additional Company Operating Profit. Given that RB expected to generate further gains prior to the expiry of the GA patent in 2016, it is apparent that RB expected to achieve [...] financial gains as a consequence of the Withdrawal.

- 8.45. In determining the appropriate increase at Step 3 in this case, the OFT has also had regard to the fact that this specific form of abuse (the withdrawal and de-listing of a product) had not previously been found to be an infringement of the Chapter II prohibition or Article 102 TFEU at the time of the Infringement. Given the complex nature of the analysis that has been necessary in this case, the OFT considers the absence of guiding case law at the time of the Infringement is, in the circumstances of this case, a relevant factor in determining the appropriate level of penalty. Accordingly, the OFT considers that it is appropriate to recognise this by adopting a lower increase at Step 3 than would have otherwise been applied. However, the OFT considers that only a modest adjustment is appropriate in this regard given RB's intention to use the Withdrawal as a means of hindering the development of full generic competition.
- 8.46. In the specific circumstances of this case, and having assessed the above factors in the round, the OFT considers that it is proportionate to increase RB's penalty to [...]. This adjustment increases RB's penalty after Step 3 to approximately [...] per cent of Reckitt Benckiser Group plc's total worldwide turnover and approximately [...] per cent of Reckitt Benckiser (UK) Limited's turnover. Further RB's penalty after Step 3 is approximately [...] per cent of Reckitt Benckiser Group plc's worldwide operating profits and [...] per cent of Reckitt Benckiser (UK) Limited's operating profits. Whilst such figures remain comparatively small the OFT considers that they will act as a sufficient deterrent to RB, and notes that the adjusted penalty would amount to a substantial part of the relevant turnover identified in Step 1. The OFT also notes that the adjusted penalty would mean that the Step 1 figure would have been subject to a multiplier of slightly over [10 – 15]. Given the circumstances and matters already referred to, the OFT considers that such a multiplier is proportionate.
- 8.47. The OFT also considers that this penalty represents a sufficient deterrent to other dominant companies contemplating similar conduct, in particular noting that similar conduct employed in

future will not benefit from the modest reduction made in the specific circumstances of this case in recognition of the absence of guiding case law at the time of the Infringement (see paragraph 8.45 above).

8.48. RB's penalty after Step 3 is £[...].

**e) Step 4: adjustment for aggravating and mitigating factors**

8.49. The OFT may increase a penalty at Step 4 of the penalty calculation where there are aggravating factors, or decrease it where there are mitigating factors.<sup>673</sup>

8.50. In this case, the OFT has decided to make no increase in penalty for aggravating factors.

8.51. The OFT is satisfied that RB has demonstrated that it has taken adequate steps to ensure compliance, in particular, by investing significant resources into developing a comprehensive and effective competition law compliance policy.<sup>674</sup> Accordingly, the OFT has recognised this as a mitigating factor and decreased RB's penalty by five per cent at Step 4 of the penalty calculation.

8.52. RB's penalty after Step 4 is £[...].

**f) Step 5: adjustment to prevent the maximum penalty from being exceeded and to avoid double jeopardy**

8.53. The OFT may not fix a penalty that exceeds 10 per cent of the worldwide turnover of the undertaking in its last business year before the date of the OFT's infringement Decision, calculated in accordance with the provisions of the 2000 Order, as amended by

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<sup>673</sup> Penalty Guidance, paragraph 2.14.

<sup>674</sup> OFT File Part 10, document 22.01. See Penalty Guidance, at paragraph 2.16 and OFT1227 *Drivers of Compliance and Non-compliance with Competition Law* (May 2010), at paragraph 1.14.

the 2004 Order.<sup>675</sup> This turnover is not restricted to an undertaking's turnover in the relevant product market and relevant geographic market.<sup>676</sup>

- 8.54. The OFT has assessed RB's penalty against the test set out in the previous paragraph and is satisfied that no reduction to RB's penalty at Step 5 of the penalty calculation is necessary in this case.
- 8.55. Also, the OFT must, when setting the amount of a penalty for a particular course of conduct, take into account any penalty or fine that has been imposed by the Commission or by a court or other body in another Member State in respect of the same course of conduct.<sup>677</sup> As there is no such applicable penalty or fine in respect of RB's conduct, no adjustments are necessary in this case.
- 8.56. RB's penalty after Step 5 remains £[...].

**g) Early resolution reduction**

- 8.57. As noted at paragraph 2.26 above and Annexe A below, RB concluded an Early Resolution agreement with the OFT. The Early Resolution agreement anticipated a decrease in the penalty of up to 15 per cent if RB co-operated fully throughout the investigation and until the conclusion of any resulting action by the OFT as set out in the agreement. The OFT is satisfied that RB has fully co-operated with the terms of its Early Resolution agreement and has therefore decreased RB's penalty by 15 per cent after Step 5 of the penalty calculation.
- 8.58. On this basis, RB's penalty after Step 5 would be £[...].

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<sup>675</sup> Section 36(8) of the Act and the 2000 Order, as amended by the 2004 Order.

<sup>676</sup> Penalty Guidance, paragraph 2.17.

<sup>677</sup> *Ibid*, at paragraph 2.20.



- 8.59. On entering into the ERA it was necessary for the OFT to stipulate the penalty that it would impose upon RB. Under the terms of the ERA, the OFT stated that it would impose a penalty of £10,175,000 after a reduction for early resolution.
- 8.60. To determine the appropriate penalty to which the early resolution discount would apply, the OFT applied the framework in the Penalty Guidance. As regards Step 1, it followed its policy at the time and took account of relevant turnover in the last business year before the ERA at Step 1 (see paragraph 8.26 above). On this basis, RB's relevant turnover was £[...]. Largely as a result of this lower starting point at Step 1, the penalty that the OFT stated it would impose is slightly lower than that set out in paragraph 8.58.<sup>678</sup>
- 8.61. In all the circumstances of this case, the OFT considers that it would be proportionate and appropriate to impose the penalty agreed under the ERA, and not to seek to impose the higher penalty. In particular, given the small difference between the two penalty figures, the OFT considers that both the penalty agreed in RB's ERA and the penalty calculated by reference to RB's relevant turnover in the last business year preceding the date on which the Infringement ended are sufficient to meet the twin objectives of the OFT's penalties policy, and are proportionate, having regard to RB's size and financial position.
- 8.62. The OFT therefore imposes a penalty of £10,175,000.

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<sup>678</sup> Steps 1, 2, 4 and 5 were followed as set out above. However, a higher increase was adopted at Step 3 (see paragraph 8.46). The reason for this difference is that the early resolution calculation had, by being based on turnover in the business year preceding the ERA, taken account of price decreases under the PPRS (see paragraph 2.119 above) and a fall in RB's market share since the Withdrawal.

**h) Payment of the penalty**

8.63. The OFT requires RB to pay the penalty applicable to it as set out at paragraphs 8.24 to 8.62 above and in Annexe A below.

8.64. The penalty will become owed to the OFT in its entirety by 14 June 2011 and must be paid to the OFT by close of banking business on that date.<sup>679</sup> If the penalty is not paid, and either an appeal against the imposition or amount of that penalty has not been made or such an appeal has been made and determined in the OFT's favour, the OFT may commence proceedings to recover the amount as a civil debt.

**Ann Pope for and on behalf of the Office of Fair Trading**

**Senior Director, Markets and Projects**

**12 April 2011**

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<sup>679</sup> Details of how to pay are notified in the letter accompanying this Decision.

## **ANNEXE A: TEXT OF THE EARLY RESOLUTION AGREEMENT, SIGNED 14 OCTOBER 2010**

Dear Sirs

**Reckitt Benckiser Healthcare (UK) Limited and Reckitt Benckiser Group plc  
(together 'RB')**

**Case CE/8931-08: Abuse of a dominant position by Reckitt Benckiser**

### **Competition Act 1998**

As you are aware, the Office of Fair Trading (the 'OFT') proposes to make a decision that RB infringed the Chapter II prohibition of the Competition Act 1998 and Article 102 of the Treaty on the Functioning of the European Union (the 'TFEU') in June 2005 by withdrawing and de-listing NHS presentation packs Gaviscon Original Liquid from the market for the supply of alginates and antacids by prescription in the UK (the 'Infringement'). The OFT's proposed decision was set out in the Statement of Objections dated 23 February 2010 (the 'Statement').

You have indicated RB's willingness to admit its involvement in relation to the Infringement. You have also indicated RB's willingness to co-operate in the OFT's desire to expedite the process of concluding this investigation (the 'Investigation'). Further to discussions between the OFT and RB, this letter (the 'Agreement') sets out the terms upon which the OFT would be prepared to resolve its investigation of the Infringement, were RB to accept these terms.

1. RB will, by signing the Agreement, admit its involvement in the Infringement (as set out in the appendix to this Agreement).
2. RB will maintain continuous and complete co-operation throughout the Investigation and until the conclusion of any action by the OFT arising as a result of the Investigation; and reference to such action includes any action taken by the OFT in any proceedings before the

Competition Appeal Tribunal (the 'CAT') arising from a decision of the OFT in connection with the Infringement.

3. In relation to the Infringement, save as otherwise agreed by the OFT, such co-operation in the present case may include but may not be limited to, if requested by the OFT:
  - a. RB using reasonable endeavours to secure the complete and truthful co-operation of its current and former directors, officers, employees and agents and to ensure that these individuals, if requested by the OFT, provide the OFT with specific and valuable information relevant to the Infringement.
  - b. In relation to any CAT proceedings, RB using reasonable endeavours to facilitate and secure the complete and truthful co-operation of its current and former directors, officers, employees and agents, in:
    - i. assisting the OFT or its counsel in the preparation for those CAT proceedings
    - ii. if requested by the OFT or its counsel, attending those CAT proceedings, and
    - iii. speaking to any relevant witness statements and being cross-examined on such witness statements in those CAT proceedings.
4. The OFT will accept from RB a concise memorandum indicating any material factual inaccuracies in each of the Statement and any Supplementary Statement of Objections (a 'Supplementary Statement') that the OFT may address to it, which should be received by the OFT by two weeks from signing this Agreement in respect of the Statement and by such reasonable deadline that the OFT may set in relation to any Supplementary Statement. Should any of the memorandum in respect of (i) the Statement or (ii) any Supplementary Statement, in the opinion of the OFT, go so far as to contest RB's liability for all or any part of the Infringement or

represent that the penalty should be other than as set out in the Agreement, or otherwise exceed the scope identified in the previous sentence, the OFT will notify RB of its concerns. Should RB not agree promptly to amend its representations in a manner which satisfies the OFT, the OFT may treat any agreement on the terms set out in the Agreement as ceasing to have effect and shall notify RB accordingly.

5. In relation to the Infringement, RB will refrain from seeking further access to documents on the OFT's file, other than those documents directly relied on and referred to in the Statement and any Supplementary Statement.
6. If, following consideration of any memorandum submitted by RB pursuant to paragraph 4 above and any other information, the OFT considers that RB has infringed the Chapter II prohibition and Article 102 TFEU, the OFT will adopt a decision in respect of the Infringement (the 'OFT's Decision') which will:
  - a. as to substance,
    - i. set out the OFT's findings of the facts which had taken place in materially the same form as set out in the Statement and any Supplementary Statement, subject to any amendments deemed necessary and appropriate by the OFT as a result of any memorandum referred to in paragraph 4 above or any other information
    - ii. note RB's admission as to involvement in the Infringement and conclude that such infringement had been committed
    - iii. have a copy of the Agreement annexed to it.
  - b. as to penalty,
    - i. set out the OFT's approach to calculating the penalty in accordance with its published guidance

- ii. set out clearly the factors considered in determining a penalty on RB
  - iii. impose a penalty on RB of £11.970 million before any discount for co-operation
  - iv. note that the OFT anticipates that the penalty figure for RB will also include a reduction in recognition of the procedural co-operation as set out in the Agreement, which will enable the OFT to complete the Investigation more speedily and effectively. A reduction of up to 15 per cent is available for procedural co-operation with the Investigation. If RB co-operates fully as set out in the Agreement the OFT will therefore impose a penalty on RB of £10.175 million.
- 7. In relation to the Infringement, if RB brings appeal proceedings before the CAT in respect of the OFT's Decision, the OFT reserves the right to make an application to the CAT:
  - a. to increase the penalty imposed on RB in relation to the Infringement, and
  - b. to require RB to pay the OFT's full costs of the appeal regardless of the outcome of the appeal.
- 8. The OFT reserves the right, without further notice, to adjust the figures in applying Steps 1 to 5 of its guidance on penalties in Competition Act 1998 cases, provided the final penalty remains no higher than that set out in paragraph 6.b.iv above. For the avoidance of doubt, the OFT reserves the right to make further adjustments that reduce the final penalty as set out in paragraph 6.b.iv above without further notice.
- 9. The OFT agrees that any press announcement by it concerning the Agreement shall not be made until the Agreement has been signed by RB and the OFT. Any announcements, interviews or briefings made by RB to the stock exchange, press or other third parties shall not contradict, or be reasonably capable of being construed so as to

contradict, any of the OFT's proposed findings in relation to the Infringement set out in the Statement or any Supplementary Statement.

10. In relation to the Infringement, in the event that RB wishes to withdraw its admission, seek access to documents on the file other than those relied on in the Statement and/or any Supplementary Statement, or submit representations that exceed the scope envisaged by paragraph 4 above, RB will notify the OFT that it is terminating the Agreement. All terms of the Agreement, including but not limited to the agreed final penalty and procedural co-operation reduction referred to at paragraph 6 above, will then cease to have effect and the OFT will pursue the Investigation in accordance with the normal procedures.
11. The OFT may, subject to the provisions of paragraph 12 below, terminate the Agreement and impose a penalty in accordance with section 36 of the Competition Act 1998 in relation to the Infringement if, at any time before the conclusion of the case including any proceedings before the CAT (whether by adopting a decision or otherwise), it determines that any of the conditions in paragraphs 1 to 5 above has not been complied with.
12. Before terminating the Agreement, the OFT shall serve written notice to RB of the nature of the alleged non-compliance and that the OFT is considering terminating the Agreement with RB. RB will then be given a reasonable opportunity to respond to the notice and to remedy any breach within a reasonable period of time from the service of the notice.
13. All information, documents and other evidence provided by RB to the OFT under the Agreement shall, notwithstanding the termination of the Agreement (whether by revocation, the conclusion of the Investigation, including any proceedings before the CAT, in relation to the Infringement or otherwise), remain the property of the OFT and may be used by the OFT to facilitate the performance of its functions by or under any enactment.

14. Nothing in the Agreement affects any of the OFT's separate ongoing or future investigations into possible infringements of the Competition Act 1998 and/or Articles 101 and 102 of the TFEU or of the Enterprise Act 2002 outside the scope of the Statement or any Supplementary Statement.

If RB accepts the terms set out in the Agreement, a duly authorised representative of RB should sign the Agreement as indicated below and return a faxed or scanned copy to the OFT. The copy bearing the original signature of the duly authorised representative should then be returned to the OFT as soon as reasonably practicable thereafter. The OFT will send to RB a counter-part of the Agreement bearing the original signature of the duly authorised representative of the OFT and will also send a faxed or scanned copy to RB. The Agreement will become effective when RB and the OFT have signed their respective counter-part of the Agreement.

Yours faithfully

Ann Pope

Senior Director, Markets and Projects, Goods



## ANNEXE B: THERAPEUTIC INDICATIONS OF SELECTED PPIS, H2RAS, ALGINATES AND ANTACIDS

Table B1: Therapeutic indications and recommended doses (in adults) for selected PPIs

| Therapeutic indication                                                            | Esomeprazole                                                      | Omeprazole                       | Pantoprazole                  | Lansoprazole                        | Rabeprazole Sodium                                               |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------|----------------------------------|-------------------------------|-------------------------------------|------------------------------------------------------------------|
| Treatment of GORD (incl. reflux oesophagitis)                                     | 40mg once daily for 4-8 weeks                                     | 20mg once daily for 4-8 weeks    | 20mg once daily for 4-8 weeks | 30mg once daily for 4-8 weeks       | 20mg once daily for 4-8 weeks                                    |
| Symptomatic treatment of GORD in absence of oesophagitis (acid-related dyspepsia) | 20mg once daily for up to 4 weeks, then 20 mg daily when required | 10-20mg once daily for 2-4 weeks | 20mg once daily for 2-4 weeks | 15-30mg once daily for 2-4 weeks    | 10mg once daily for up to 4 weeks, then 10mg daily when required |
| Maintenance of GORD                                                               | 20mg once daily                                                   | 20mg once daily                  | 20mg once daily               | 15-30mg once daily                  | 10-20mg once daily                                               |
| Treatment of duodenal ulcers                                                      | -                                                                 | 20mg once daily for 4 weeks      | 40mg once daily for 2 weeks   | 30mg once daily for 2 weeks (BNF: 4 | 20mg once daily for 4 weeks                                      |

|                                      |                                                 |                                                |                                            |                                                   |                                                   |
|--------------------------------------|-------------------------------------------------|------------------------------------------------|--------------------------------------------|---------------------------------------------------|---------------------------------------------------|
|                                      |                                                 |                                                |                                            | weeks)                                            |                                                   |
| Treatment of gastric ulcers          | -                                               | 20mg once daily for 8 weeks                    | 40mg once daily for 4 weeks                | 30mg once daily for 4 weeks (BNF: 8 weeks)        | 20mg once daily for 6 weeks                       |
| Treatment of NSAID-associated ulcers | 20mg once daily for 4-8 weeks                   | 20mg once daily for 4 weeks                    | 20mg once daily for 4 weeks                | 30mg once daily for 4 weeks                       | -                                                 |
| Eradication of Helicobacter pylori   | 20mg twice daily for 1 week                     | 30mg twice daily for 1 week                    | 40mg twice daily for 1 week                | 20mg twice daily for 1 week                       | 20mg twice daily for 1 week                       |
| Zollinger-Ellison syndrome           | Initially 40mg twice daily, then 80-160mg daily | Initially 60mg once daily, then 20-120mg daily | Initially 80mg once daily, then 80mg daily | Initially 60mg once daily, then up to 180mg daily | Initially 60mg once daily, then up to 120mg daily |

Sources: Summaries of Product Characteristics (SPCs) from the electronic Medicines Compendium (eMC), at <http://emc.medicines.org.uk>, and relevant sections of the British National Formulary (BNF), 57th edition, March 2009.

Notes: Branded products of Esomeprazole, Omeprazole, Pantoprazole, Lansoprazole, and Rabeprazole Sodium include Nexium Tablets, Losec Capsules and MUPS Tablets, Protium, Zoton FasTab Tablets, and Pariet Tablets, respectively. Lansoprazole doses in BNF may differ from those in product literature.

**Table B2: Therapeutic indications and recommended doses (in adults) for selected H2RAs**

| Therapeutic indication                                    | Cimetidine                                          | Nizatidine                                                | Famotidine                            | Ranitidine                                               |
|-----------------------------------------------------------|-----------------------------------------------------|-----------------------------------------------------------|---------------------------------------|----------------------------------------------------------|
| Treatment of symptoms of GORD (incl. reflux oesophagitis) | 400mg 4 times daily for 4 to 8 weeks                | 150-300mg twice daily for up to 12 weeks                  | 20-40mg twice daily for 6 to 12 weeks | 150mg twice daily or 300 mg once daily for up to 8 weeks |
| Treatment of duodenal ulcers                              | 400mg twice daily (or 800mg once daily) for 4 weeks | 150mg twice daily (or 300mg once daily) for 4 weeks       | 40mg once daily for 4 weeks           | 150mg twice daily (or 300 mg once daily) for 4 weeks     |
| Treatment of gastric ulcers                               | 400mg twice daily (or 800mg once daily) for 6 weeks | 150mg twice daily (or 300mg once daily) for 4 weeks       | 40mg once daily for 8 weeks           | 150mg twice daily (or 300 mg once daily) for 4 weeks     |
| Treatment of NSAID-associated ulcers                      | 400mg twice daily (or 800mg once daily) for 8 weeks | 150mg twice daily (or 300mg once daily) for up to 8 weeks | -                                     | 150mg twice daily (or 300mg once daily) for 8-12 weeks   |
| Zollinger-Ellison syndrome                                | 400mg 4 times daily                                 | -                                                         | 20mg 4 times daily                    | 150mg 3 times daily                                      |

Sources: Summaries of Product Characteristics (SPCs) from the electronic Medicines Compendium (eMC), at <http://emc.medicines.org.uk>, and relevant sections of the British National Formulary (BNF), 57th edition, March 2009.

Notes: Branded products of Cimetidine, Nizatidine, Famotidine, and Ranitidine include Tagamet Tablets, Axid Capsules, Pepcid Tablets, and Zantac Tablets, respectively.

**Table B3: Therapeutic indications and recommended doses (in adults) for selected alginate-based products**

| Therapeutic indication                                                                                                                                   | Gaviscon Advance                                            | Gaviscon Liquid                                              | Peptac                                                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|
| Treatment of symptoms of GORD and dyspepsia, such as: gastric reflux; heartburn(incl. heartburn of pregnancy); acid indigestion; and reflux oesophagitis | 5-10 ml 4 times daily (after the main meals and at bedtime) | 10-20 ml 4 times daily (after the main meals and at bedtime) | 10-20 ml 4 times daily (after the main meals and at bedtime) |

Sources: Summaries of Product Characteristics (SPCs) from the electronic Medicines Compendium (eMC), at <http://emc.medicines.org.uk>, and relevant sections of the British National Formulary (BNF), 57th edition, March 2009, and 50th edition, September 2005.

**Table B4: Therapeutic indications and recommended doses (in adults) for selected antacid products**

| <b>Therapeutic indication</b>                    | <b>Tums</b>                                       | <b>Mucogel</b>                                                                                |
|--------------------------------------------------|---------------------------------------------------|-----------------------------------------------------------------------------------------------|
| Treatment of or relief from indigestion          | One or two as required, up to a max of 16 per day | 10-20ml three times daily 20 minutes to one hour after meals, and at bedtime, or as required. |
| Treatment of or relief from gastric hyperacidity | One or two as required, up to a max of 16 per day | 10-20ml three times daily 20 minutes to one hour after meals, and at bedtime, or as required. |
| Antacid therapy for gastric and duodenal ulcer   | -                                                 | 10-20ml three times daily 20 minutes to one hour after meals, and at bedtime, or as required. |
| Antacid therapy for gastritis                    | -                                                 | 10-20ml three times daily 20 minutes to one hour after meals, and at bedtime, or as required. |
| Relief from heartburn                            | One or two as required, up to a max of 16 per day | 10-20ml three times daily 20 minutes to one hour after meals, and at bedtime, or as required. |
| Relief from dyspepsia                            | One or two as required, up to a max of 16 per day | 10-20ml three times daily 20 minutes to one hour after meals, and at bedtime, or as required. |
| Relief from flatulence.                          | One or two as required, up to a                   | -                                                                                             |

|  |                   |  |
|--|-------------------|--|
|  | max of 16 per day |  |
|--|-------------------|--|

Source: Summaries of Product Characteristics (SPCs) from the electronic Medicines Compendium (eMC), at <http://emc.medicines.org.uk>.

## ANNEXE C: EPHMRA AND ATC CLASSIFICATION

Table C1: Summary of EPhMRA classification in the A group

| First Level                        | Second Level                                                        | Third Level                                 | Notes                                                                                                                            |
|------------------------------------|---------------------------------------------------------------------|---------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| A: Alimentary Tract and Metabolism | A1: Stomatologicals, mouth preparations, medicinal dentrifices, etc | ...                                         |                                                                                                                                  |
|                                    | A2: Antacids, antiflatulents and anti-ulcerants                     | A2A: Antacids, antiflatulents, carminatives | Includes plain antacids and combinations with alginic acid. Gaviscon products and other alginates are in this third-level class. |
|                                    |                                                                     | A2B: Anti-ulcerants                         | Includes PPIs and H2RAs (in separate fourth-level classes).                                                                      |
|                                    |                                                                     | A2C: Other stomach disorder preparations    | Includes herbal preparations and also plain alginic acid (but not Gaviscon products).                                            |
|                                    | A3: Functional gastro-intestinal disorder drugs                     | ...                                         |                                                                                                                                  |
|                                    |                                                                     | ...                                         |                                                                                                                                  |



Source: EPhMRA Anatomical Classification Guidelines 2009

**Table C2: Summary of the ATC classification in the A group**

| First Level                        | Second Level                                 | Third Level                           | Fourth Level                                            |
|------------------------------------|----------------------------------------------|---------------------------------------|---------------------------------------------------------|
| A: Alimentary tract and metabolism | A01: Stomatological preparations             | ...                                   | ...                                                     |
|                                    | A02: Drugs for acid-related disorders        | A02A: Antacids                        | ...                                                     |
|                                    |                                              | A02B: Drugs for peptic ulcer and GORD | A02BA: H2RAs                                            |
|                                    |                                              |                                       | A02BB: Prostaglandins                                   |
|                                    |                                              |                                       | A02BC: PPIs                                             |
|                                    |                                              |                                       | A02BD: Combinations for eradication of <i>H. Pylori</i> |
|                                    |                                              |                                       | A02BX: Other drugs for peptic ulcer and GORD            |
|                                    | A02X: Other drugs for acid-related disorders | None                                  |                                                         |

|  |                                                       |     |     |
|--|-------------------------------------------------------|-----|-----|
|  | A03: Drugs for Functional Gastro-intestinal disorders | ... | ... |
|  | ...                                                   | ... | ... |

Source: ATC website