

Evaluation of the OFT's
decision in 2011 on abuse of
a dominant position by
Reckitt Benckiser Healthcare
(UK) Limited and Reckitt
Benckiser Group

© Crown copyright 2015

You may reuse this information (not including logos) free of charge in any format or medium, under the terms of the Open Government Licence.

To view this licence, visit www.nationalarchives.gov.uk/doc/open-government-licence/ or write to the Information Policy Team, The National Archives, Kew, London TW9 4DU, or email: psi@nationalarchives.gsi.gov.uk.

Contents

	<i>Page</i>
1. Summary	3
2. Introduction	7
Background to the evaluation	7
Overview of the OFT Decision	7
3. Objectives and methodology	11
Objectives	11
Methodology for estimating impact on consumers	12
Direct market impact of the OFT Decision	13
Value of the possible savings to the NHS	14
4. The market for alginates and antacids	16
Introduction	16
Market overview	16
Overview of the AA market by prescription	16
Factors affecting competition in the market for AA drugs by prescription	18
Competition in the supply of prescription drugs	18
The impact of the GP prescribing decision on competition	19
The impact of the dispensing decision of pharmacists on competition	25
Potential for entry in to the AA by prescription market	27
Factors influencing the likelihood of generic entry	27
Conditions for entry in to the AA by prescription market	28
Potential for generic competition in the AA by prescription market by prescription	30
5. Direct market impact of OFT Decision	31
Introduction	31
Methodology	32
Market structure 2002 to 2013	33
Dispensing of AA liquid products prior to the Withdrawal	33
Dispensing of AA liquid products around the time of the Withdrawal	34
Dispensing of AA liquid products following the Withdrawal and the impact of the OFT Decision and investigation	35
Prices and costs 2002 to 2013	37
Conclusion	39
Overall impact	39
Could the OFT have intervened earlier	41
6. Possible savings to the NHS	43
Introduction	43
SoS and others' compensation claim	43
Overview of the claim	43
RB's response to claimants	44
Economic literature on the impact of generic competition in the UK	45
Overview	45
Evidence on changes in market share and prices	47
Case studies	48
Introduction	48
Selection of case studies	49
Case study 1: Fluticasone nasal spray	50
Case study 2: Liquid Fluoxetine	53
Estimate of possible savings to the NHS	55

Introduction.....	55
Estimated market shares and prices in the absence of the Withdrawal.....	58
Estimated market share acquired by generic versions of GL	61
Estimated possible savings	62
7. Conclusions	65
Appendix A: Remuneration of prescribed drugs though the primary care channel...	68
Appendix B: Differences in prescribing AA drugs in different parts of the UK	70
Appendix C: SoS and others claim.....	72
Appendix D: Key literature on the impact of generic competition in the UK.....	74
Appendix E: Selection of the case studies	76
Appendix F: Sensitivity of the estimated possible savings to alternative assumptions.....	78
Sensitivity to alternative assumptions about GA growth	78
Sensitivity to alternative assumptions about the price of generic versions of GL	79

1. Summary

- 1.1 As part of its performance framework agreement with the Department for Business, Innovation and Skills (BIS)¹ each year the Competition and Markets Authority (CMA) is required to undertake two ex post evaluations of past actions by the UK competition authorities (including one market study or investigation). For the year 2014/15, one of the cases the CMA has chosen to evaluate is the OFT Decision on the abuse of dominance by Reckitt Benckiser (RB) in the market for the supply of alginate and antacids by prescription (the Decision). In 2005 RB withdrew prescription packs of Gaviscon Liquid (GL) from supply to pharmacists (the Withdrawal). In 2011, the Office of Fair Trading (OFT) found this action to constitute an abuse of a dominant position.²
- 1.2 We undertake evaluations for a number of reasons, including to: learn lessons; assess the validity of past decision-making; and to evaluate the impact of the Decision. That is not to say that each evaluation undertaken by the CMA will look extensively at each of these. Rather, each will tend to focus on one or more of them depending on the nature of the decision being examined as well as other factors such as the available sources of information and resourcing requirements.
- 1.3 In this evaluation we have focused on the impact of the OFT investigation and Decision. The validity of the decision-making has not been a particular focus in this case because RB admitted to the abusive conduct. However, we do consider, at a high level, two aspects of the investigation and Decision where there is the potential for lessons to be learnt and which are also relevant for how we might view the impact of the Decision. These are: would the OFT have achieved a greater impact if the investigation and Decision had come earlier; and does the OFT Decision not to issue any directions in this case appear reasonable.
- 1.4 Our main focus in this evaluation has been on assessing the impact on consumers, for whom in the context of a public healthcare market we use taxpayers as a proxy.³ We look at the direct impact arising from the OFT

¹ For further details on the CMA performance framework agreement with BIS, see [Competition and Markets Authority: Performance Management Framework](#), January 2014.

² See 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, April 2011 ('OFT Decision').

³ As the primary objective of the CMA is to promote competition for the benefit of consumers, our evaluation tends to focus on the impact on consumer welfare whilst also considering the impact on overall economic welfare. In the case of a public healthcare market such as this one, where consumers either do not pay for services received or only pay a small proportion of the total cost, we use the cost to the taxpayer as a proxy for consumers. For the purposes of this evaluation we approximate this by net ingredients cost of AA drugs before discounts (often referred to as clawback) as this information is publically available to download from NHS information centres.

Decision as well as possible savings that might have accrued to the NHS were it not for the conduct by RB. The former is relevant to the objective of improving the functioning of the market and in doing so bringing benefits to consumers, whilst the latter informs our understanding of the impact of anti-competitive behaviour and the importance of rigorous enforcement and the deterrence of similar actions. We have not, however, examined issues as to the effectiveness of steps taken by the NHS to mitigate the impact of the Withdrawal which was disputed in litigation between the NHS and RB (see paragraph 6.8 below and Appendix B).

- 1.5 The OFT noted in the Decision that it did not expect as a result of its decision a significant direct market impact. However, we investigate if that was in fact the case. We look at the impact of the OFT investigation and Decision on direct market outcomes such as changes in: the number of suppliers of competing products; the markets share(s) of the incumbent supplier and competitors; and the price of alginate and antacid (AA) products. Our analysis uses prescription cost analysis (PCA) data for the United Kingdom obtained from various NHS information centres. We look for changes both following the announcement of the investigation and following the publication of the Decision. We also held discussions with a variety of stakeholders including the NHS, the Department of Health, manufacturers of generic drugs⁴, relevant trade bodies and pharmaceutical advisors to primary care organisations to help understand the reasons for any changes in the market or lack thereof. As noted in paragraph 1.10 below, we did not hold discussions with RB on these aspects.
- 1.6 Our analysis of PCA data showed no discernible direct market impact following the announcement of the OFT investigation or publication of its Decision. The reasons for this lack of impact are consistent with the reasons put forward at the time of the Decision by the OFT. Specifically, the lack of impact appears to be largely due to the success of RB's Withdrawal strategy in switching patients from GL to the (still patented) Gaviscon Advance (GA) along with patient and GP inertia and difficulties in prescribing alternatives to GA. The potential for GPs to switch away from GA to using GL or a generic version of it appears to have been severely restricted by the basic functionality of the GP prescribing software which did not suggest the availability of these alternatives to GA.
- 1.7 Our review of the factors that influence generic competition once an originator drug goes off patent did not identify any particular reason why, absent the Withdrawal, there could not have been a more significant impact from generic

⁴ Some of which also manufacture branded drugs.

competition in the market for AA drugs by prescription. There are a number of characteristics of this market which might limit, to some extent, the impact of generic competition, in particular: the fact the AA drugs are typically liquid products which limits the number of potential generic entrants; and the fact that AA drugs are compound drugs which could reduce the tendency of GPs to prescribe generically. However, there are also factors that lead us to believe that successful generic competition would have been possible in this market, absent the Withdrawal, once the generic name ARFOS had been assigned. These include: there being no barrier to high levels of generic prescribing of AA drugs by GPs especially as they are strongly encouraged to do so in most circumstances and they actually do so in large quantities where this is possible; pharmacists having strong incentives to dispense cheaper generic drugs when they can do so and appearing to be willing to do so in the case of AA drugs; and the potential for some additional generic entry.

- 1.8 The conclusion that there was the potential for more significant generic competition in this market implies that the NHS may have been able to have spent less on AA drugs were it not for the infringement of competition law by RB. Indeed the Secretary of State for Health (SoS) and others filed a claim for compensation of £90 million on this basis in the High Court. In February 2014 the claim was settled confidentially with no admission of liability by RB. Claims for compensation were also brought against RB by other parties, including certain generic manufacturers and suppliers. We did not review all the materials relating to those claims in preparing this evaluation; however, we note that those claims conflict in some aspects with the claim brought by the SoS.
- 1.9 As the value of the settlement is not publicly available we have estimated the possible savings to the NHS absent the Withdrawal. It is not possible to make a simple direct comparison between the value of the claim by the SoS and others and our estimate of these savings. As with any estimate of how the world would have evolved 'but for' a particular chain of events a number of assumptions need to be made and any estimated value is therefore subject to considerable uncertainty. In this case there is a range of plausible assumptions that could be made to generate an estimate of the possible savings and we consider that we have been deliberately conservative in the assumptions we have made. The estimates of possible savings that we have generated are appropriate for the purposes of an evaluation of competition enforcement only and are not intended for any other purpose, for example the calculation of damages.
- 1.10 We generate a range of estimated values for the possible savings drawing on a range of evidence including: the economic literature on the impact of generic competition in the UK; two case studies on the impact of generic

competition from two markets that are broadly similar to the AA market by prescription; and publicly available court documents from the claim by SoS and others. We have also had discussions with a number of stakeholders including the Department of Health (DH), the NHS, primary care professionals, pharmacy chains and generic drug manufactures in order to provide some context to our desk-based work. We did not consult with RB as part of this evaluation. We use this evidence to estimate a number of plausible scenarios for the market share that would have been achieved by generic versions of GL absent the Withdrawal. Based on these we estimate the total cost to the NHS of AA drugs absent the Withdrawal and compare these to the actual cost to estimate the value of the potential savings.⁵ The range of these estimates was between £31 million and £50 million in 2005 prices (2005 was the year of the Withdrawal).

- 1.11 We did not consult with RB as part of this evaluation although we did send to it a draft copy of the report shortly before its publication. In response RB stated that it did not agree with the assumptions and methodology underlying this evaluation, particularly as regards the likelihood of generic entry and the development of the market, nor did it agree with the conclusion that significant savings could have accrued to the NHS absent the Withdrawal. RB also highlighted that the evaluation did not have regard to all the material contained in claims brought by parties other than the SoS against RB relating to the OFT Decision.
- 1.12 Our review of the characteristics of the AA market and the factors that influence the extent of generic competition suggests there were some factors that might mitigate the potential for generic competition in this market. We have therefore been conservative and selected as our base case estimate of the possible savings the bottom of our estimated range (ie £31 million).
- 1.13 The value of the estimated possible savings is sensitive to the assumptions made about the evolution of the AA by prescription market absent the Withdrawal some of which we have not been able to fully test. However, we have been deliberately conservative in our approach and the possible savings could plausibly be different from our estimate we consider our results to be reasonable.

⁵ For the purposes of this evaluation we approximate this by net ingredients cost of AA drugs before discounts (often referred to as clawback).

2. Introduction

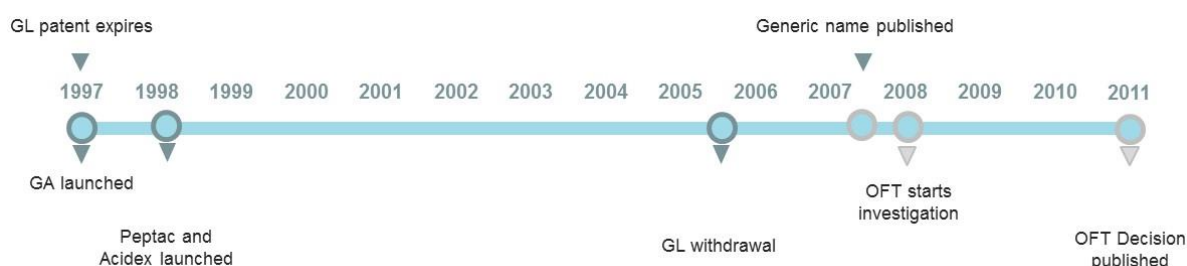
Background to the evaluation

- 2.1 The CMA is the UK's competition and consumer authority and its primary duty is to promote competition, both within and outside the UK for the benefit of consumers. It is an independent non-ministerial government department which, from 1 April 2014, brought together and took on the functions of the Competition Commission and many of the functions of the OFT. The CMA has a wide range of tools to use in addressing competition and consumer problems including carrying out investigations into mergers and markets, enforcing competition and consumer law and working with sector regulators. It also has certain other functions – in particular, considering regulatory references and appeals.
- 2.2 As part of its performance framework agreement with BIS⁶, the CMA is required to undertake two ex-post evaluations of past actions by the UK competition authorities (including one market study or investigation).
- 2.3 For the year 2014/15, one of the cases the CMA has chosen to evaluate is the OFT Decision on the abuse of dominance by RB in the market for the supply of alginate and antacids by prescription. In 2005 RB withdrew prescription packs of Gaviscon Liquid (GL) from supply to pharmacists. In 2011, the OFT found this action to constitute an abuse of a dominant position.

Overview of the OFT Decision

- 2.4 In Figure 2.1 below we set out a timeline of the key developments in the market over the past few years from the expiry of the patent on GL in 1997 to the present day.

Figure 2.1: Key developments in the market for alginates and antacids up to publication of OFT Decision



⁶ BIS (January 2014), [Competition and Markets Authority: Performance Management Framework](#).

- 2.5 Gaviscon products are alginate-based compounds. Alginates and antacids are both used to treat dyspepsia, acid reflux and/or gastro-oesophageal reflux disease (GORD)⁷. In 1997 the patent on GL expired, at about the same time RB launched a new product, Gaviscon Advance (GA).⁸ The expiry of the patent on GL was followed shortly by the launch of a generic version of it known as Acidex marketed under the brand name Peptac that was produced by Pinewood Healthcare and distributed by Teva Pharmaceuticals.
- 2.6 Between 1997 and 2005, both GL and GA were available via prescription and over the counter (OTC) in pharmacies.⁹ However, in June 2005, in advance of the publication of a generic name relevant to GL, RB withdrew prescription packs of GL from supply. Once the generic name had been published it would have been easier for Doctors to write prescriptions using the generic name instead of a brand name and the market share of GL would have faced more intense competition from generic versions of GL. Since the Withdrawal, only GA and OTC packs of GL have been available for prescription.¹⁰ Before the Withdrawal, GL was comfortably RB's leading Gaviscon product in the prescription channel. Since the Withdrawal the sales of GL through the prescription channel have fallen to an almost negligible level and GA has become by far the largest Gaviscon product.
- 2.7 The generic name Alginate Raft-Forming Oral Suspension (ARFOS) was published in August 2006 and came into effect on 1 January 2007. GL, Peptac and Acidex are listed in the British National formulary (BNF)¹¹ under the name ARFOS, whilst GA and another drug (Gastrocote) are listed under a catch-all 'Other compound alginate preparations' heading (which is unrelated to any monograph and/or generic name).¹²
- 2.8 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

⁷ The National Institute for Health and Clinical Excellence (NICE) defines dyspepsia as 'any symptom of the upper gastrointestinal tract, present for four weeks or more, including upper gastrointestinal tract, present for four weeks or more, including upper abdominal pain or discomfort, heartburn, acid reflux, nausea or vomiting'.

⁸ GA treat the same symptoms but has a different formulation to GL and therefore has a separate patent which expires in 2016.

⁹ Prescription packs are for supply to the NHS to be dispensed in response to a prescription. OTC drugs are sold directly to consumers without the need for a prescription.

¹⁰ Prescription and OTC packs of drugs are marketed and priced separately. Doctors are able to prescribe drugs for which only OTC packs are available such as GL. In response to these prescriptions Pharmacists will dispense an OTC pack.

¹¹ The British National Formulary is a pharmaceutical reference book that contains a wide spectrum of information and advice on prescribing and pharmacology, along with specific facts and details about many medicines available on the National Health Service.

¹² For further details, see [British National Formulary website: 1.1.2 Compound alginates and proprietary indigestion preparations](#).

development of full generic competition to its Gaviscon portfolio in the prescription channel.¹³

- 2.9 In its Decision published on 12 April 2011, the OFT considered that:
- RB held a dominant position in relation to the market for the UK supply of alginates and antacids (AA) by prescription; and
 - RB abused that dominant position through its conduct, including withdrawing and de-listing NHS presentation packs of GL in 2005 (the 'Withdrawal').
- 2.10 In its Decision, the OFT found that the relevant product market in this case is no wider than the supply of alginates and antacids by prescription in the UK.¹⁴ The OFT considered that RB held a dominant position in the relevant market (whether or not antacids were included in any relevant market definition) by retaining a market share of over 80% at least between 2004 and 2008.
- 2.11 The OFT found that the Withdrawal tended to restrict competition or was capable of having that effect¹⁵, noting that: RB expected the effect of the Withdrawal would be to hinder the development of full generic competition; RB expected the Withdrawal would enable it to preserve a very high market share; and at the time of the Withdrawal it would have been reasonable to expect the Withdrawal to significantly limit the GP provision of 'open' prescriptions. An open prescription is where GPs prescribe a drug by the generic name and pharmacies are free to choose to dispense any product that is described by the generic name. The OFT's view was that the Withdrawal could reasonably be expected to reduce the number of open prescriptions issued because when GPs used their prescribing software to search for Gaviscon products only GA would be found against which only closed prescriptions could be issued.¹⁶
- 2.12 The OFT imposed a financial penalty of £10.2 million, reduced from £12 million to reflect RB's admission and decision to cooperate as part of an early resolution agreement with the OFT.
- 2.13 In the Statement of Objections (SO), the OFT proposed to direct RB to reintroduce and re-list NHS packs of GL as a remedy. However, Pinewood,

¹³ The allegations were originally made public on the BBC's Newsnight programme after a whistle-blower had taken the story to them.

¹⁴ As outlined above, the OFT did not consider it necessary to determine whether antacids were in the same relevant markets as alginates, as it did not consider that such a distinction impacted upon its finding in relation to dominance.

¹⁵ See [OFT Decision](#), paragraph 6.164.

¹⁶ See [OFT Decision](#), paragraph 6.148.

Teva (the manufacturers/distributors of a generic version of Gaviscon Liquid) and the Department of Health (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 had 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 considered that it would be disproportionate to require RB to re-introduce NHS packs of GL.

- 2.14 The Decision by the OFT was followed by a claim for compensation to the High Court by the Secretary of State (SoS) and the National Health Service Business Services Authority (NHSBSA) as well as a number of Strategic Health Authorities and Primary Care Trusts ('SoS and others').¹⁷ The SoS and others submitted a claim for £90 million in compensation.¹⁸ This was settled out of court in February 2014 for an undisclosed and confidential amount with no admission of liability by RB. Claims for compensation were also brought against RB by other parties, including by generic manufacturers or suppliers such as Teva and Pinewood. We did not review all the materials relating to those additional claims in preparing this evaluation.

¹⁷ The Secretary of State for Health and others vs Reckitt Benckiser, Claim No. HC1100319.

¹⁸ The Secretary of State for Health and others vs Reckitt Benckiser, Claim No. HC1100319.

3. Objectives and methodology

Objectives

- 3.1 We undertake evaluations for a number of reasons, including: to learn lessons; to assess the validity of past decision-making; and to evaluate the impact of the Decision. That is not to say that each evaluation undertaken by the CMA will look extensively at each of these but will tend to focus on one or more of them depending on the nature of the decision being examined, as well as other factors such as the available sources of information and resourcing requirements.
- 3.2 In this evaluation we have focused on impact of the OFT investigation and Decision. The validity of the decision-making has not been a particular focus as in this case given that RB admitted to the abusive conduct. However we do consider, at a high level, two aspects of the investigation and Decision where there is the potential for lessons to be learnt and which are also relevant for how we might view the impact of the Decision. These are: would the OFT have achieved a greater impact if the investigation and Decision had come earlier? and does the OFT Decision to not issue any directions in this case remain appropriate?
- 3.3 When assessing the impact of an investigation and decision it is important to understand its objectives. In the case of competition enforcement there tend to be a number of general objectives including, but not limited to: bringing an end any abuse of competition law; applying a proportionate punishment; if possible, improving the functioning of the market; and the deterrence of further abuses of competition law.¹⁹ Each of these have more or less relevance depending on the specific characteristics of a case.
- 3.4 Our main focus in this evaluation has been on assessing the direct impact on consumers as well as assessing the possibility of cost savings to the NHS for AA drugs that might have accrued in the absence of the Withdrawal. The primary objective of the CMA is to promote competition for the benefit of consumers and our evaluation work tends to focus on the impact on consumers rather than on wider measures of economic benefit which also take into account benefits accruing to other parties such as private companies. In the case of a public healthcare market such as this one, where consumers either do not pay for services received or only pay a small proportion of the total cost, we use taxpayers as a proxy for consumers. We

¹⁹ The deterrence effect of covers a wide spectrum including deterrence of abuses in the particular market, similar types of abuses in other markets and more generally abuses of various types in the wider economy.

look at the direct impact from the OFT Decision in reducing costs to taxpayers as well as the value of any possible savings for the taxpayer that might have been realised in the absence of the conduct by RB. The former is relevant to the objective of improving the functioning of the market and in doing so bringing benefits to consumers, whilst the latter informs our understanding of the potential impact of anti-competitive behaviour and the importance of rigorous enforcement and the deterrence of similar actions. We have not, however, examined issues as to the effectiveness of steps taken by the NHS to mitigate the impact of the Withdrawal which was disputed in litigation between the NHS and RB (see paragraph 6.8 below and Appendix B).

- 3.5 Deterrence per se, particularly in relation to a specific case, can be difficult to evidence and we have not attempted to do so in this evaluation. We do however note that the OFT published work assessing the extent of the deterrence effect from the enforcement of competition law²⁰ and the CMA is currently undertaking joint work with the European Commission and the Netherlands Competition Authority to better understand the deterrence impact of competition policy.²¹

Methodology for estimating impact on consumers

- 3.6 In general we would consider that the main direct impacts on consumers of a decision such as this one would arise through an increase in competition in the market in question leading to better outcomes for consumers across a range of measures including reduced prices, better quality and greater choice and innovation.²² As part of this evaluation we estimate the impact on direct market outcomes in the AA market resulting from this Decision by looking at changes in variety of metrics such as price, market shares, number of suppliers and products as well as the overall cost to the NHS.
- 3.7 In assessing the direct impact on consumers of the OFT Decision we note that at the time of its Decision the OFT did not think that there would be much change in the AA market following the Decision. This was because GPs and patients had changed their behaviours following the Withdrawal and this was unlikely to change due to inertia from GPs and patients. This was the main reason why the OFT did not issue a direction to RB to reintroduce prescription packs of GL.

²⁰ [Assessing the impact of competition interventions on compliance and deterrence, A report by London Economics for the OFT 2011.](#)

²¹ The CMA jointly hosted a conference on this matter in September 2015.

²² See the OFT report: [Evaluating the impact of the OFT's 2001 abuse of dominance case against Napp Pharmaceuticals.](#)

- 3.8 As part of this evaluation we have also estimated the value of the possible savings to the NHS (and therefore to taxpayers) that might have been realised in the absence of the Withdrawal. We have not, however, examined issues as to the effectiveness of steps taken by the NHS to mitigate the impact of the Withdrawal which was disputed in litigation between the NHS and RB (see paragraph 6.8 below and Appendix B). Though this value may not represent a direct benefit to consumers it is important to understand the extent of any possible savings as this helps us to understand the importance of competition enforcement in the pharmaceutical market and more generally. Estimating the value of the possible savings that may have occurred in this specific market can help us understand the potential impact of competition enforcement when deterring similar behaviours.
- 3.9 In the context of the possible savings we note that the Decision by the OFT was followed by a claim for compensation by the SoS and others in the High Court. The claim was intended to secure compensation for any additional cost incurred by the NHS as a result of RB's actions. As we discuss later the NHS action was a direct follow on from the OFT Decision and the claim relied heavily upon the evidence set out within it. Claims for compensation following the OFT Decision were also brought against RB by other parties, including certain generic manufacturers or suppliers. We did not review all the materials relating to those claims in preparing this evaluation, and we note that some of these claims conflict with the assumptions underlying the claim by the SoS.
- 3.10 In the next chapter we provide background on the workings of the market for drugs supplied by prescription in general and the AA market in particular. This provides a framework for our analysis of:
- the direct impact on consumers of the OFT investigation and Decision (set out in Chapter 5); and
 - the value of the possible savings to the NHS absent the Withdrawal (set out in Chapter 6).

Direct market impact of the OFT Decision

- 3.11 In order to assess the direct market impact of the OFT investigation and Decision we have analysed the changes in the AA market since the investigation and Decision in the context of the longer-term development of this market. To do this we undertake a number of pieces of quantitative and qualitative analysis. These include analysis of:
- Prescribing behaviours – Using Prescription Costs Analysis (PCA) data collated by the UK Health and Social Care Information Centres (HSCIS)

we investigated if and how GPs prescribing behaviour changed after the announcement of the OFT investigation in 2008 and/or following the OFT Decision in 2011. We also explored through interviews with relevant stakeholders and desk based research the reasons for our findings with regard to any changes or otherwise in GP prescribing behaviour.

- Prices – Using PCA data we have examined how the cost per quantity of AA drugs have changed over the past few years since the OFT intervention.
- Market structure – Using Information from the PCA data and desk based research we have examined changes in market shares and entry into the AA by prescription market.
- Total cost for the NHS – Using the PCA data we estimate the change in total cost to the NHS of procuring AA drugs.

3.12 The PCA data provides information on Net Ingredient Cost (NIC) of drugs and the volumes of prescription and quantity of drugs provided. NIC refers to the basic price as listed in the Drug Tariff²³ of drugs multiplied by volume and does not include any dispensing costs or fees. Although the intention behind the design of the NHS reimbursement system is that the amount paid by the NHS represents the amount paid by the pharmacies for drugs (plus a profit margin) but in practice these values often differ.²⁴ For the purposes of this evaluation we use the NIC data to estimate prices and cost as it is easily accessible from publically available sources.

Value of the possible savings to the NHS

3.13 To estimate the value of a possible savings to the NHS we have analysed how the AA market might have developed absent the Withdrawal. To do this we have undertaken several pieces of quantitative and qualitative analysis. The pieces of analysis we have undertaken include:

- examination of the NHS claim against RB – we have used publicly available documents to evaluate the parameters of the NHS claim for

²³ [The Drug Tariff](#) provides information on what will be paid to contractors for NHS Services including both reimbursement (eg the cost of drugs and appliances supplied against an NHS Prescription form) and remuneration (eg professional fees/allowances which are paid as part of the NHS pharmacy contract).

²⁴ Pharmacies are reimbursed for its NIC less a deduction or 'clawback' of part of the average discount at which it is assumed to have purchased the medicines from manufacturers and wholesalers, and the rate of deduction is larger for higher values of monthly NIC, to in theory reflect the greater discounts available to pharmacies purchasing larger quantities of medicines. However, while clawback is intended to reflect the purchasing discounts a pharmacy received across all of its medicines in aggregate, it will not necessarily accurately reflect the level of discount earned on a specific product.

compensation for the alleged overcharge. As noted above, we have not reviewed all materials relating to other claims brought against RB in relation to the OFT Decision, some of which conflict with the NHS claim;

- analysis of two relevant case studies – we studied the impact of patent expiry in markets similar to Gaviscon but where there was no behaviour similar to the Withdrawal; and
- review of academic literature on the impact of generic competition in pharmaceutical markets, in particular the UK market, after the expiry of the patents on originator drugs.²⁵

3.14 We use these pieces of analysis to generate a range of quantified scenarios for what the expected impact of generic competition might be in pharmaceutical markets where competition was unfettered by behaviour such as the Withdrawal. We then select a base case impact from this range based on evidence we have collated on the factors that influence generic competition and the characteristics of the AA market.

²⁵ An originator drug is as a novel drug that was under patent protection when launched onto the market. GL or GA are examples.

4. The market for alginates and antacids

Introduction

- 4.1 In this section we provide an overview of the AA market and describe how competition works in the market for prescription drugs including the key influences on the development of competition in prescription drug markets. We also consider what the key barriers to entry for generic entrants into the UK drug market are and how they apply to the AA by prescription market.
- 4.2 This chapter provides the background for our assessment of the direct market impact of the OFT Decision and the possible savings to the NHS. Understanding the market and the key influences on the development of competition within it is important for assessing the reasons behind our findings with regard to direct impact and also calibrating estimates of the possible savings to the NHS.

Market overview

Overview of the AA market by prescription

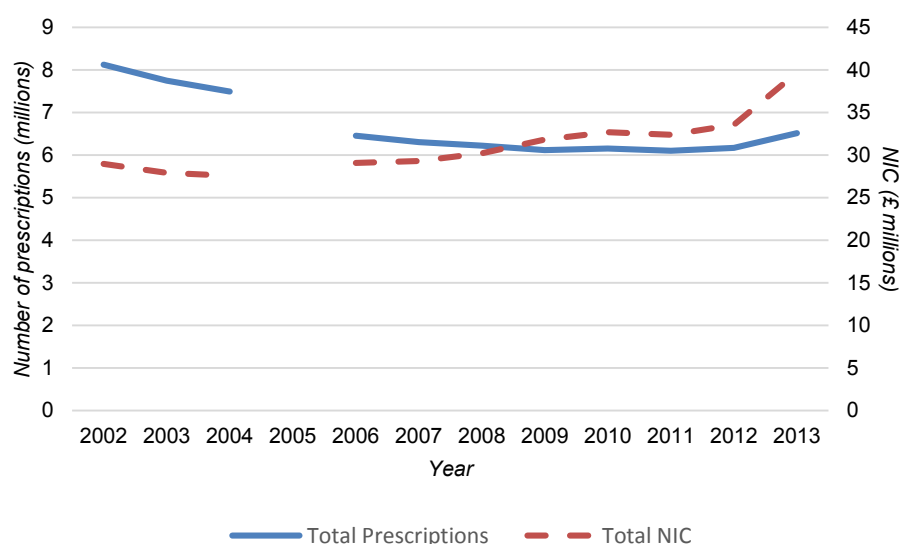
- 4.3 Antacids are used to treat dyspepsia, acid reflux and gastro-oesophageal reflux disease (GORD) by neutralising the acid in the stomach. Alginates have a different mode of treatment. They contain a foaming agent called sodium alginate (derived from seaweed) that reacts with the other active ingredients 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.
- 4.4 Most alginate and antacid products are available through both NHS prescriptions and the OTC in community pharmacies. The Withdrawal affected only the supply of the products in the NHS prescription channel.
- 4.5 AA drugs on prescription are provided either by GPs and community pharmacies²⁶ (primary care) or by hospitals and hospital pharmacies (secondary care). Each of these routes are different in the way they procure and supply prescription drugs. Our analysis, and the description of the market set out in the remainder of this section, has focused on the provision of AA

²⁶ Community pharmacists were known in the past as chemists. Community pharmacies are situated in high street locations, in neighbourhood centres and in supermarkets. There are several different types and sizes of community pharmacies, ranging from the large chains with shops on every high street or in edge of town supermarkets, to small individually owned pharmacies.

drugs through primary care. This is because the primary care route is by far the most important for the supply of AA drugs.²⁷

4.6 Figure 4.1 shows how the size of the AA by prescription market has evolved since 2003 both in terms of the number of prescriptions issued and the NIC of AA drugs. As noted in paragraph 3.12 the NIC refers to the basic price as listed in the Drug Tariff of drugs multiplied by volume and does not include any dispensing costs or fees. This approximates the amount paid to by the NHS to pharmacists for the provision of AA drugs.²⁸ The number of prescriptions issued declined from over 8 million in 2002 to closer to 6 million in 2008 and has remained around that level since then. In terms of NIC, the value of these prescriptions grew steadily from around £29 million in 2002 to £33 million in 2012, before a sharp increase to £39 million in 2013.

Figure 4.1: Size of the AA by prescription market



Source: CMA analysis of data retrieved from the websites of the NHS Information Centres in England, Scotland, Wales and Northern Ireland. Data for year 2005 was unusable.

4.7 The market is largely consists of liquid products (either solutions or suspensions) and these accounted for more than 74% of the market by value

²⁷ The value of hospital procurement and prescription of AA drugs is relatively small. CMA analysis of data we obtained from the Central Medicines unit (CMU) suggests that in 2013/14 the value of AA drugs procured and prescribed by hospitals is less than 10% (approximately £300,000) of the annual value of those prescribed by GPs.

²⁸ When pharmacy contractors are reimbursed for the cost of medicines and appliances dispensed, a deduction is made to their payments, known as 'discount deduction' (sometimes referred to as 'clawback'). The level of discount varies depending on the value of products dispensed by a pharmacy in a given month and reflects the assumed discount that pharmacies receive from wholesalers. The intention is that the amount paid by the NHS represents the cost paid by the pharmacies for drugs (plus a profit margin) but in practice these values often differ.

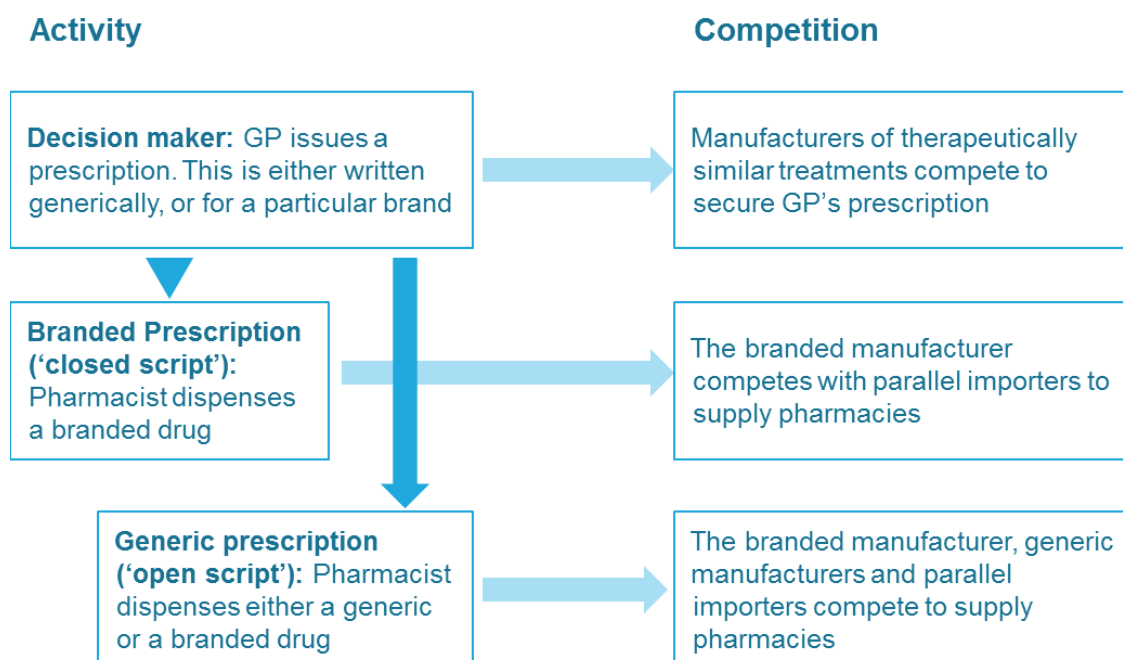
and in excess of 80% of the market by volume between 2003 and 2012.²⁹ The other main form of AA drugs are tablets.

Factors affecting competition in the market for AA drugs by prescription

Competition in the supply of prescription drugs

4.8 The OFT report on the Pharmaceutical Price Regulation Scheme (PPRS)³⁰ identified how competition for the supply of prescription drugs in primary care works. Figure 4.2 below is an adapted version of a figure from the PPRS report and provides an overview of how competition works.

Figure 4.2: Competition in the supply of drugs in primary care



Source: Adapted from: The Pharmaceutical Price Regulation Scheme. An OFT market study.

4.9 The key decisions that are made on the demand side are those taken by GPs and pharmacists when prescribing and dispensing drugs. A GP can issue a prescription that is either 'closed' or 'open' where:

- closed prescriptions are written for a brand name and so only that specific drug can be dispensed in response to them; and

²⁹ However, there was a notable dip in the market share of liquid products between 2012 and 2013 both in volume (from 74% to 67%) and volume terms (from 80% to 75%).

³⁰ The Pharmaceutical Price Regulation Scheme. An OFT market study (2007).

- open (or 'generic') prescriptions are written for a generic drug name (often the name of a drug's active ingredient) and so any therapeutically equivalent drug which meets the prescription can be dispensed.
- 4.10 On the supply side drug manufacturers compete to influence the prescribing and dispensing decisions of GPs and pharmacists.

The impact of the GP prescribing decision on competition

- 4.11 In this section we first discuss the key factors that influence the GP prescribing decision and how these apply to the AA market. We then give an overview of the rates of generic prescribing in the UK and consider the extent of and potential for generic prescribing in the AA by prescription market.
- 4.12 As we discuss below, the prescribing decision, and in particular the rate of open prescribing, is a key influence on the types of drugs that are purchased by the NHS and therefore on the potential for competition from generic versions of originator drugs. In general the rates of generic prescribing of drugs in the UK are very high but this does not appear to be that case for AA drugs. However, as we explain below, we do not consider there to be any insurmountable barrier to high rates of generic prescribing of AA drugs.

Factors influencing the prescribing decision

- 4.13 The OFT report on PPRS sets out several factors that influence GPs' prescribing decisions (and their assessments of cost and clinical effectiveness).³¹ These include the GP contract; national and local guidance; marketing activity by pharmaceutical companies; their own judgment and the influence of peers; and patient preference. The work undertaken by the Gaviscon case team as part of this evaluation suggests that these factors are all still influential in GPs' prescribing decision but would add to those the influence of GPs' prescribing software. The functionality of prescribing software can have a big influence of GP prescribing, particularly with regard to the prescribing of generic equivalents to branded drugs.

GP contract

- 4.14 The PPRS report noted that the General Medical Services (GMS) contract was the most important influence on the GP's prescribing decision and that the contract provided GPs with only weak financial incentives to prescribe cost effectively. Our understanding is that the GMS contract for GPs is largely

³¹ [The Pharmaceutical Price Regulation Scheme. An OFT market study \(2007\)](#), paragraph 2.29.

unchanged, certainly with regard to financial incentives for prescribing, since the publication of the PPRS study.

GP prescribing software

- 4.15 To facilitate generic prescribing the most commonly used types of GPs' prescribing software are 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. 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. Some prescribing software used by GPs allows primary care organisations (PCOs, a general term for English commissioning care groups (CCGs)³²) or individual GP practices to tailor the choices provided to GPs to reflect local guidance. As we describe in more detail below, the functionality of the basic GP software, combined with the Withdrawal, the large scale switching to using GA and the fact the generic name, ARFOS, did not cover GA would appear to have had a significant effect on the prescribing of AA drugs.
- 4.16 The use of ScriptSwitch³³, which is a software package which supplements the GP's normal prescribing software, has become increasingly common. ScriptSwitch is described as primarily a medicines management tool which can help to improve consistency and conformity in pricing as well as helping to improve cost efficiency. It draws on a range of national guidance and databases from bodies such as the National Institute of Clinical Excellence (NICE) National Prescribing Centre³⁴ but is also tailored to local needs. ScriptSwitch works at the point at which a drug is prescribed by GPs and has the functionality to automatically display a prescribing recommendation should the locally tailored database require this. So, for example, it would be possible to make recommendations to GPs through ScriptSwitch that they prescribe products other than GA even though there are no generic versions of it.
- 4.17 It is not clear that the use of ScriptSwitch has had much of an impact on the prescribing of alginates. Potentially it would be a mechanism for influencing the prescribing of AA drugs but the (limited number of) primary care professionals we received information from suggested that whilst the

³² Established by the Health and Social Care Act 2012 they came into being on 1 April 2013. Succeeding Primary Care Trusts.

³³ More detail is on the [ScriptSwitch website](#).

³⁴ For more information see its [website](#).

organisations they worked for did use ScriptSwitch, there were no recommendations provided to GPs through it relating to prescribing AA drugs.

National Guidance

- 4.18 National bodies such as the NICE, the Scottish Medicines Consortium (SMC), the Scottish Intercollegiate Guidelines Network (SIGN) and the All Wales Medicines Strategy Group (AWMSG) provide guidelines on clinical and cost effective care including the use of medicines and prescribing.³⁵ In addition the NHS provides a range of medicines management services to support cost effective prescribing including producing prescribing comparators for some drug classes.³⁶ As we discuss later, GP are encouraged to prescribe generically where possible.
- 4.19 However, whilst a significant amount of guidance and other initiatives are in place to assist GPs to prescribe cost effectively, our review of these documents and our discussions with various stakeholders, including the DH, suggest that very little of this is directly applicable to the choices that GPs will make when prescribing AA drugs. For example, the latest NICE guidelines on the treatment of Dyspepsia and GORD³⁷ hardly mentions AA drugs.³⁸ Furthermore, the DH told us that AA drugs were not covered by the NHS work on prescribing comparators as, given the resource intensive nature of the work, it tended to focus on larger markets where the potential for savings are greater.

Local measures

- 4.20 In all four parts of the UK, the delivery of frontline healthcare, including medicines, is centred on PCOs, and what are usually referred to as Health Boards in Wales, Scotland and Northern Ireland. Collectively, PCOs receive around 80% of NHS funds and individually they manage the delivery of most health care to populations of 100,000 to 300,000.

³⁵ In Northern Ireland the NICE guidelines are reviewed locally by the National Executives' Department for Health and then, where applicable, certified for use in Health and Social care.

³⁶ Including the production of cost and volume comparators within therapeutic classes and a potential generic savings report a various organisational levels. [See NHS Prescription Services: Prescribing comparators.](#)

³⁷ [NICE clinical guideline 184.](#)

³⁸ They are only mentioned in the context of the treating patients who have long-term symptoms using 'the effective lowest dose by trying as-required use [of drugs such as protein pump inhibitors or PPIs] when appropriate, and by returning to self-treatment with antacid and/or alginate therapy'. NICE clinical guideline 184, paragraph 2.2.5.

- 4.21 PCOs may seek to encourage GPs to prescribe cost effectively through local incentive schemes or guidance³⁹ and other arrangements. The implementation of such schemes is a choice for the local PCOs and where they do choose to implement incentive schemes they have significant flexibility regarding the scope and format of them.⁴⁰
- 4.22 Our desk research and discussions with various stakeholders including the DH, members of the Pharmaceutical Advisory Group (PAG)⁴¹ and manufacturers of generic drugs, has revealed that there is very little information aggregated at a national level about local prescribing incentive schemes or joint formularies. However, the discussions did suggest that there will be some significant regional variation in the coverage and format of local initiatives and in the extent to which they influence GP prescribing behaviour. One message that was repeated by several stakeholders was that the prescribing of AA drugs may well not be a particular focus of local initiatives given they represent a fairly small proportion of total expenditure, and therefore potential savings, for PCOs.⁴² This is despite PCOs themselves having fairly strong financial incentives to manage expenditure on drugs efficiently as the cost of the drugs they prescribe comes directly from their own budgets.

Pharmaceutical company activity

- 4.23 Pharmaceutical firms are active in seeking to persuade GPs of the benefits of their products in order to get them prescribed. During the evaluation we have only been able to obtain views from a limited number of professionals directly involved in primary care regarding the impact of pharmaceutical company activity on the prescribing of AA drugs. One observation that was made was that brand reputation and/or the identity of the firm manufacturing a drug would tend to be less relevant to the prescribing choice in a mature market, such as the AA by prescription market. In a mature market the drugs and

³⁹ For example many PCOs have local formularies, either on their own or jointly with other PCOs, which include recommendations and guidance on prescribing. These recommendations and guidance can be delivered via ScriptSwitch.

⁴⁰ Little information is available at a national level regarding the coverage and format of these schemes. In our discussions with a small number of pharmaceutical advisers to CCGs in England it was suggested that these schemes would generally include prescribing targets for GP surgeries, for example with regard to rates of generic prescribing for a range of therapeutic categories of drugs or the level of antibiotic prescribing. Where these targets are met the GP surgery will generally receive a small financial reward to be used within the practice.

⁴¹ The PAG is a semi-formal group that aims to promote good practice in medicines management throughout PCOs in England. Its membership comprises 20 Pharmaceutical Advisers to CCGs from various regions across England as well as members from NHS England, the DH and the Royal Pharmaceutical Society.

⁴² This included the DH, generic manufacturers and the ABPI. We received responses from two CCGs one of which suggested they recommended Petpac in preference to GA and GL (although they did not have any software such as ScriptSwitch which might be used to provide the recommendation at the point of prescribing) and the other that noted the current price differential as not sufficient for them to do so. Where the recommendation was made the rate of prescribing of Peptac (relative to GA and GL) was more than twice that in the area where no recommendation was made.

manufacturers are well known in comparison to market where the products and/or manufacturers are newer and perhaps more unproven.

Rates of generic prescribing

- 4.24 For competition to be effective, particularly when originator drugs have gone off patent it is important that there are high rates of open prescribing by GPs as this will encourage market entry and acquisition of market share by generic alternatives to the originator.

Generic prescribing of drugs in the UK

- 4.25 GPs are encouraged to write prescriptions using the drug's chemical name, whether or not the product in question is out of patent, unless there are specific clinical reasons not to.⁴³ This is typically known as 'generic prescribing' and is encouraged throughout a product's life cycle. 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.
- 4.26 In general, rates of generic prescribing in the UK are very high. The EC Pharmaceutical Sector Inquiry found that over the period 2000 to 2007, the market share of generic pharmaceuticals was about 60% (by volume) in the UK.⁴⁴ This was the third highest rate of generic prescribing in the EU behind Germany and Poland.⁴⁵ More recently the HSCIC published data showing that in England in 2011 83% of all drugs in primary care were prescribed generically and 84% of 'Gastro-intestinal system' drugs, which includes AA drugs, were prescribed generically.⁴⁶

Generic prescribing of AA drugs

- 4.27 The evidence suggests that throughout the product lifecycle GPs prescribe generically in large quantities for most drugs. However, the picture is different with regard to the prescribing of AA drugs and in particular alginates.

⁴³ See for example this [NHS article on brand names and generics](#) or the guidance on generic prescribing published by the [Greater Manchester Medicines Management Group](#).

⁴⁴ Figure 11, p62. The EC European commission – DG COMP, *Pharmaceutical Sector Inquiry* (8 July 2009).

⁴⁵ The report from DG COMP show that the ranges varies significantly and are less than 20% in Belgium, France, Finland, Spain and Italy.

⁴⁶ [Prescriptions Dispensed in the Community: England, Statistics for 2001 to 2011, HSCIS 2012](#).

- 4.28 Alginates tend to be prescribed by brand name rather than generically. Primary care professionals have told us that this is largely because these are compound drugs containing several active ingredients and therefore it is generally easier and more accurate to prescribe the drugs by brand name. A consequence of this was that, as the OFT found, the assigning of a generic name would be particularly important in this market as it would facilitate generic prescribing and would allow GPs to find generic alternatives through their prescribing software. As noted in the OFT Decision, RB itself recognised that the situation with regard to GL and GA was unusual because most products have a ‘monograph from birth’ as they tend to have a single active ingredient which unambiguously identifies that drug.⁴⁷
- 4.29 A number of stakeholders also mentioned that patient preference played a greater role in the prescribing of alginate drugs than it does for most other drugs. This was due to the fact that unlike most drugs prescribed in the UK, alginates tend to be liquids and patients can have reasonably strong preferences regarding the taste and texture of liquid products. This is another factor that may drive relatively high rates of prescribing by brand for alginates.
- 4.30 CMA analysis of NHS England data for February 2015 shows that just 11% of ‘alginate acid compound drugs’ were dispensed against a generic prescription.
- 4.31 However, we would not consider the above to be insurmountable barriers to large scale generic prescribing of alginates given: 1) the nationwide push for drugs to be prescribed generically; 2) the assigning of a generic name covering two of the major drugs in the market; 3) what healthcare professionals have told us about the therapeutic equivalence of the leading brands (see below).
- 4.32 With regard to the three leading alginate products, pharmacists and primary care professionals indicated to us that they would regard GA, GL and Peptac as therapeutically equivalent.⁴⁸ The products were considered to work in the same way and with similar effectiveness. The main difference being the strength of the GA and, it was also noted, that GA contained less sodium.⁴⁹

⁴⁷ See [OFT Decision](#), paragraph 6.59.

⁴⁸ In particular one large pharmacy chain suggested that when purchased over the counter they expect that based on the products SPC they would expect that pharmacists working in their branches would consider the three equivalent. The responses we received from pharmaceutical advisors to CCGs indicated that they were happy for GPs to prescribe either Gaviscon or Peptac. Desk based research of recommendations in local formularies suggests that it is common to list Peptac alongside GA as regards ‘Compound alginates and proprietary indigestion preparations’ that can be prescribed.

⁴⁹ GA has twice the concentration of sodium alginate and contains potassium carbonate rather than sodium carbonate.

4.33 Rather we would suggest that the low rates of generic prescribing are in large part due to the Withdrawal followed by the large scale switching to prescribing GA. Once GPs and patients had switched to using GA it would mitigate against the use of the generic name ARFOS after it had been introduced in 2007 for a number of reasons, including:

- GA was not covered by the name ARFOS, so GPs would not use it to prescribe GA and ARFOS would not be suggested by a generic name by the basic functionality of the prescribing software;
- AA drugs do not appear to have been a particular focus of attention for national and local initiatives to encourage more cost effective prescribing, which could have been achieved by switching patients from the more expensive GA to Peptac and other potential generic versions of GL; and
- GPs appear to have very weak direct financial incentives through their contracts to drive a shift away from GA through prescribing of ARFOS themselves.

The impact of the dispensing decision of pharmacists on competition

4.34 In this section we discuss the dispensing decision of pharmacists and the factors that influence that decision. We consider how this might influence competition, or the potential for competition, in the AA by prescription market.

4.35 Drugs supplied through primary care are prescribed by GPs and distributed through community pharmacies. In the community segment, pharmaceutical companies distribute supplies through a limited number of pharmaceutical wholesalers, who in turn sell products on to community pharmacies.⁵⁰ Wholesalers are able to obtain a discount from pharmaceutical companies when purchasing drugs in bulk. Additionally some manufacturers supply drugs directly to pharmacies and in some cases medicines are imported from other jurisdictions (Parallel imports).⁵¹

4.36 We describe in detail how pharmacists are remunerated for the provision of drugs in response to a prescription in Appendix A. The mechanism for remuneration is designed so that pharmacists are strongly incentivised to reduce the cost of the drugs they dispense. We note that whilst there are mechanisms in place to ensure that the amount of remuneration that the NHS pays to pharmacies is the same as the amount they pay to wholesalers and/or

⁵⁰ Based on desk research and our discussion with stakeholders.

⁵¹ As set out in the [Annex B of the OFT's Market Study: Pharmaceutical Price Regulation Scheme \(February 2007\)](#).

manufacturers (plus an allowance for profit on the buying of pharmaceuticals known as retained margin), this is not always the case.

- 4.37 Pharmacists' dispensing decisions are guided by a multitude of professional standards, guidance and regulation.⁵² The primary concern in all cases will be the wellbeing of the patient. However, due the remuneration mechanism, they also consider the cost implications of their dispensing decisions.
- 4.38 As part of this evaluation we received a small number of responses to an information request sent to retail and wholesale pharmacy chains.⁵³ The responses covered a range of issues relevant to the decisions made by pharmacists employed by the chains when dispensing drugs in general and when dispensing AA drugs in particular.
- 4.39 The responses suggested that, as would be expected, a pharmacist's dispensing decision would depend to a large extent on whether a prescription was for a branded product or was an open prescription. As described above, when in receipt of a branded prescription they are required to prescribe the specified product. When dispensing against an open prescription pharmacists will take into account a range of factors related to the wellbeing of the patient, including the previous medication the patient had been on and, to some extent, patient preference. Commercial considerations such as dispensing a preferred brand and/or a less expensive product would also influence the decision all else being equal.
- 4.40 In the particular case of AA drugs at least one major pharmacy mentioned they would expect pharmacists in their outlets to regard GL, GA and Acidex/Peptac as therapeutically equivalent given the Summary of Product Characteristics (SPC) set out in each products' Marketing Authorisation.⁵⁴ However, it was noted that in response to a generic prescription for ARFOS only GL and Acidex/Peptac could be dispensed. The same pharmacy chain also stated that in response to a prescription for ARFOS, Peptac was the most commonly dispensed of the available products.
- 4.41 Where a pharmacist had discretion regarding which type of AA drug to dispense it was noted by the pharmacy chains, as well as a number of other stakeholders, that patient preference would be a consideration in the dispensing decision, perhaps more so than in the case of some other

⁵² For example, the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, the standards required by and the guidance issued by the Pharmacist's professional body the Royal Pharmaceuticals Society and the regulator the General Pharmaceutical Council.

⁵³ Whilst we received only a small number of responses to our information request those we received came from businesses that covered a significant share of prescription drugs supplied by wholesale and retail pharmacies.

⁵⁴ The SPC is the basis of information for healthcare professionals on how to use the medicine and it is specified in the marketing authorisation. The marketing authorisation is effectively a licence to bring a drug to market.

categories of drugs. This was because the majority of these types of drug were liquid products and patients often have clear preferences with regard to the taste and texture of the liquid products, especially if they have had previous experience of a product.

- 4.42 Pharmaceutical companies seek to influence the decision of pharmacists regarding the dispensing of drugs in response to an open prescription. One of the large pharmacy chains that we spoke to noted that there were a number of methods used by pharmaceutical companies to influence the dispensing of drugs which might include promotions or discounting. However these tended to be more common for OTC drugs.
- 4.43 Where a pharmacist receives a closed prescription, then clearly they have no discretion regarding which drugs they dispense. In response to a prescription for GA, for example, they would always prescribe GA. However it would seem fairly likely that in response to a AFROS prescription they would be prepared to dispense either the generic version of GL currently available, Peptac, or other generic versions that may emerge given: the financial incentives they face; the views expressed on the therapeutic equivalence of GA, GL and Peptac; and the indication from one large pharmacy chain that they generally dispense Peptac in response to prescriptions for ARFOS.

Potential for entry in to the AA by prescription market

- 4.44 As we discuss in more detail in Chapter 5, the market for AA drugs has been very stable since the time of the Withdrawal and, with the exception of Peptac, there has been no entry of note since the expiry of the patent on GL. Furthermore, as we discuss in Chapter 6, the level of entry observed in the AA by prescription market since the expiry of, at that time, the most popular drug in the market is significantly below that commonly observed in UK drug markets.
- 4.45 In this section we briefly consider what are considered to be the key barriers to entry in the UK prescription drug market and how relevant they are to the AA by prescription market.

Factors influencing the likelihood of generic entry

- 4.46 In 2002 the DH and the Association of British Pharmaceutical Industry (DH/ABPI 2002) published an extensive study on competition in the supply of branded medicines to the NHS. As part of the study they looked at what was described as off patent competition and the impact of competition from generic drugs. They identified a number of factors that influence why generic

entry into some markets may not happen or be relatively slow.⁵⁵ These included the:

- size of market: in most cases, generic companies are not interested in small and/or rapidly declining markets;
- 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 and the existence of additional manufacture or process patents;
- availability of raw material: there may be some cases where the supply of the raw material is controlled by the originator company, either by use of patents or by other means; and
- generic prescribing: there are wide variations in the rate of generic prescribing between individual products. Generic prescribing is often lower for compound products because it is much simpler for prescribers to write and pharmacists to recognise the branded name.

Conditions for entry in to the AA by prescription market

4.47 At the time of the investigation RB asserted that two of these factors represented barriers to entry that were particularly applicable to the AA by prescription market and as such the typical features and benefits of generic competition did not apply to the same extent as they would to other markets.⁵⁶ The two barriers identified were:

- the size of market – RB suggested that the AA by prescription market was relatively small; and
- the nature of the product - Gaviscon is primarily supplied in liquid form and RB argued that liquid product markets typically attract more limited generic entry because they need to be produced relatively close to the point of use.

⁵⁵ See section 5 of component 3 of [PPRS - The Study into the Extent of Competition in the Supply of Branded Medicines to the NHS Department of Health and the Association of the British Pharmaceutical Industry December 2002](#).

⁵⁶ See OFT Decision, paragraph 2.89.

- 4.48 However, in its Decision the OFT did not agree that the AA by prescription market was small. In 2004 (the year prior to the Withdrawal) the UK market for GL and Peptac alone (ie excluding the still in patent GA) had a NIC of £13 million and was not experiencing declining sales, thus placing it in the high value category identified by the DH/ABPI (2002) report.⁵⁷ The OFT also noted that, although it was indeed the case that alginates are typically delivered in liquid form, one liquid alginate producer (Pinewood) had already entered the market.⁵⁸
- 4.49 In our discussions with generic manufacturers it was noted by all of them, consistent with the view expressed by the OFT in its Decision, that because GL was predominantly a liquid product this did limit the number of potential generic entrants into the alginates market. This is because compared to solid dose drugs, liquid products are expensive to transport and store and therefore tend to be produced close to the point of use. Liquid drug markets tend to be more localised and therefore tend to be smaller and attract fewer entrants as a consequence. In addition, particularly in the case of the UK, the preferred delivery mechanism for medicines tends to be tablets or capsules therefore liquids tend to be produced in relatively small volumes. Consequently, the number of potential suppliers of liquid products into the UK market is limited to companies with specialist production facilities for liquids in and around the UK. It was suggested to us that there were around four or five of these.
- 4.50 One other potential barrier in to the AA by prescription market that was discussed in the DH/ABPI (2002) study was the fact that Gaviscon is a compound medication. GPs are more likely to prescribe originator drugs, rather than generic drugs, when they are compound medications because the originator is more recognisable than its generic competitors in such cases. However, as noted above, GPs' rates of generic prescribing in the UK are in general very high and, given the generic name ARFOS was issued subsequent to the Withdrawal (and the DH/ABPI report), GPs are facilitated in the prescribing of generic alternatives by the basic functionality of their prescribing software. Hence we would not consider this to be an insurmountable barrier to high rates of generic prescribing.
- 4.51 Our discussions with stakeholders indicated that that there are around four or five possible suppliers of a generic versions of GL into the UK and that some of these companies might be interested in producing a generic version of GL. Although the market is far from the largest in terms of UK prescription drugs, it was considered to be large enough to attract more than the one existing

⁵⁷ Ibid.

⁵⁸ See [OFT Decision](#), paragraph 2.90, p49.

generic entrant. In addition it was specifically mentioned by a few manufacturers that this market would be attractive to companies with the ability to supply liquid products into the UK because it was one of the only volume liquid products to have come off patent in the last ten years. We are also aware that at least one other drug company was considering supplying a generic version of GL into the UK market had it not been for the Withdrawal.

Potential for generic competition in the AA by prescription market by prescription

- 4.52 There are a number of factors that influence the potential for generic competition in a drug market. These include the prescribing decision of doctors (mainly GP's in the case of the AA by prescription market), the dispensing decision of pharmacists and barriers to entry by potential generic competitors.
- 4.53 Our review of these factors and how they relate to the AA by prescription market by prescription suggest that there are some characteristics of this market which might limit, to some extent, the impact of generic competition. These were: the fact that the AA drugs are typically liquid products which limit the number of potential generic entrants; and the fact that AA drugs are compound drugs which could reduce the tendency of GPs to prescribe drugs generically.
- 4.54 However, our review has uncovered nothing that would lead us to conclude that reasonably successful generic competition was not possible in this market. We consider that once the generic name ARFOS had been assigned, absent the Withdrawal, there would be no significant barriers to a high level of generic prescribing by GPs. We note that they are encouraged to prescribe generically in most circumstances and do so in large quantities for most other drugs. Furthermore pharmacists have strong incentives to dispense cheaper generic drugs and would appear to be willing to do so in the case of AA drug. In addition there appears to be some interest from other drug companies, in addition to Pinewood in supplying a generic version of GL.

5. Direct market impact of OFT Decision

Introduction

- 5.1 This chapter looks at the direct market impact of the OFT Investigation, which was opened in November 2008,⁵⁹ and the OFT Decision, published in April 2011, on the market for AA drugs by prescription. In particular we look at the impact on market structure, the prices of AA drugs and the total cost to the NHS of these.
- 5.2 Although the market was defined as no wider than the market for alginates and antacids in the OFT Decision, the analysis presented in this section focuses on a slightly narrower set of drugs than this. The analysis of market impacts focuses on liquid AA products as these are comfortably the largest segment of the AA by prescription market and they are the most directly substitutable with one another. It is within this narrower set of more directly substitutable products where we would be most likely to observe any direct market impact of the OFT Decision. A focus on a limited number of liquid products also permits a simpler presentation of the analysis, particularly when comparing prices per dose/quantity.
- 5.3 Our prior expectation before undertaking the analysis was that there would be little or no direct market impact from the OFT Decision. This is because in the Decision the OFT indicated that it did not expect there to be a significant impact. This view was supported by submissions to the investigation by a variety of interested parties, including the DH and Pinewood, which argued that GP and patient inertia made large scale switching back to GL (and generic versions of this) from GA unlikely.⁶⁰
- 5.4 We note that the analysis of the market outlined in this section is relevant not only for the assessment of the direct impact but also for our estimate of the possible savings in Chapter 6. In Chapter 6 we estimate the expenditure by the NHS on AA drugs in the absence of the Withdrawal and compare it to the actual market outturn following the Withdrawal.
- 5.5 In the remainder of this section we briefly describe the methodology we follow, then we present our analysis of changes in key market indicators over the period 2002 to 2013 before making an assessment of the direct impact of the OFT investigation and Decision. First we look at the market structure in terms

⁵⁹ We might expect market impacts following the announcement of the investigation as behaviour sometimes changes once problematic practices are uncovered and/or following a decision to find the practices abusive and therefore prohibit them.

⁶⁰ See [OFT Decision](#), paragraph 8.5.

of overall volumes of AA liquid products dispensed and the relative market shares of the key products. We then look at changes in the NIC before discounts per item dispensed (our measure of price) and changes in the overall NIC before discounts (we use this as our measure of total cost to the NHS).⁶¹

Methodology

- 5.6 Data on the prescribing of AA drugs was retrieved from the websites of the NHS information centres. The data provides information on the items dispensed by pharmacists in response to a GP prescription. We obtained this information for the period 2002 to 2013. The data provided us with the number of items prescribed, the NIC and the quantity dispensed in England,⁶² Wales,⁶³ Scotland⁶⁴ and Northern Ireland.⁶⁵
- 5.7 We looked at trends in prices, quantities and the total cost of AA's dispensed by prescription across the UK.⁶⁶ To estimate the direct impact of the OFT intervention we not only need to observe the changes in the market since the investigation and Decision but we also need to develop a counterfactual to this. The counterfactual we use is an estimate of how the market would have evolved without the OFT intervention.
- 5.8 There are many different possible approaches to assessing a counterfactual. For the purposes of this evaluation we use a fairly simple assessment of the market before and after the intervention. Essentially, we assume that the market would have continued to evolve in the same way it had for a number of years prior to the OFT investigation. We consider this to be a reasonable approach for this evaluation because, as our analysis below shows, the AA market had been in a fairly steady state for a number of years prior to the investigation. It therefore seems reasonable to assume that this would have continued for a number of years (certainly until the end of the time series of data we have available (ie 2013)).
- 5.9 We consider that there are a number of distinct periods within the time series of data from 2002 to 2013 during which we might expect there to be differing

⁶¹ The actual cost to the NHS will differ to from this value to an extent once discounts have been applied.

⁶² [NHSBSA Prescription Cost Analysis \(PCA\) Data.](#)

⁶³ [The Welsh Government: Prescriptions dispensed in the community.](#)

⁶⁴ [Information Services Division Scotland: Prescriptions dispensed in the community.](#)

⁶⁵ [Health and Social Care NI: Prescriptions dispensed in the community.](#)

⁶⁶ Although Scotland records the Gross Ingredient Cost (GIC), it is comparable to NIC (Net Ingredient Cost) in England, Wales and Northern Ireland (See [IDS Scotland Prescribing & Medicines: Prescription Cost Analysis 2013](#), p19).

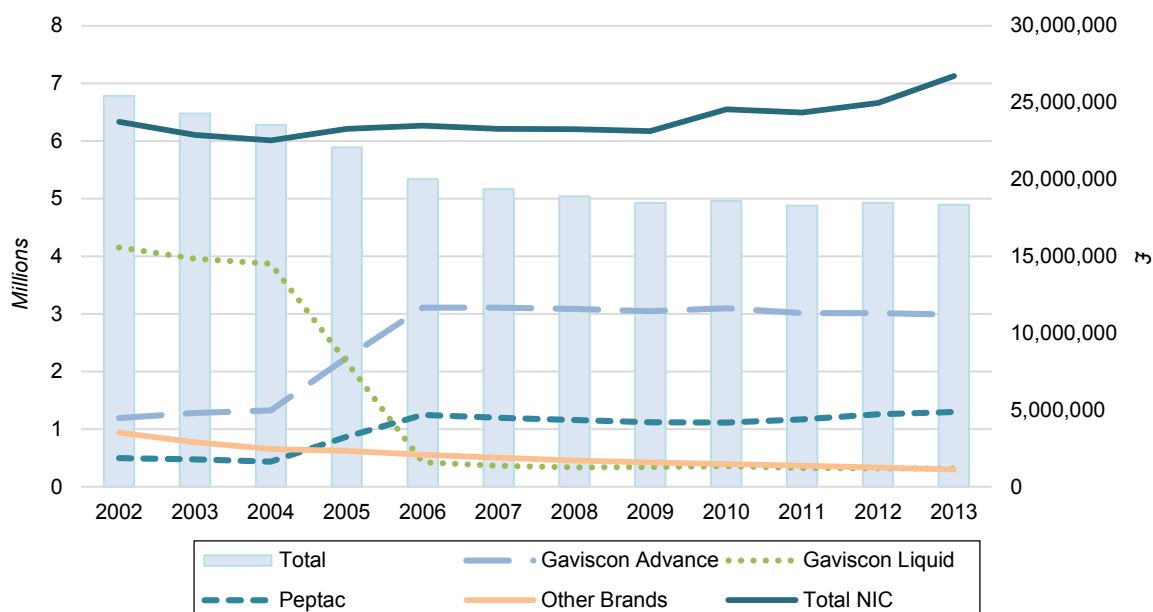
market conditions and consequently different market outcomes. These periods are as follows:

- prior to the Withdrawal (2002 to 2004);
- the year of the Withdrawal (2005);
- following the Withdrawal and before the OFT investigation (2006 to 2008); and
- after the OFT investigation.

Market structure 2002 to 2013

5.10 In Figure 5.1 we present analysis of the AA liquid products dispensed in response to GP prescriptions since 2002. It provides information on total items dispensed and how these are split between the two main Gaviscon brands, Peptac (the most popular non-Gaviscon product) and ‘other’ brands. In addition it presents the total remuneration to pharmacies (measured by the NIC before discounts) for the dispensing of AA liquid drugs.

Figure 5.1: Total number of items dispensed in response to prescriptions



Source: CMA analysis of data retrieved from the websites of the NHS information centres in England, Scotland, Wales and Northern Ireland.

Dispensing of AA liquid products prior to the Withdrawal

5.11 Prior to the Withdrawal in 2005 the market was relatively stable but there is some evidence that the overall number of prescriptions was declining slightly

and that there was some limited movement towards the prescribing of GA instead of GL. The total number of items dispensed fell from 6.7 million in 2002 to 6.3 million in 2004. This reduction in items dispensed was spread across GL, Peptac and other brands.⁶⁷ Volumes of GA dispensed increased slightly from 1.2 million to 1.3 million

Dispensing of AA liquid products around the time of the Withdrawal

- 5.12 The prescribing data clearly shows significant changes in dispensing of AA drugs around the time of the Withdrawal in 2005. Volumes of GA dispensed increased markedly from 1.3 million in 2004 to 3.1 million in 2006, whilst the corresponding volumes for GL declined sharply from 3.8 million in 2004 to 0.4 million in 2006.⁶⁸ During this period the volumes of Peptac increased from 0.5 million to 1.2 million^{69,70} suggesting that the Withdrawal strategy led to the combined Gaviscon brands ceding at least some market share to the closest alternative to GL.
- 5.13 In addition there was a notable decline in the total volume of items dispensed. Total items dispensed fell from 6.3 million in 2004 to 5.3 million in 2006. The fall may reflect, to some extent, the fact that the recommended dosage for GA was half that of GL. However, the fall in the number of items dispensed is less than might be expected if all of the patients who would have been prescribed GA instead of GL took dosages that were reflective of the relative strengths of each product.⁷¹ One explanation for this put forward by several stakeholders is known as 'glugging' whereby the volume of medicines consumed by patients may well not comply with the recommended dosage and there is often a tendency for patients to overconsume more concentrated medicines. The fall in volume of items dispensed may not be attributable in its entirety to the switch from prescribing GA instead of GL as there had also been a significant fall in these volumes in the two years prior to the Withdrawal. Items dispensed declined from 6.8 million in 2002 to 6.3 million in 2004.
- 5.14 We did not find any reason to believe that there were other factors that would have resulted in underlying growth or decline in the number of items dispensed or that might have offset or reinforced any effect from increased

⁶⁷ Between 2002 and 2005 volumes dispensed of: GL fell from 4.2 million to 3.9 million; Peptac fell from 0.5 million to 0.4 million; and other brands fell from 0.9 million to 0.6 million

⁶⁸ The combined share of the Gaviscon brands of total items dispensed fell from 83% in 2004 to 66% in 2006.

⁶⁹ Volumes of other brands dispensed fell slightly 0.65 million to 0.55 million.

⁷⁰ Between 2004 and 2006 Peptac's share of total items dispensed increased from 8% to 19%, whilst the share of other brands increased from 10% to 15%.

⁷¹ CMA analysis of prescription data suggests that the average volume per item dispensed was 519ml for GA and 526ml for GL. If patients were consuming half the volume of product when using GA compared with the volume consumed when using GL then we would have expected decline in the number of items dispensed of around 50%, all else being equal, rather than the decline of approximately 15% that actually occurred.

usage of the more concentrated GA product. Several stakeholders noted that they considered the AA market by prescription to be a mature drug market, and had been for some years. Aside from the Withdrawal, little had happened in recent years which they considered might lead changes in the underlying drivers of usage of AA products.

Dispensing of AA liquid products following the Withdrawal and the impact of the OFT Decision and investigation

5.15 Since 2006 the market has remained fairly stable both in terms of overall number of items dispensed and the number of items dispensed for each of the three main brands. Total items dispensed were 5.3 million in 2006 and by 2008, the year prior to the OFT investigation, they had declined slightly to 5.0 million. In the year the OFT published its Decision, 2011, 4.9 million items were dispensed and again in 2013 the number of items dispensed was 4.9 million. In Table 5.1 below we set the number of items dispensed and the percentage of the total for each of the key AA liquid products as well as ‘other’ products at various points in time after the Withdrawal.

Table 5.1: Items dispensed and market shares after the Withdrawal for key AA products

	2004 Year prior to Withdrawal	2006 Year after Withdrawal	2008 Year OFT announced investigation	2011 Year OFT Decision is published	2013 Last year of data
Gaviscon Advance	1.3	3.1	3.1	3.0	3.0
% of total	21%	58%	61%	62%	61%
Gaviscon Liquid	3.9	0.4	0.3	0.3	0.3
% of total	62%	8%	7%	7%	6%
Peptac	0.4	1.2	1.2	1.2	1.3
% of total	6%	23%	23%	24%	26%
Other brands	0.7	0.6	0.5	0.4	0.3
% of total	11%	10%	9%	8%	6%
Total	6.3	5.3	5.0	4.9	4.9

Source: CMA analysis of data retrieved from the websites of the NHS information centres in England, Scotland, Wales and Northern Ireland.

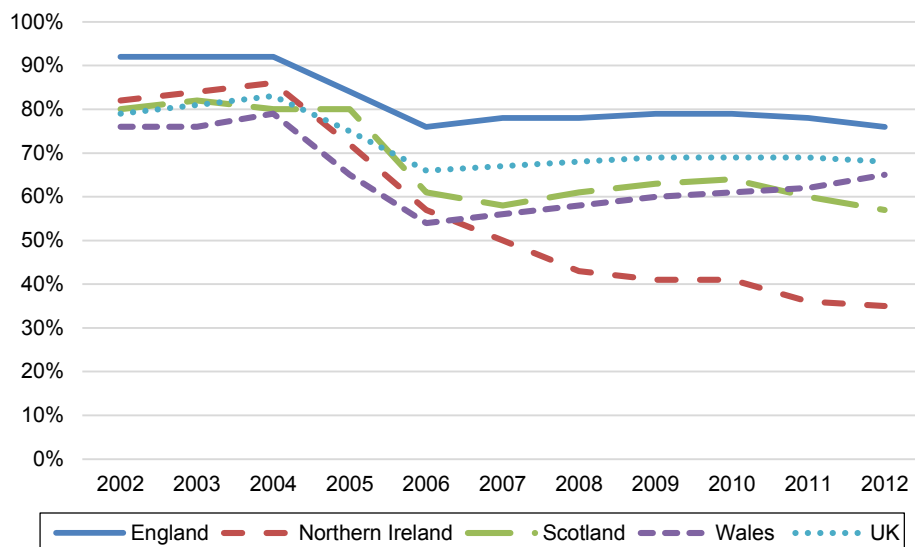
5.16 The analysis presented in Figure 5.1 and Table 5.1 is not strongly indicative of any impact on the items dispensed for the main AA products from the OFT investigation or Decision. The overall size of the AA by prescription market, the number of items dispensed of the key products and the relative market shares of these products were very stable from the year after Withdrawal up until 2013. There is little or no perceptible change in dispensing following the opening of the OFT investigation or the publication of its Decision.

Variation in AA prescribing across the UK

5.17 As illustrated in Figure 5.2 analysis of a more disaggregated breakdown of the prescription data reveals that underlying the UK wide picture there were some big differences in the relative market share across different parts of the UK. In

particular the market share of Peptac is significantly higher (and consequently the market shares of the Gaviscon brands significantly lower) in Scotland, Wales and, most notably, Northern Ireland than in England. We present more details of the analysis on Appendix B.

Figure 5.2: Market share of combined Gaviscon liquid brands in different parts of the UK



Source: CMA analysis of data retrieved from the websites of the NHS information centres in England, Scotland, Wales and Northern Ireland.

5.18 We asked a small number of stakeholders what might drive the differences in rates of prescribing.⁷² The response was that there was no clear answer but that a combination of factors would influence prescribing at a local level. Two factors that were mentioned specifically as having the potential to influence local prescribing rates were local advice on prescribing and differences in the intensity of marketing activity by pharmaceutical companies in different regions. In addition a recent report by the NAO suggested that ‘Some of the variation [In prescribing between the nations] may be due to differences in prescribing practices with the average number of doses per prescription item potentially differing between the nations’.⁷³

5.19 It is possible that, for example, around the time of the Withdrawal the marketing of RB was more intense in England than elsewhere or it might have been the case that national and local healthcare bodies in Scotland, Wales and Northern Ireland were more active in trying to switch prescribers to Peptac. However, we have no evidence suggesting that either of these were

⁷² Including the DH and one of the pharmaceutical advisers to a CCG.

⁷³ ‘Healthcare across the UK: A comparison of the NHS in England, Scotland, Wales and Northern Ireland’. NAO (2012), paragraph 2.21.

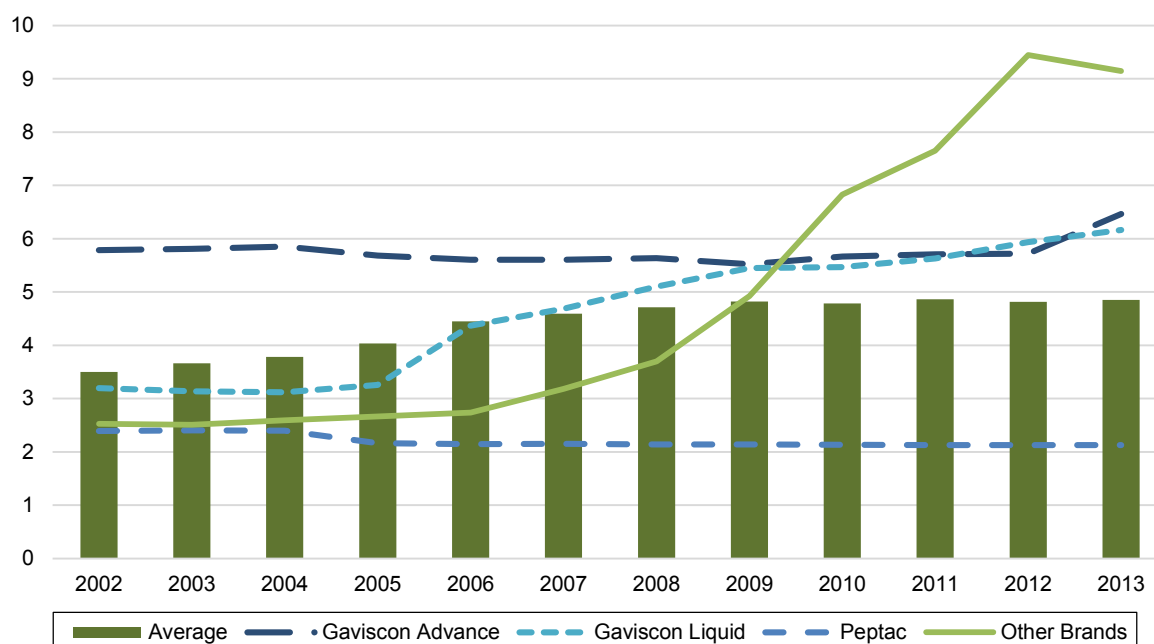
factors were directly responsible for differences in AA prescribing behaviour across the UK.

5.20 The difference in rates of prescribing began to become pronounced soon after the Withdrawal. There appears to be no impact on rates of prescribing in different parts of the UK around the time of the announcement of the OFT investigation or the publication of its Decision.

Prices and costs 2002 to 2013

5.21 In Figures 5.3 and 5.4 below we present our analysis of the price (NIC per item) and total remuneration paid to pharmacies (the total cost to the NHS), measured by NIC before discounts, of AA liquid products supplied in response to a prescription in the UK.

Figure 5.3: Average NIC (£) per item dispensed



Source: CMA analysis of data retrieved from the websites of the NHS information centres in England, Scotland, Wales and Northern Ireland.

5.22 The average price paid for GA remained fairly stable throughout the majority of the period. There was little discernible change in prices around the time of the Withdrawal or the announcement of the OFT investigation or publication of its Decision. There was however, a sharp increase in the price of GA between 2012 and 2013.⁷⁴ This follows a split of the GA products into two separate brands. These being GA (Reckitt) and GA (Forum) in 2013, with the former

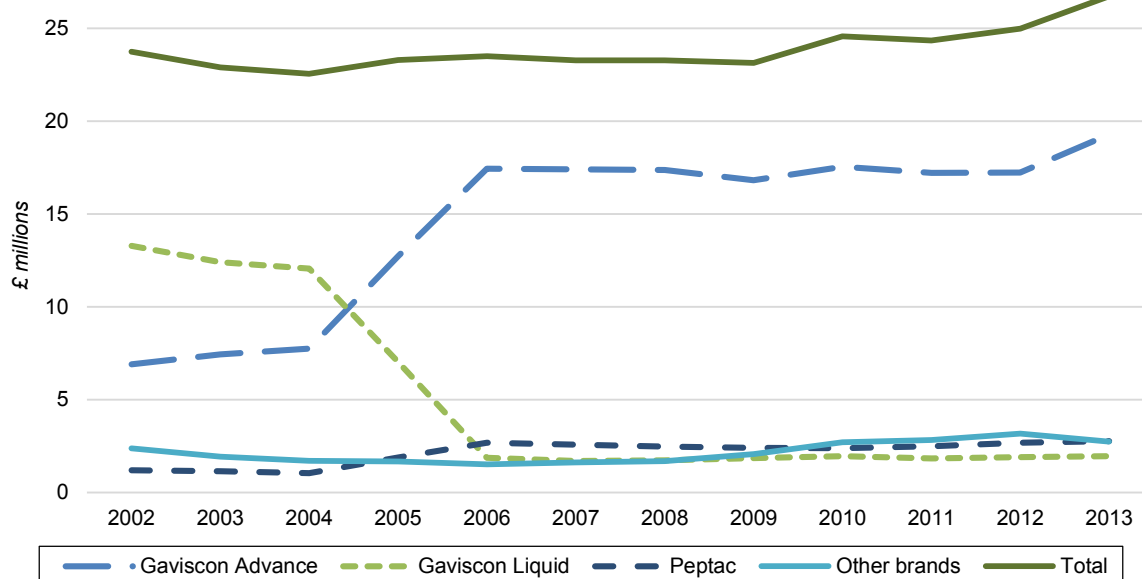
⁷⁴ In 2002 the average price of GA was £5.8 per item and £5.7 in 2012 before increasing to £6.5 in 2013.

priced significantly higher than the latter. The weighted average price of these two products in 2013 is higher than the average price paid for GA in 2012.

- 5.23 The price of GL increased sharply following the Withdrawal in 2005 from £3.3 per item in 2005 to £4.4 per item in 2006. Our understanding is that the increase in price occurred because on receiving a prescription for GL pharmacists would dispense an OTC pack of this product as prescription packs were no longer available.⁷⁵ OTC products are typically more expensive than products supplied through the prescription channel and this is reflected in the increase in price for GL. After 2005 the price of OTC packs of GL increased steadily.
- 5.24 The average price for Peptac was just above £2.5 per item between 2002 and 2004 before falling to £2.16 per item in 2006 and it has remained at about this level since then. In 2013 the price of Peptac was £2.12 per item. There was no notable change in the price of Peptac either around the announcement of the OFT investigation or publication of its Decision.
- 5.25 For the 'other brands' average prices increased substantially after 2006. The main reason behind this increase has been an increase in the price of sodium bicarbonate liquid antacid products. This most likely reflects an increase in the cost of the key ingredients.
- 5.26 Figure 5.4 shows the total remuneration (NIC before discounts) paid to pharmacies by the NHS for AA liquid products

⁷⁵ Prescription and OTC packs of drugs are marketed and priced separately. GPs are able to prescribe drugs for which only OTC packs are available (such as GL). In response to these prescriptions Pharmacists will dispense an OTC pack and will be remunerated by the NHS at the OTC price.

Figure 5.4: Total NIC of AA liquid products



Source: CMA analysis of data retrieved from the websites of the NHS information centres in England, Scotland, Wales and Northern Ireland.

5.27 The total NIC of AA liquid products to the NHS and the NIC of all of the main liquid AA brands as well as ‘other’ liquid AA brands has remained fairly stable since 2006 although the overall NIC did begin to increase after 2009. After 2009 the NIC of AA liquid drugs increased from £23.1 million in 2009 to £24.9 million in 2012 and then to £26.7 million in 2013. The increases in NIC appear to be largely attributable to increases in the price of ‘other’ brands (from 2009) and GA (after 2012).

5.28 Since the opening of the OFT investigation the prices of some important products (GA and sodium bicarbonate antacid) and the overall cost to the NHS of AA liquid drugs appears to have increased. This does not appear to be attributable to the OFT investigation or Decision. The relevant factors behind the increase in cost appear to be the increasing cost of sodium bicarbonate and the splitting of GA products into two brands from 2013.

Conclusion

Overall impact

5.29 As expected when the OFT Decision was published in 2011 there was little or no discernible direct market impact of the OFT investigation following either the announcement of the investigation in 2008 or the publication of the Decision in 2011. The analysis presented above shows that there was no clear impact of the level or trend in relative markets shares, prices or overall

cost to the NHS for the liquid AA products either post 2008 or post 2011. If anything, the overall cost and the price of some key products increased after 2008. However, the reasons for this do not appear to be attributable to the OFT investigation.

- 5.30 Likely explanations for these findings are the apparent success of the Withdrawal along with the workings of the prescribing process as described in Chapter 4. Once GPs had switched to mostly prescribing GA there were a number of aspects of the prescribing process that would help to ensure that this remained the case including: the lack of a generic name covering the compound GA formula; the basic functionality of GP prescribing software which meant it would not suggest alternatives to GA; and a relative lack of focus on AA drugs from national and local prescribing guidance and medicine management initiatives. It is also possible that patient preference for the taste and texture of a familiar liquid product may also have helped to maintain GA's market share.
- 5.31 There was nothing about the OFT Decision that would have changed the situation as described above because whilst the behaviour of RB was found to be abusive, the impact of the Withdrawal was manifest almost immediately after it and significantly in advance of the opening of the OFT investigation. Furthermore the Decision did not make any directions that might have been expected to change how the AA market was functioning. As discussed in paragraph 2.13 the OFT did consider making a direction that RB reintroduce prescription packs of GL but did not do so after a number of stakeholders submitted that this would not have any material impact on the AA by prescription market.
- 5.32 During the evaluation we did not find any evidence to suggest the judgment of the OFT not to make any directions was flawed. A number of stakeholders (including generic drug manufacturers and the DH) told us that they still consider that reintroducing prescription packs of GL would have had little impact on the market and no stakeholders suggested otherwise. In addition to this our review of the factors that influence competition in the AA market, as set out in Chapter 4, support the view that once GPs had switched to prescribing GA then it would have been difficult for them to switch to GL, Peptac or ARFOS prescriptions. The review also suggests that there has not been any significant change in these factors since the publication of the Decision that would mean the reintroduction of prescription packs of GL would now be any more likely to make an impact.

Could the OFT have intervened earlier

- 5.33 Given the limited evidence of any significant direct impact from the OFT Decision and the time elapsed between the Withdrawal in 2005 and the publication of the Decision in 2011 we consider whether it would have been reasonable for the OFT to intervene earlier. We also consider whether earlier intervention by the OFT could reasonably have been expected to lead to a more significant direct impact.
- 5.34 Competition enforcement in the UK, particularly abuse of dominance, has generally been complaints based. In other words investigations are generally started following the receipt of a complaint by third parties rather than following from intelligence gathering by the competition authorities. This approach reflects the complexity of detecting potential abusive behaviour through monitoring of the whole economy and consequent resourcing requirement of doing this. As a result the ability of the OFT to actively detect potential abuses of competition law would have been quite limited. Rather than actively detecting potential abuses the competition authorities have instead generally sought to prevent abusive behaviour occurring through a combination of education to promote compliance with competition law and robust enforcement action where such behaviour is brought to their attention.
- 5.35 In this particular market intervention by the OFT would have needed to have been at a very early stage to achieve any lessening of the impact of the Withdrawal. As Figure 5.1 shows the impact of the Withdrawal on the AA market by prescription was very rapid. The Withdrawal occurred in 2005 and there was an immediate and significant swing in the share of items dispensed in the AA market to GA and away from GL. By 2006 GA had by far the largest market share and since then the relative markets shares of the main brands in the market has remained fairly consistent. Therefore any intervention by the OFT would have needed to be shortly after the Withdrawal if it were to prevent or mitigate its impact.
- 5.36 It is possible that if the OFT had been aware of the behaviour at a very early stage the impact of the Withdrawal could have been lessened. It is possible, for example, that the opening of an investigation could have caused RB abort or suspend the Withdrawal or that the OFT would have been able to use its powers to abort or suspend it.⁷⁶ In the case of the Withdrawal the behaviour only came to light only after the revelations of a whistle-blower who was a former executive of RB. There was no complaint to the OFT closer to the time

⁷⁶ One mechanism by which it could have done this was through its power to impose interim measures where it considered there was the potential for substantial and irreversible customer harm. In practice for a variety of reasons this power was hardly ever used.

of the Withdrawal despite a number of parties such as rival drug manufactures and the DH and NHS having a direct interest in preventing or mitigating the impact of the Withdrawal.

- 5.37 In these circumstances and given the limited capacity of the OFT to actively detect potential abuses of competition law it would seem unreasonable to expect that the OFT should have picked up on the behaviour by RB prior to the revelations of the whistle-blower.
- 5.38 As noted in the CMA 2015/16 Annual Plan,⁷⁷ the CMA is increasingly placing a greater emphasis on more proactive intelligence led enforcement of competition law. This is particularly in the area of cartel enforcement but also in other areas of enforcement. One possible area of learning from this evaluation, as well as our wider experience of the pharmaceutical sector, may be that there could be merit in taking a more proactive approach to monitoring drug markets when originator drugs go off patent.

⁷⁷ Competition and Markets Authority Annual Plan 2015/16, pp14 & 15.

6. Possible savings to the NHS

Introduction

- 6.1 In this section we estimate the possible savings to the NHS that may have occurred absent the Withdrawal. From the analysis presented in Chapter 5 we can see how the AA market by prescription actually evolved following the Withdrawal. To generate an estimate of the possible savings we first estimate how the market would have evolved if the Withdrawal had not occurred and on that basis estimate what the total cost to the NHS of AA drugs would have been. The difference between this estimate and the actual cost is the estimated value of the possible savings.
- 6.2 Given the inherent uncertainty in making an estimate of the market outcomes in the absence of the Withdrawal we estimate a range of plausible outcomes for the possible savings and select a base case from the range using qualitative evidence we have collated on the potential for competition in the AA by prescription market. We also check the sensitivity of these estimates to some alternative assumptions about the how the market might have developed in the absence of the Withdrawal.
- 6.3 To do this we use a variety of sources of evidence, these are:
- evidence from the publicly available documents on the claim by the SoS and others;
 - evidence on the impact of competition following the loss of patent by the originator drugs in two markets similar to the AA market by prescription; and
 - evidence from the economic literature on the impact of competition in drug markets in the UK after loss of patent.
- 6.4 In the remainder of this chapter we summarise the various pieces of evidence and present our estimate of the range for the value of the possible savings to the NHS and the sensitivity of this to alternative assumptions.

SoS and others' compensation claim

Overview of the claim

- 6.5 The Decision by the OFT was followed by a claim for compensation by the SoS and others. The claim was submitted to the High Court in February 2011 and the SoS and others claimed compensation in the region of £90 million.

This claim was settled out of court in February 2014 for an undisclosed and confidential amount and with no admission of liability by RB.

6.6 The claim was based in large part on an estimate of the costs the NHS would have saved in the absence of the Withdrawal.⁷⁸ It also includes an estimate of damages caused not only by the Withdrawal but also an alleged policy by RB to delay the issuing of the generic name ARFOS.⁷⁹ The details of the NHS methodology and the dataset they used are not publicly available.

6.7 We set out some more details of the claim in Appendix C.

RB's response to claimants

6.8 RB's statement of defence admits that their conduct in withdrawing GL infringed the Chapter II prohibition against abuse of dominance.⁸⁰ It also does not dispute the OFT's Decision on the scope of the relevant market for the purposes of the claim and admits their position of dominance. However, RB denied any allegations related to the alleged delay policy or that the infringement in relation to the Withdrawal had any adverse effects on the claimants. They also argued the claimant failed to take reasonable steps to mitigate their loss, including by:

- (a) mandating or issuing guidance to prescribing doctors to issue prescriptions by reference to the ARFOS generic name or specific alternative raft forming alginates;
- (b) encouraging or requiring doctors to use ScriptSwitch or other similar software to issue prescriptions by reference to ARFOS or specific alternatives;
- (c) encouraging or requiring doctors to use prescribing clerks to amend repeat prescriptions of patients to refer to ARFOS or specific alternatives.⁸¹

6.9 From the publicly available court documents in the SoS claims it is clear that whilst the SoS and related organisations including the NHS considered that there was a substantial overcharge, RB did not agree that this was the case. Claims for compensation were also brought against RB by other parties, including certain generic manufacturers or suppliers. We did not review all the

⁷⁸ CMA view based on a review of the publicly available parts of the Amended Claim Form submitted by SoS and others.

⁷⁹ See [OFT Decision](#), paragraph 2.17.

⁸⁰ RB's Amended defence, paragraph 42.

⁸¹ RB's Amended defence, paragraph 81.

materials relating to those claims in preparing this evaluation and we note that those claims conflict in some aspects with the claim brought by the SoS.

6.10 As part of its Decision or assessment of the appropriate penalty the OFT was not required to make any attempt to quantify the effect on competition of the infringement by RB. However, in its Decision the OFT did make reference to RB's internal forecasts of the effect of the Withdrawal, although much of the detail has been redacted.⁸² Based on documented evidence of RB's own forecasts, the OFT concluded that absent the Withdrawal, among other things, RB:

- anticipated the onset of full generic competition;
- considered that a proportion of the closed scripts which had previously been written for GL would instead be open scripts referring to the new generic name corresponding to GL;
- would then have to provide discounts to pharmacists in order to compete with generic producers of drugs; and
- forecast a decrease in net revenue from the Gaviscon brand, as a result of full generic competition.

6.11 However, with the Withdrawal, RB forecast a proportion of those patients who have been prescribed GL would be prescribed GA. This would enable it to preserve a significant market share and the price levels observed prior to the Withdrawal.

Economic literature on the impact of generic competition in the UK

Overview

6.12 As part of this evaluation we reviewed a range of literature on the impact of generic competition on drug markets when originator drugs go off patent. At a high level the literature provides a body of evidence across international markets that when drugs go off patent,⁸³ this is often followed a short time afterwards by: (a) entry into the market by several generic drug manufacturers; (b) the ceding of substantial market share by the originator brand to generic entrants; and (c) a significant reduction in average prices for that category of drugs. However the exact impact varies substantially

⁸² [OFT Decision](#), paragraphs 6.124–6.140.

⁸³ Generic competition in some cases does occur when originator drugs are still within patent however, the reviewed literature focuses on off patent competition.

depending on a number of factors such as the possible barriers to generic entry such discussed in paragraph 4.46.

- 6.13 We do not discuss the wider literature in detail in this report but instead focus on a small number of reports/papers which are the most directly relevant to the impact of generic competition in the UK drug market. These are the DH/ABPI (2002) report discussed earlier, the 2009 European Commission Inquiry into the pharmaceutical sector (EC (2009))⁸⁴ and an academic paper published by Dr Panos Kanavos of LSE (Kanavos (2014)). Below we provide an overview of the findings of these studies. More detail is provided in Appendix D.
- 6.14 These studies are of particular interest because, unlike much of the literature, they draw on evidence specifically from UK drug markets. In addition the evidence they use is drawn from examination of data across a wide range of drug categories rather than focusing on specific case studies or a limited range of drugs.
- 6.15 The studies suggest that it is not always the case that generic entry occurred following the loss of patent by an originator drug. The proportion of drug categories for which loss of patent protection was followed by entry by a generic version was less than 50% for two of the studies (DH/ABPI (2002),⁸⁵ Kanavos (2014)⁸⁶) and 66% in the case of the third (EC (2009)).
- 6.16 The studies indicate that where there is generic entry in a drug market on average generic entrants achieve a significant proportion of sales in that market. In addition where generic entry does occur this is associated with a significant reduction in average prices. The reduction in average price is mostly due to the lower price of new entrant generic product rather than a reduction in the price of the originator drugs. The evidence on the change in the price of the originator drugs is that they tend to either fall slightly or stay at approximately the same level following generic entry.
- 6.17 This impact of generic entry is observed relatively quickly with Kanavos (2014) showing a significant impact within three months and all of them showing significant impacts within one year. The impact of generic entry seems to have become more significant over time with the studies that cover

⁸⁴ [Pharmaceutical Sector Inquiry, European Commission \(2009\)](#). A more condensed paper looking mainly at the impact of generic entry can be found in [Glowicka et al \(July 2008\), Generic entry in prescription medicines in the eu: main characteristics, determinants and effects](#). All of the authors were members of the Chief Economist Team of DG Comp.

⁸⁵ Of 137 chemical entities, which were identified as having lost patent protection in the UK between 1990 and 2000 generic entry had occurred in 47 (34%) of cases.

⁸⁶ Of 90 molecules observed for the UK which lost patent protection between 1998 and 2010, after two years a generic version had been launched in 46.7% of cases.

more recent periods observing much greater market penetration by generics and consequently greater reductions in prices and costs.

Evidence on changes in market share and prices

DH/ABPI (2002)

6.18 The DH/ABPI (2002) study in general only finds evidence of notable penetration by generic and cost/price reductions in what it terms 'significant products' (with a NIC of over £3 million per year).⁸⁷ Of the 28 chemical entities classed as significant generics achieved a market share of 20% or more (by value) in only ten cases. Significant reductions in the overall cost of drugs was only observed for 'High' NIC products (greater than £10 million per year). In this High NIC category costs to the NHS were reduced on average by 25%. For the 'mid' (>£3 million per year, <£10 million per year) and 'low' NIC categories (<£3 million per year) cost savings were, on average, 2% and 0.3% respectively.

EC (2009)

6.19 The EC sector inquiry (2009) found on average EU-wide generic penetration and price reductions that were much greater. Across the sample of 128 molecules,⁸⁸ where there was entry by at least one generic, the EC found that one year after patent expiry generics had on average a market share of 30% by volume increasing to 45% after two years. The average price of the generics was 25% less than the originator price at patent expiry after one year and 40% less after two years. The study also noted that on average the price of the originator brands had fallen to 85% of the price at patent expiry after two years.

Kanavos (2014)

6.20 The most recent of the three studies is Kanavos (2014). This study covers 12 EU member states and reports findings for each state separately. For the UK the study covers 90 molecules. In the case of the UK the study found that, where there was at least one generic entrant, the market shares by volume of the combined generic versions after patent expiry:

⁸⁷ This represented 28 of the 137 chemical entities that lost patent between 1900 and 2000.

⁸⁸ Of these 84 are relevant for the UK.

- were on average 15.5% after three months, 35.8% after 12 months and 46.5% after 24 months;
- for the bottom decile of molecules (by value of sales) 13.9% after three months, 36.5% after 12 months and 43.4% after 24 months; and
- for the top decile (by value of sales) the values were 25.4% after three months, 35.0% after 12 months and 46.6% after 24 months.

6.21 Kanavos found that the average UK prices of the generic versions were:

- 60.6% of the originator price at expiry 12 months after patent expiry were and 30.6% of this price after 24 months;
- 76.7% of originator price after twelve months and 56.5% after twenty four months for molecules that were in the bottom decile; and
- 54.3% of originator price after twelve months and 26.5% after twenty four months for the top decile.

6.22 The study also found that where there had been at least one generic entrant, originator prices twelve and twenty four months after patent expiry were, respectively, 99.1% and 96.9% of the price at the time of patent expiry. Where there was no generic entry the originator brand prices were 107.8% of the price at patent expiry after twelve months and 103.4% of this price after twenty four months.

Case studies

Introduction

6.23 In this section we discuss the two case studies we used as evidence for the possible savings to the NHS absent the Withdrawal. For each case study, we provide background about the product and use calculate the number of generic entrants; the market share they gained and the pricing strategy of the different firms. More detail on the selection of the case studies can be found in Appendix E.

6.24 To evaluate changes in markets share, NIC before discounts per dose dispensed (our measure of price) and changes in the overall NIC before discounts (we use this as our measure of total cost to the NHS) for the case study drugs.⁸⁹ The 'Prescription Cost Analysis' annual data from the HSCIC

⁸⁹ The actual cost to the NHS will differ to from this value to an extent once discounts have been applied.

described in paragraph 5.6. However, for the purposes of the case studies, unlike for our analysis of the AA market, we just used data for England, rather than the UK. This was mainly due to timing of the patent expiry of the case study drugs which meant that we needed a longer time series of data than we used for the analysis presented in Chapter 5. The additional length of time series (ie prior to 2002) was not available via the web portals of the various NHS information centre portals but we were able to secure the data for England, and England only, directly from HSCIC for the period 1998 to 2013. However, the NHS in England accounts for the vast majority of drugs purchased by public bodies in the UK. We therefore consider that it is not unreasonable to extrapolate from the analysis of case studies produced with data just for the England to a UK wide conclusion. This will be less robust than using data for the whole UK given, for example, the potential for variation in prescribing in different parts of the UK (such as we discuss in paragraph 5.17), but not to an unacceptable degree.

Selection of case studies

- 6.25 We have tried to identify case study drug markets where: incumbent drugs have come off patent and where the market has similar characteristics to the AA by prescription market; and where behaviours similar to the Withdrawal did not occur. Markets like these can be used to create a counterfactual to the AA by prescription market. They provide an insight into the possible evolution of the AA by prescription market ‘but for’ RB’s Withdrawal. Once these markets have been identified we can use changes in key market parameters, including the market share gained by the generic entrants, and the price changes of the different drugs as evidence of what might have happened in the AA by prescription market absent the Withdrawal.
- 6.26 The relevance of the case studies depends on the similarity between the chosen markets and the AA by prescription market. The more similar the comparison market is, the more pertinent the case study will be. However, because a limited number of drugs come off patent each year and each has its own characteristics, we are limited in our choice for case studies.
- 6.27 In our search for relevant case studies we sought advice from the stakeholders that we interviewed during the evaluation and we also sought the help of experts from the Centre for Medicines Optimisation at Keele University and from the Regional Drug & Therapeutics Centre to select the most relevant examples. Based on our literature review and some initial discussions with stakeholders we drew up a list of criteria that we would like from an ideal case study. The criteria included: the market was dominated by liquid products; the market was of similar size to the AA by prescription

market; and the products were generally available both over the counter and by prescription.

- 6.28 We were aware that no product would match all the criteria and asked the experts to use their discretion to decide which criteria could be dropped for the purposes of finding a feasible case study. Five candidate products⁹⁰ were suggested initially. However, only one of these, Fluticasone, appeared suitable after further examination as it was the only one that was both a liquid⁹¹ and not potentially within the market definition used by the OFT in its Decision of 'no wider than the market for alginates and antacids'. In addition to this, another case study which fit most of our criteria was suggested by one of the generic drug manufacturers we spoke to. This was fluoxetine hydrochloride or liquid fluoxetine.

Case study 1: Fluticasone nasal spray

Background

- 6.29 Fluticasone is the active ingredient in a nasal spray which targets allergic and non-allergic inflammation of the nose and is also used in nasal drops. It is a common treatment for hay fever. There are two forms of fluticasone: fluticasone propionate and fluticasone furoate. The patent for the former expired in 2006 and the latter is still patent protected. There are several substitutes for fluticasone which are not biosimilar,⁹² such as mometasone and flurisolide based products.
- 6.30 Like AA drugs, fluticasone is sold over the counter as well as by prescription. The market size by NIC for prescription fluticasone was between £10 million and £20 million between 1998 and 2013 and so it is slightly smaller than the market for prescription AA drugs.
- 6.31 The only product in the market from 1998 and 2006 was the originator product, Flixonase which uses fluticasone propionate as the active ingredient. This was sold as a nasal spray from 1998 and as nasal drops from 1999, and it is produced by GlaxoSmithKline.⁹³ Following the expiry of the patent there was just one significant branded generic entrant,⁹⁴ Nasofan, which entered

⁹⁰ Omeprazole, Ranitidine, Maalox, Fluticasone and Levocetirizine/cetirizine/desloratadine/loratadine.

⁹¹ This was noted by a number of stakeholders as being a particularly important determinant of the number of potential generic entrants, see paragraph 4.49.

⁹² Biosimilars are a type of biological product that are licensed because they are highly similar to an already approved biological product, known as the biological reference product (reference product), and have been shown to have no clinically meaningful differences from the reference product

⁹³ Flixonase was renamed 'Pirinase' in 2013, but for clarity it will be referred to as Flixonase in this analysis

⁹⁴ Branded generics are sold under a brand name or trade mark whereas unbranded generics are sold exclusively by generic name.

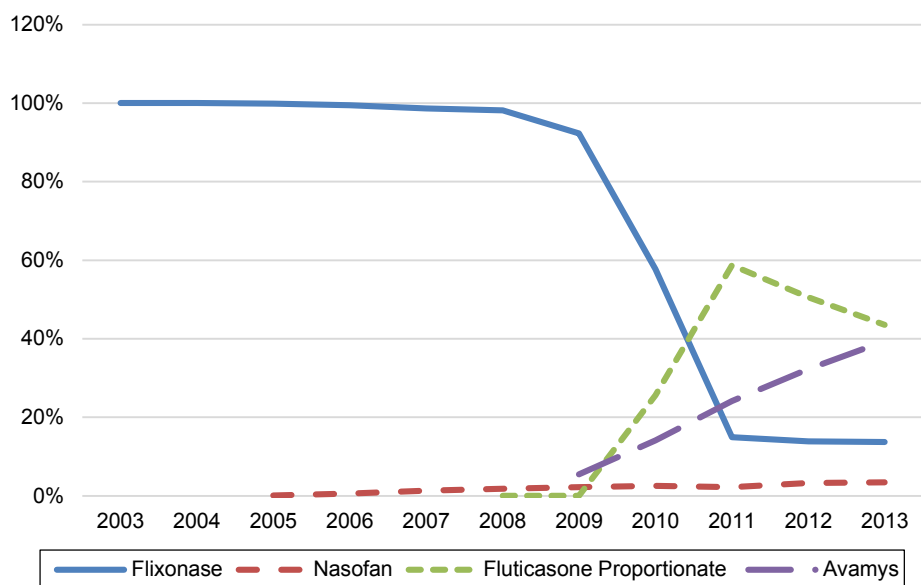
the market in 2006 and it is produced by Teva UK. Unbranded generic versions of the drug fluticasone propionate entered the market in 2008. In 2009, a few years after generic entry, GlaxoSmithKline launched a related product, Avamys, which uses fluticasone furoate as an active ingredient and so is still patent protected.⁹⁵ This is a further feature in common with the AA by prescription market, ie the existence of an extremely similar but not bio-identical secondary product produced by the originating firm. RB introduced GA and GlaxoSmithKline introduced Avamys. Both treat similar conditions to the original drug, but have small changes to the active ingredients and so are covered by a new patent.

- 6.32 We exclude nasal drops from our analysis. Nasal drops are more expensive by dosage and it is not clear that a dose of drops is comparable with a dose of the spray and therefore comparison between the drops and the spray can be difficult. There is also evidence to suggest that they are intended for the treatment of different symptoms.⁹⁶
- 6.33 In Figure 6.1 we present our analysis of the market share by dose of fluticasone spray. Generic entry took place slowly in the market for fluticasone spray. Flixonase had 100% of the spray market share by dosage until generic entry in 2006, and over 90% of the market until 2009, after which unbranded generic version(s) of Fluticasone Propionate began to acquire market share and the secondary originator product Avamys was launched. By 2011 the market share of Flixonase had fallen to 15% with the market share of the unbranded generic version(s) being 58% and that of Avamys being 24%. After 2012 Avamys gained some market share at the expense of generic Fluticasone Propionate.

⁹⁵ This is consistent with the evidence from one drugs manufacturer that suggested that it routinely produces counterparts to their own originator products after the leading patent expires.

⁹⁶ According to the Electronic Medicines Compendium the therapeutic indication for Flixonase Nasal Spray is 'The prophylaxis and treatment of seasonal allergic rhinitis (including hay fever) and perennial rhinitis' whilst the indication for Flixonase Nasule Drops is 'the regular treatment of nasal polyps and associated symptoms of nasal obstruction.' See: [electronic Medicine Compendium](#).

Figure 6.1: Market shares of Fluticasone Propionate spray by dosage



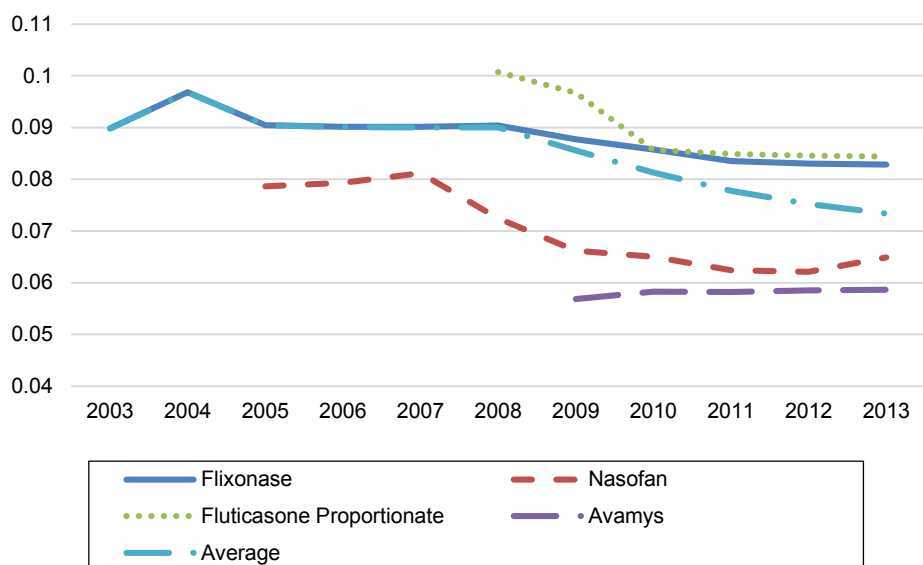
Source: CMA analysis of data retrieved from the websites of the NHS information centre in England.

6.34 In Figure 6.2 below we set out our analysis of the how the price of fluticasone, in terms of NIC per dose, has evolved since 2003. Before 2008 the average price of Fluticasone Propionate was, with the exception of 2004, £0.09. This was largely unaffected by the entry of the branded generic Nasofan but after the entry of unbranded generic versions of Fluticasone Propionate in 2008 the average price began to fall. It fell from £0.09 in 2008 to £0.07 in 2013, a reduction of 18.4%.⁹⁷ By 2013 the price of Flixonase had fallen to £0.08 (or 8.4%),⁹⁸ the same price as the generic Fluticasone Propionate. Rather than the entry of generic versions of the drug it would appear that the more substantial impact on the average price was the entry into the market of the secondary originator product, Avamys, which was priced at £0.06 per dose.

⁹⁷ Numbers may not match exactly due to rounding.

⁹⁸ Numbers may not match exactly due to rounding.

Figure 6.2: NIC per dose (£) of Fluticasone Propionate spray



Source: CMA analysis of data retrieved from the websites of the NHS information centre in England.

Case study 2: Liquid Fluoxetine

6.35 The next case study looks at the market for liquid fluoxetine hydrochloride. Fluoxetine is a type of antidepressant, created by Eli Lilly and marketed as 'Prozac'. It is primarily sold in the UK in tablet form.

6.36 Both AA products and fluoxetine can be provided as liquids or in tablet form. However, whereas Gaviscon is primarily sold as a liquid, fluoxetine is primarily sold as a tablet. It is possible that there may be some pressure on the prices of the liquid products from tablet versions as tablet dosage forms of drugs are generally (and in the case of fluoxetine) cheaper. However, markets for the liquid and tablet products are often separable given liquid products tend to be prescribed for particular categories of patient such as children and those who have significant difficulty taking solid medication.

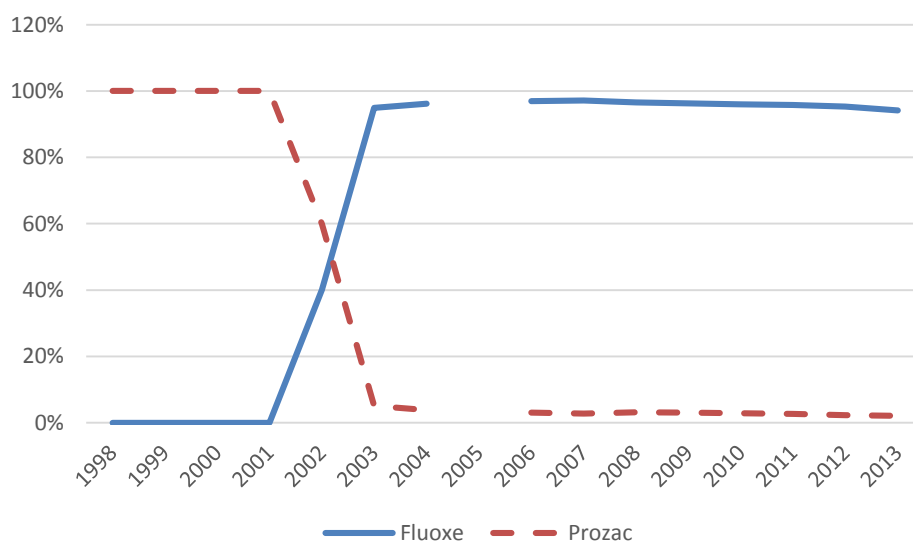
6.37 Another difference with the AA by prescription market is that the market for Fluoxetine has grown significantly in volume terms since patent expiry, whereas the AA by prescription market has been in a fairly steady state for a number of years.⁹⁹ Since 2002 the volume of Fluoxetine dispensed had grown in almost every year with total volume growth of 59% by 2013. The observed differences in market growth may have implications for the potential for reductions in the price/cost of drugs with a faster growing market potentially being more attractive to new entrants and also increasing the potential for scale economies. In addition the fact that the average price of Fluoxetine has

⁹⁹ As we discuss in paragraph 4.21 it is considered to be a mature drug market.

fallen market of itself generate more demand with, for example, it being prescribed in preference to other anti-depressants¹⁰⁰ or prescriptions being provided to more 'marginal' patients.

- 6.38 The patent on liquid Prozac expired in August 2001. The first generic non-branded fluoxetine liquid entered in 2002. Later two branded generics entered the market, these were: 'Prozit' which is manufactured by Pinewood and entered the market in 2007; and 'Prozep' which is manufactured by Chemidex Pharma Ltd and entered the market in 2008. In the year of patent expiry the value of market for liquid fluoxetine was £30 million by NIC in 2007, but this fell to £10 million in 2011 following generic entry and price decreases. The size of the market for fluoxetine at the time of patent expiry is similar to that of the AA market by prescription.
- 6.39 As shown in Figure 6.3, once generic entry occurred the market share of unbranded generic products increased rapidly accounting for 40% of the market for fluoxetine (in ml) in 2002 and 97% in 2003. Unbranded generic drugs maintained their high market share until the end of the dataset in 2013. Branded generic drugs accounted for less than 4% of the market by ml in each year since entry. The originator Prozac had a market share of 100% until generic entry occurred, this dropped to 60% in 2002 and fluctuated between 2% and 6% thereafter.

Figure 6.3: Market shares of Fluoxetine by ml

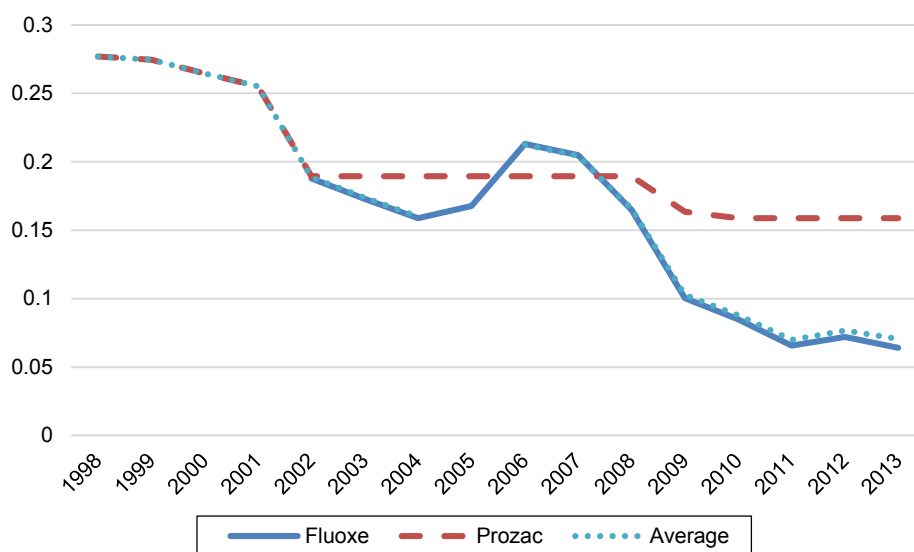


Source: CMA analysis of data retrieved from the websites of the NHS information centre in England.

¹⁰⁰ Fluoxetine is in a class of antidepressants known as selective serotonin reuptake inhibitors (SSRIs) and there are several other types of SSRIs.

6.40 Figure 6.4 sets out our analysis of the evolution of average prices of Fluoxetine products between 2002 and 2013. Between the year prior to the loss of patent and 2013 the average price of liquid Fluoxetine fell by around 73% from around £0.25 to £0.07 per ml.¹⁰¹ The average price of Prozac fell in the year of generic entry from £0.25 in 2001 to £0.19 in 2002, the same price as generic versions of Fluoxetine. After 2002 the average price of Prozac remained constant until 2008 before falling to £0.16 in 2009 and it has remained at that level since then. After 2003 the price of generic fluoxetine fell to £0.07 in 2013. With the exception of 2006 and 2007 this price has been falling across this entire period.

Figure 6.4: NIC per ml (£) of Fluoxetine



Source: CMA analysis of data retrieved from the websites of the NHS information centre in England.

6.41 Overall the cases studies, particularly that of fluoxetine, show significant penetration by generic products and a significant reduction in average price following the expiry of the patent on the originator drug. Certainly the impact of competition following the loss of patent in these markets was significantly greater than that observed in the AA by prescription market.

Estimate of possible savings to the NHS

Introduction

6.42 In this section we estimate the possible savings to the NHS absent the Withdrawal. The possible savings would be the result of the NHS paying higher prices for AA drugs than they otherwise would have done. The

¹⁰¹ Numbers may not match exactly due to rounding.

evidence that we have reviewed as part of this evaluation supports the view that there is a reasonable likelihood that possible savings to the NHS were not realised as a result of the Withdrawal. We have not, however, examined issues as to the effectiveness of steps taken by the NHS to mitigate the impact of the Withdrawal which was disputed in litigation between the NHS and RB (see paragraph 6.8 below and Appendix B. In this section we use NIC before discounts per item dispensed as our measure of price and changes in the overall NIC before discounts as our measure of total cost to the NHS).¹⁰²

- 6.43 The SoS and others claim suggests that following the assigning of the generic name ARFOS they would have expected effective generic competition in the AA by prescription market leading to a significant reduction in the cost of AA drugs to the NHS. Furthermore, the OFT Decision considered 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 and costs for the NHS than would have otherwise been the case. The market developments since were consistent with this.¹⁰³ In addition, our review of the factors that influence generic competition set out in Chapter 4 does not suggest that there is anything specific about the AA market by prescription that would lead us to think that more significant generic competition was not possible in this market.
- 6.44 The evidence from the wider economic literature and the two case studies set out in this chapter also supports a possible saving to the NHS. This evidence from the literature shows that in drug markets where the originator drug goes off patent and there is generic entry the market share acquired by generic entrants and the consequent reduction in average prices for that category of drug are significantly greater than observed in the AA by prescription market. This is also the case in the two case study markets.
- 6.45 In the remainder of this section we present our estimates of the possible savings to the NHS. We use evidence from the economic literature, our case studies and our analysis of the AA market to estimate how the market for AA drugs by prescriptions would have evolved in the absence of the Withdrawal. We estimate:
- the relative market share and prices of the key categories of products in the market (GA, GL, generic equivalents of GL and other) in the absence of the Withdrawal; and

¹⁰² The actual cost to the NHS will differ to from this value to an extent once discounts have been applied.

¹⁰³ [OFT Decision](#), paragraphs 6.159 & 6.161.

- a range of plausible values for the market share of GL that would have been acquired by generic entrants absent the Withdrawal.
- 6.46 We then use these prices and market shares to calculate a range of estimates of the overall cost of AA drugs to the NHS absent the Withdrawal. We then compare these to the actual cost to the NHS to generate a range of estimates for the possible savings.
- 6.47 As was the case with the direct market impact we focus our analysis on liquid AA products. We do not consider tablet products in our estimate of the possible savings. This does not mean that there was no potential for generic competition in the tablet part of the market but we considered that generic entry would be most likely in the significantly larger liquids part. Although, as we discuss in paragraph 4.46, competition in drug markets is generally more intense for tablet rather liquid products in this particular market the value of tablet sales is small. Indeed the only generic entry observed to date has been by a liquid product. However, we would consider that an estimate of the possible savings just taking into account liquid products is conservative. Focusing on just liquids also has the effect of simplifying the analysis as there is no need to compare prices across different dosage forms.
- 6.48 In calculating our estimate of the possible savings we assume that there would be no additional acquisition of market share by generics, beyond that which actually occurred in the AA market by prescription until the generic name ARFOS was published in 2007. After the publication of the name ARFOS generic prescribing would be more straightforward for GPs and therefore generic entry more likely. However, this does not mean that there would be no possible savings before 2007. As we set out below we estimate that had the Withdrawal not occurred, it is likely that GL would have had a higher market share and would have been priced at a lower price than GA. Our estimates therefore reflect an impact on the cost to the NHS before the assigning of the generic name ARFOS.
- 6.49 We assume there is no impact from the Withdrawal after 2016 when the patent expires on GA. After 2016 it is likely that generic versions of GA will enter the market and the impact of generic competition will supersede the impact of the Withdrawal.¹⁰⁴
- 6.50 As we note in paragraph 6.6, the details of the method used to generate the initial claim for damages of £90 million are not publicly available. Our

¹⁰⁴ This is not to say that there would be no impact on the cost to the NHS as it is possible, for example, that GA and generic versions of it could have a higher market share than they would otherwise and that these products are more expensive on average than GL and its generic equivalents. However, we have made a very conservative estimate that the value of overcharge after this is zero.

methodology may well differ from the methodology used in the claim. In addition, as we explain in appendix C the claim by the SoS and others appears to be wider than our estimate of the possible savings as it includes an element of damages for an alleged policy by RB to delay¹⁰⁵ the introduction of the generic name ARFOS and also damages related to the purchasing of tablets as well as liquids.¹⁰⁶ Our estimates of the possible savings therefore cannot be simply compared to the size of the claim. We also note that, as the sensitivity analysis we present below demonstrates, the value of the estimated possible savings is sensitive to the assumptions made about the evolution of the AA by prescription market absent the Withdrawal. We have been deliberately conservative in our approach and the possible savings could plausibly be higher than our estimate.

Estimated market shares and prices in the absence of the Withdrawal.

6.51 In Table 6.1 below we set out our estimates of the market share of the key categories of drugs in the market of AA by prescriptions as well as the overall number of items dispensed by pharmacists. We draw on the actual market share in the AA by prescription market between 2002 and 2013 and make a number of assumptions about how these would have evolved from 2006 onwards in the absence of the Withdrawal. The assumptions are as follows:

- The market share of 'other' brands between 2002 and 2013 was as observed in the PCA data and between 2014 and 2016 was assumed to be the same level as in 2013.
- The market share of GA grew between 2005 and 2016 at a rate of 5% a year, approximately equivalent to the growth in dispensing of GA observed between 2002 and 2004.
- Market shares of GL and generic equivalents was the remainder of the market after the market shares of GA and other.

6.52 Applying these assumptions essentially means that in the absence of the Withdrawal we assume that the GL and generic versions of it would have remained the dominant product in the market but that GA would have continued to grow its market share at the expense of these at a rate consistent with that observed immediately prior to the Withdrawal.

¹⁰⁵ The OFT closed any investigation into the alleged delay policy by RB on the grounds of administrative priorities. As this was not part of the OFT Decision our estimate of overcharge does not include any element related to the alleged delay policy.

¹⁰⁶ For the reasons noted in paragraph 6.47 our estimate of the overcharge focuses on liquid products only.

6.53 In terms of overall volumes dispensed we assume that the same number of items were dispensed between 2006 and 2013 as were actually dispensed. We then assume that the volumes of items dispensed between 2013 and 2016 was the same as in 2013. There are some possible reasons why this might not be the case. It is possible that the overall number of items dispensed may have been higher due to: higher consumption because GL, and therefore generic equivalents, are less concentrated than GA; or because generic competition would lead to a lower price for AA liquid products and this would increase demand for these products. Neither of these outcomes are certain given, as we discuss in paragraphs 5.13 and 5.14: the extent to which patients do consume different concentrations of a liquid AA products differently is very unclear; and the AA by prescription market is conserved mature there the extent to which there would be scope for GP to prescribe AA drug in higher volumes, either due to prescribing them instead of other drugs or prescribing them to more 'marginal' patients, is uncertain.

Table 6.1: Estimated market shares by item dispensed and overall volume dispensed absent the Withdrawal

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Other (%)	10.6	10.4	9.8	9.1	8.5	8.0	7.5	6.8	6.1	6.1	6.1	6.1
GA (%)	20.4	21.4	22.5	23.6	24.8	26.0	27.3	28.7	30.1	31.7	33.2	34.9
GL and generic equivalents (%)	69.0	68.2	67.7	67.3	66.7	66.0	65.1	64.5	63.7	62.2	60.7	59.0
Total (%)	100	100	100	100	100	100	100	100	100	100	100	100
Volume of items dispensed (millions)	5.89	5.33	5.17	5.04	4.93	4.96	4.88	4.93	4.90	4.90	4.90	4.90

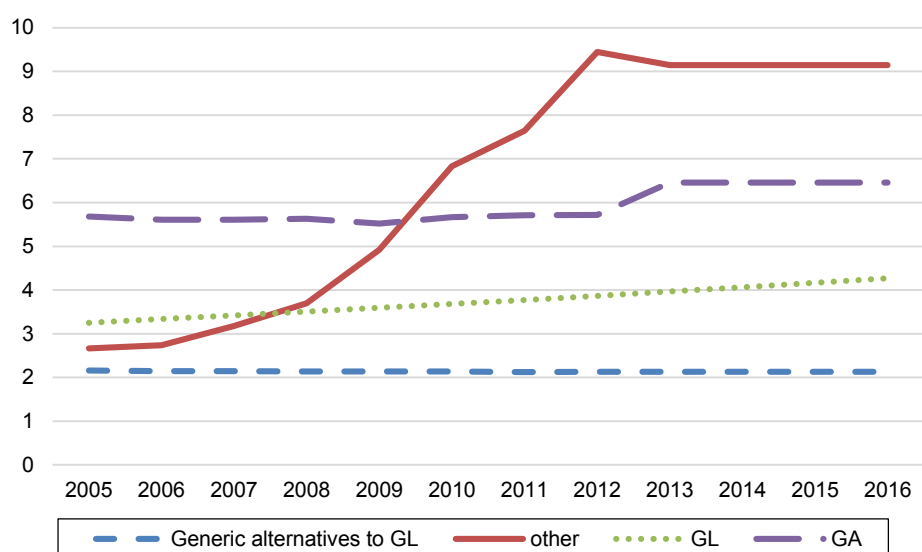
Source: CMA analysis.

6.54 In Table 6.2 and Figure 6.5 below we set out our estimates of the prices of the key categories of drugs in the AA by prescription market absent the Withdrawal. As with our approach to estimating market shares we draw on the actual market data from between 2002 and 2013 and make a number of assumptions about how these would have evolved from 2006 onwards in the absence of the Withdrawal. To estimate prices the assumptions we have made are as follows:

- The price of GA and other brands was as observed in the PCA data between 2006 and 2013 and at the 2013 level thereafter.
- The price of generic equivalents to GL are assumed to be the same price as Peptac was between 2005 and 2013, then at the 2013 Peptac price from 2013 until 2016.
- The price of GL was as observed in the PCA data between 2002 and 2004 and for each year after 2004 the price was the previous year's price inflated by an assumed inflation rate of 2.5%.

6.55 Applying these essentially means that absent the Withdrawal for the most part prices would have evolved after the Withdrawal in a similar manner to how they actually did. The main difference with actual market prices is the much lower estimated price of GL over the period as after the Withdrawal prescription packs of GL were unavailable and the price paid by the NHS per item of GL dispensed in response to prescriptions was the (much higher) OTC price. We have assumed that prescription packs of GL remained available and that the price of these between 2005 and 2016 in real terms was similar to what it was immediately prior to the Withdrawal.

Figure 6.5: Estimated NIC per item (£) dispensed absent the Withdrawal



Source: CMA analysis.

6.56 We consider these assumptions on changes in prices to be fairly conservative as it might be expected that absent the Withdrawal there would have been entry, in addition to Peptac, by generic versions of GL. This would have put downward pressure on the prices of GL and Peptac. This would be consistent with the economic literature and our case studies which provide evidence suggesting that the difference between the price of the originator drug (in this case GL) and generic equivalents is often significantly greater than is apparent from our estimated prices. We also note that, as discussed in paragraph 4.51, there was interest supplying a generic version of GL from at least one other drug company absent the Withdrawal.

Table 6.2. Estimated NIC per item (£) dispensed absent the Withdrawal

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Generic alternatives to GL	2.16	2.15	2.15	2.14	2.14	2.14	2.13	2.13	2.13	2.13	2.13	2.13
Other	2.67	2.74	3.18	3.70	4.92	6.83	7.65	9.45	9.14	9.14	9.14	9.14
GL	3.25	3.34	3.42	3.50	3.59	3.68	3.77	3.87	3.97	4.06	4.17	4.27
GA	5.68	5.61	5.61	5.63	5.52	5.67	5.71	5.72	6.46	6.46	6.46	6.46

Source: CMA analysis.

Estimated market share acquired by generic versions of GL

- 6.57 Following the assigning of the generic name ARFOS in 2007 we assume that the proportion of the AA by prescription market accounted for by 'GL and generic equivalents' would be subject to more intense generic competition. This would arise because GPs would be able to search for and find a generic name for GL through the basic functionality of their prescribing software and would most likely respond to the incentives they face to prescribe generically in greater numbers.
- 6.58 In Table 6.3 below we set out a number of scenarios for the proportion of the market share of GL that would have been captured by generic versions of GL in the absence of the Withdrawal after the assigning of the name ARFOS. The scenarios are based on our review of the economic literature and our two case studies.

Table 6.3. Scenarios for markets share acquired by generic versions of GL

	<i>Percentage of market acquired by generic versions of GL</i>									
	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Kanavos (2014) – lower decile	36	43	43	43	43	43	43	43	43	43
Kanavos(2014) – median	35	47	47	47	47	47	47	47	47	47
Kanavos (2014) – upper decile	35	47	47	47	47	47	47	47	47	47
EC sector study (2009)	30	45	45	45	45	45	45	45	45	45
Fluoxetine case	40	95	95	95	95	95	95	95	95	95
Fluticasone case	5	58	40	40	40	40	40	40	40	40

Source: CMA analysis.

- 6.59 The Kanavos and EC Sector scenarios are based on the observed average market share acquired by generic drugs following the expiry of originator drug patents in samples used in those studies where there was entry by a least one generic. We assume that generic versions of GL achieve the same level of market share as observed by generic products on average in these studies. The studies only report the level of generic market shares for a two year window after patent expiry therefore. We assume that after two years generic penetration remains at a constant level.
- 6.60 The fluoxetine and fluticasone scenarios assume that the market share achieved by generic versions of GL is the same as that observed for generic products in those markets after patent expiry. In the case of fluticasone we only observe from the available data a short period (two years) after generic entry so after this the level of generic market share is assumed to remain constant. For Fluoxetine we have data available for more than ten years after patent expiry and the entry of generics, but in this case by the second year after expiry the share of generics drugs in this market remains constant.

6.61 For each of the scenarios we are able to generate an estimate of the combined 'GL and generic equivalents' market share for each year (from Table 6.1) acquired by generic versions of GL. We do this by assuming that the generic share of the GL and equivalent volumes in each year are the same as is suggested by each of the scenarios reported in Table 6.3. So, for example, the EC Sector Study scenario for the year 2013 has a generic market share of 45%, whereas our estimated combined GL and generic equivalents share of AA by prescription for 2013 is 63.7%. We therefore estimate the total share of the AA by prescription market accounted for by generic versions of GL in 2013 as the multiplication of these, ie 28.7%.

Estimated possible savings

Estimated range and base case for possible savings

6.62 To estimate the value of the possible savings to the NHS we first estimate the cost of AA drugs absent the Withdrawal and then compare this to the actual cost of AA drugs to the NHS. We generate a range of estimates using the scenarios we have developed for generic acquisition of market share before selecting a base case.

6.63 For each scenario we estimate the cost to the NHS of AA drugs in each year from 2005 to 2016 (as measured by NIC before discounts) absent the Withdrawal by a simple multiplication of our estimates of market shares and prices of GA, GL, generic versions of GL 'other' brands and the total volume of AA liquid drugs dispensed for each year during this period. We do this for each scenario in set out in Table 6.3. The key difference between each annual estimate of cost is the assumed market shares of generic versions of GL. Where a scenario suggests a greater market share for generic drugs this will lead to a lower estimated cost of AA liquid drugs to the NHS and hence the estimated possible savings will be larger.

6.64 For the actual cost to the NHS of AA liquid drugs we use the reported NIC of these according to PCA data.

Table 6.4 NPV of estimated savings

Scenario	2005 prices £m		
	NPV of estimated cost to NHS between 2005 and 2016	NPV of actual cost to NHS between 2005 and 2016	NPV of estimated possible savings to NHS between 2005 and 2016
Kanavos – lower decile	229.6	198.1	31.4
Kanavos – median	229.6	198.0	31.6
Kanavos – upper decile	229.6	196.7	32.9
EC Sector	229.6	197.4	32.2
Fluxoxetine	229.6	179.0	50.6
Fluticasone	229.6	198.4	31.2

Source: CMA analysis.

6.65 The range of estimated savings from our scenarios is between £31.2 million and £50.6 million. Only one of these, based on the Fluoxetine case study, is greater than £33 million. As we discuss in paragraphs 4.53 and 4.54, our review of the characteristics of this market suggested that whilst there is the potential for significant generic competition in this market there are also some factors that might mitigate the impact of this. We therefore consider that a base case value for possible savings towards the conservative end of our estimated range would be appropriate, especially as the majority of our estimates are towards the lower end of the range. We consider a conservative estimate for the possible savings to the NHS resulting from the Withdrawal to be around £31 million in 2005 prices.

Sensitivity of the possible savings to some alternative assumptions

6.66 In Appendix F we present analysis of the sensitivity of the estimated possible savings set out in Table 6.4 to alternative assumptions to those set out in paragraphs 6.51 and 6.54. In particular we make alternative assumptions about:

- the growth of the volumes of GA dispensed absent the Withdrawal; and
- the price of generic equivalents of GL absent the Withdrawal and subsequent to the assigning of the generic name ARFOS.

6.67 We present the results of our findings for each sensitivity separately but note that in principle it is possible for both the growth in the market share of GA and the price of generic equivalents to be different from the assumptions we set out above. If we were to make different assumptions for both growth in GA and generic prices then any consequent change to the estimated savings arising from these changes would be cumulative. Therefore, the values presented below should not be taken to be an upper and lower bound on the possible savings to the NHS but instead an indication how sensitive our estimate is to changes in the underlying assumptions.

Sensitivity to alternative assumptions about the growth in market share of GA

- 6.68 The range of estimated savings is reasonably sensitive to alternative assumptions about the growth in the market share. In the analysis we present in Table 6.3 the estimated savings are based on an assumption of 5% a year growth in the market share of GA and the range of estimated saving is between £31.2 million and £50.6 million. If we assume that the growth in GA market share is 0% a year this range is £44.9–£72.5 million. An assumed 10% a year growth in the market share of GA results in an estimated range of the possible savings of between £23.0 million and £37.3 million.

Sensitivity to alternative assumptions about the price of generic equivalents to GL

- 6.69 In addition to evidence on the levels of market share achieved by generic drugs the economic literature and our case studies also provide evidence on the price achieved by generic drugs on entering the market. When we use this evidence to create a series of scenarios for the generic price and combine them with the scenarios in Table 6.2 for generic market shares this results in a range of estimated possible savings of between £32.1 million and £56.9 million.

7. Conclusions

- 7.1 In this evaluation we have focused on the impact of the OFT investigation and Decision. The validity of the decision-making has not been a particular focus in this case because RB admitted to the abusive conduct. However, we do consider, at a high level, two aspects of the investigation and Decision where there is the potential for lessons to be learnt and which are also relevant for how we might view the impact of the Decision. These are: would the OFT have achieved a greater impact if the investigation and Decision had come earlier? and does the OFT Decision not to issue any Directions in this case appear reasonable?
- 7.2 Our main focus in this evaluation has been on assessing the impact on consumers for whom in the context of a public healthcare market we use taxpayers as a proxy.¹⁰⁷ We look at the direct impact arising from the OFT Decision as well as possible savings to the NHS were it not for the conduct by RB. The former is relevant to the objective of improving the functioning of the market and in doing so bringing benefits to consumers, whilst the latter informs our understanding of the impact of anti-competitive behaviour and the importance of rigorous enforcement and the deterrence of similar actions.
- 7.3 The OFT noted in the Decision that it did not expect a significant direct market impact because of changes in GP and patient behaviour following the Withdrawal. However, we investigate if that was in fact the case.
- 7.4 Our analysis of PCA data showed no discernible direct market impact from the OFT investigation or Decision. The reasons for this lack of impact are consistent with the reasons put forward at the time of the Decision by the OFT. Specifically, the lack of impact appears to be largely due to the success of RB's Withdrawal strategy in switching patients from GL to the (still patented) GA along with patient and GP inertia and difficulties in prescribing generic alternatives to GA. The potential for GPs to switch away from GA to using GL or a generic version of it appears to have been severely restricted by the basic functionality of the GP prescribing software which did not suggest the availability of these alternatives to GA.
- 7.5 Our review of the factors that influence competition once an originator drug goes off patent did not identify any particular reason why, absent the

¹⁰⁷ As the primary objective of the CMA is to promote competition for the benefit of consumers, our evaluation tends to focus on the impact on consumer welfare whilst also considering the impact on overall economic welfare. In the case of a public healthcare market such as this one, where consumers either do not pay for services received or only pay a small proportion of the total cost, we use taxpayers as a proxy for consumers. For the purposes of this evaluation we approximate this by net ingredients cost of AA drugs before discounts (often referred to as clawback) as this information is publically available to download from NHS information centres.

Withdrawal, there would not have been a more significant impact from generic competition in the market for AA drugs by prescription. There are a number of characteristics of this market which might limit, to some extent, the impact of generic competition, in particular: the fact the AA drugs are typically liquid products which limit the number of potential generic entrants; and the fact that AA drugs are compound drugs which could reduce the tendency of GPs to prescribe generically. However, there are also factors that lead us to believe that reasonably successful generic competition could have been possible in this market, absent the Withdrawal, once the generic name ARFOS had been assigned. These include: there being no barrier to high levels of generic prescribing of AA drugs by GPs especially as they are strongly encouraged to do so in most circumstances and they actually do so in large quantities where this is possible; pharmacists having strong incentives to dispense cheaper generic drugs when they can do so and appearing to be willing to do so in the case of AA drugs; and there being some interest in entering this market from another supplier.

7.6 This conclusion that there was the potential for more significant generic competition in this market implies that the NHS could have saved money on its purchase of AA drugs were it not for the infringement of competition law by RB. Indeed the Secretary of State for Health and others filed a claim for compensation of £90 million on this basis in the High Court. In February 2014 the claim was settled confidentially with no admission of liability by RB.¹⁰⁸ Claims for compensation were also brought against RB by other parties, including certain generic manufacturers and suppliers. We have not reviewed all of the material from these claims in preparing this evaluation, but note that these claims conflict in some aspects with the SoS claim.

7.7 As the value of the settlement is not publicly available we have estimated the possible saving to the NHS absent the Withdrawal. We generate a range of estimated values for the possible savings drawing on a range of evidence including: the economic literature on the impact of generic competition in the UK; two case studies of the impact of generic competition from two markets that are broadly similar to the AA market by prescription; and publicly available court documents from the claim by SoS and others. The estimates of possible savings that we have generated are appropriate only for the purposes of an evaluation of competition enforcement and are not intended for any other purpose, for example the calculation of damages.

¹⁰⁸ The details of the method used to generate the initial claim for damages of £90 million is not publicly available. As we explain in Appendix C the claim by the SoS and others appear to be wider than our estimate of the overcharge as it includes element of damages for an alleged delay policy by RB and also includes an element of damages in relation to the purchase of alginates in tablet form.

- 7.8 We use this evidence to estimate a number of plausible scenarios for the market share that would have been achieved by generic versions of GL absent the Withdrawal. Based on these we estimate the total cost to the NHS of AA drugs absent the Withdrawal and compare these to the actual cost to estimate the value of possible savings.¹⁰⁹ The range of these estimates was between £31 million and £50 million in 2005 prices (2005 was the year of the Withdrawal).
- 7.9 Given that our review of the characteristics of the AA by prescription market and the factors that influence the extent of generic competition suggests there were some factors that might mitigate the potential for generic competition in this market we have selected a value from bottom of this range. Therefore, we selected as our base case estimate of the possible savings a value of £31 million.
- 7.10 The value of the estimated possible savings is sensitive to the assumptions made about the evolution of the AA by prescription market absent the Withdrawal. We have been deliberately conservative in our approach and the possible savings could plausibly be higher than our estimate. We have been deliberately conservative in our approach and whilst the possible savings could plausibly be different from our estimate we consider our results to be reasonable.

¹⁰⁹ For the purposes of this evaluation we approximate this by net ingredients cost of AA drugs before discounts (often referred to as clawback) as this information is publically available to download from NHS information centres. The actual cost to the NHS will differ to from this value to an extent once discounts have been applied.

Appendix A: Remuneration of prescribed drugs through the primary care channel

1. Pharmacies are reimbursed for the cost of dispensed items as follows. The total value of the prescription medicines dispensed by a pharmacy is calculated on the basis of a reference price for each drug. The price at which prescriptions are reimbursed depends on whether they are written for a brand or a generic, and on the availability of true generics in the market. The value of the medicines at these reference prices is known as the Net Ingredient Cost (NIC).
2. There are two scenarios to consider, these are 'reimbursing as a brand' and 'reimbursing as a generic' respectively.
 - (a) **reimbursing as a brand:** For branded drugs against branded prescriptions (or against generic prescriptions where no true generic is available, for example when the originator drug is still on patent) pharmacies are reimbursed at the reference price – which is the manufacturers' NHS list price – less a 'clawback'; and
 - (b) **reimbursing as a generic:** For generics, the price is determined by the Secretary of State and set out in Part VIII of the Drug Tariff which is published monthly jointly by the DH and the NHS.¹¹⁰ Pharmacies are then reimbursed at a price set down in the Drug Tariff, again less clawback.¹¹¹
3. The pricing mechanism for controlling the manufacturer's list price is the Pharmaceutical Price Regulation Scheme (PPRS).¹¹² Drug Tariff prices are set according to a variety of mechanisms, the most important of which is scheme M, where the price is based on quarterly surveys of transaction prices between manufacturers, wholesalers and pharmacies.
4. Though the funding agreement community pharmacies have with the DH community pharmacies are allowed to retain, collectively, a margin of

¹¹⁰ The Drug Tariff sets out information on the remuneration of pharmacies including the drug price that will be paid and the rules to follow when dispensing. It also provides information about drugs which cannot be prescribed or can only be prescribed under certain circumstances.

¹¹¹ The pharmacy is then reimbursed for its NIC less a deduction or 'clawback' of part of the average discount at which it is assumed to have purchased the medicines from manufacturers and wholesalers. The rate of deduction is larger for higher values of monthly NIC, to in theory reflect the greater discounts available to pharmacies purchasing larger quantities of medicines. However, while clawback is intended to reflect the purchasing discounts a pharmacy received across all of its medicines in aggregate, it will not necessarily accurately reflect the level of discount earned on a specific product.

¹¹² The PPRS is a voluntary agreement to control the prices of branded drugs sold to the NHS. It is negotiated between the DH, acting on behalf of the UK government and Northern Ireland, and the branded pharmaceutical industry, represented by the ABPI. See [DH guidance on Pharmaceutical Price Regulation Scheme 2014](#).

£800 million on the prescription drugs they supply.¹¹³ DH looks to achieve this target margin by adjusting the prices of category M drugs¹¹⁴ on a periodic basis. DH regularly measures the margin actually obtained by a sample of pharmacies. It recognises the inevitable lag in time taken to find out about what is happening in the market and the adjustment of prices, and allows pharmacies to benefit from retaining savings made for a defined period. This 'regulatory lag' incentivises pharmacies to procure prescription medications cost effectively. The intention behind the design of the NHS reimbursement system is that the amount paid by the NHS represents the amount paid by the pharmacies for drugs (plus the retained margin) but in practice these values often differ.

5. The NHSBSA remunerates pharmacies for the drugs they dispense against prescriptions from PCOs as above and then the cost of these is taken from the individual PCO budgets. The deduction from PCO budgets is made based on the prescription data they submit to the NHSBSA on a monthly basis.

¹¹³ This was increased from £500 million in the funding settlement agreed with community pharmacies for the year for 2014/15.

¹¹⁴ The Drug Tariff sets out prices for three categories of drugs A, C and M. Category M includes drugs that are readily available as a generic where the DH calculates the reimbursement price based on information submitted by manufacturers.

Appendix B: Differences in prescribing AA drugs in different parts of the UK

6. Analysis of a more disaggregated breakdown of the prescription data for AA drugs revealed that underlying the UK wide picture there were some big differences in the relative market share across different parts of the UK. In particular the market share of Peptac is significantly higher (and consequently the market shares of the Gaviscon brands significantly lower) in Scotland, Wales and, most notably, Northern Ireland than in England.
7. The Peptac market share was similar in each part of the UK prior to 2004 however the gap between market shares in England and the rest of the UK become significant around time of the Withdrawal. The increases in the market shares of Peptac between 2004 and 2006 were much more marked outside England. Following 2006 the market share of Peptac grew steadily in Scotland and in Northern Ireland, whilst in Wales it remained fairly stable.
8. The UK wide pattern of relative market shares closely resembles that of England which is to be expected given that 78% of the items dispensed during the period 2002 to 2013 were in England. We set out a more detailed analysis of market share by each part of the UK in Table 1 below.
9. Analysis of the differences in the prescribing of liquid sodium alginate products across the different parts of the UK has not been a particular focus of this evaluation and we did not have any particular prior expectation that there would be a difference before looking at the data. From our desk based research some possible explanations we considered plausible were: differences in the GP contract; GP financial incentives; prevalence of alternative prescribing software; and local prescribing advice. In addition, there is a difference in the types of PCO with CCGs, the form of PCO adopted in England and Wales, and Health Boards the preferred form of PCO in Northern Ireland and Scotland.

Table 1: Market share by number of items dispensed in response to a prescription

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	%
<i>England</i>												
Gaviscon Advance	22	24	25	47	69	70	71	72	72	71	69	
Gaviscon Liquid	70	68	67	37	7	8	7	7	7	7	7	
Peptac	9	8	7	16	24	22	22	21	21	22	24	
Other brands	16	13	11	12	11	11	10	9	9	8	7	
<i>Northern Ireland</i>												
Gaviscon Advance	14	16	16	34	50	43	36	34	35	31	30	
Gaviscon Liquid	68	68	70	38	7	7	7	7	6	5	5	
Peptac	6	6	5	19	34	42	51	53	53	54	55	
Other brands	11	10	9	9	8	7	7	6	6	10	10	
<i>Scotland</i>												
Gaviscon Advance	12	13	14	15	41	51	52	52	52	50	49	
Gaviscon Liquid	68	69	66	65	20	7	9	11	12	10	8	
Peptac	3	4	8	8	26	29	28	27	27	30	35	
Other brands	17	15	13	12	13	13	12	11	10	9	8	
<i>Wales</i>												
Gaviscon Advance	15	16	17	31	47	48	50	51	53	55	58	
Gaviscon Liquid	61	60	62	34	7	8	8	9	8	7	7	
Peptac	12	12	11	24	36	33	33	33	31	30	29	
Other Brands	12	12	10	10	10	10	9	8	8	7	6	
<i>UK</i>												
Gaviscon Advance	18	20	21	38	58	60	61	62	62	62	61	
Gaviscon Liquid	61	61	62	37	8	7	7	7	7	7	7	
Peptac	7	7	7	15	23	23	23	23	22	24	26	
Other brands	14	12	10	11	10	10	9	9	8	8	7	

Source: CMA analysis of data retrieved from the websites of the NHS information centres in England, Scotland, Wales and Northern Ireland.

10. We asked a small number of stakeholders whether any of these factors might be influential in driving the differences in rates of prescribing that we observed.¹¹⁵ The response was that there was no clear answer but that a combination of these and other factors would influence prescribing at a local level. Two factors that were mentioned specifically as having the potential to influence local prescribing rates were local advice on prescribing and differences in the intensity of marketing activity by pharmaceutical companies in different regions. In addition a recent report by the NAO suggested that ‘Some of the variation [In prescribing between the nations] may be due to differences in prescribing practices with the average number of doses per prescription item potentially differing between the nations’.¹¹⁶ It may be for example that around the time of the Withdrawal the marketing of RB was more intense in England than elsewhere or it might have been the case of that national and local healthcare bodies in the UK Scotland, Wales and Northern Irelands were more active in trying to switch prescribers to Peptac. However, we have no evidence directly suggesting that either of these were factors were important in the AA market by prescription.

¹¹⁵ Including the DH and one of the pharmaceutical advisers to a CCG.

¹¹⁶ ‘Healthcare across the UK: A comparison of the NHS in England, Scotland, Wales and Northern Ireland’. NAO (2012), paragraph 2.21.

Appendix C: SoS and others claim

1. The SoS and others claim explicitly relied on the OFT's finding of abuse of dominance, and the fact that RB entered into an Early Resolution Agreement by which it admitted its infringement of CA98.¹¹⁷
2. In addition to relying on the OFT's finding of abuse of dominance and the market definition, the DH quote evidence gathered in the course of the OFT's market investigation, such as referring to the OFT's analysis of market shares¹¹⁸ and internal emails the OFT gathered setting out RB's abusive strategy.¹¹⁹
3. In the loss and damages section of the publicly available part of the SoS and other Amended Claim Form it appears they argued that as a foreseeable consequence of the behaviour of RB loss and damages would have been suffered because:
 - (a) generic alternatives to GL (liquid and tablets) would have been available from 1 December 2005;
 - (b) between 4 June 2005 and 1 December 2005, a proportion of NHS prescribers treating GORD who in fact prescribed GA would instead have continued to use GL;
 - (c) after 1 December 2005, NHS prescribers would have begun to prescribe generic replacements to GL (liquid and tablets);
 - (d) where the generic alternative to GL was dispensed, the reimbursement price payable by the responsible PCT would have been lower than the price in fact paid for a prescription for GA; and
 - (e) in addition, RB would have reduced the prices at which GL and/or GA (liquid and tablets) were supplied to dispensing pharmacies in order to respond to the competitive threat of generic alternatives to GL.¹²⁰
4. From the description provided in the Amended Claim Form it appears that the SoS and other claimed damages caused by RB allegedly delaying the introduction of the generic name ARFOS in addition to the Withdrawal. The OFT closed its investigation into the alleged delay by RB of the introduction of a generic name on the grounds of administrative priorities. As the alleged

¹¹⁷ See, for example, SoS and others Amended Claim form, paragraphs 16–18.

¹¹⁸ See, for example, Claim, paragraph 63.7.

¹¹⁹ See, for example, Claim, paragraph 71.1 and OFT Decision paragraph 2.142.

¹²⁰ This paragraph is adapted from the SoS and others Amended Claim form paragraph 103.

delay was not a part of the OFT Decision no estimate of any possible savings relating to this is included in the estimates of the possible savings presented in Chapter 6.

5. The description also appears to suggest that the claim covered both liquid and tablet forms of Gaviscon. The market definition in the OFT's Decision, which was accepted by both the DH and RB in their subsequent litigation, includes both dosage forms. However, the OFT's finding of abuse of dominance refers only to the withdrawal of prescription packs of GL, therefore we have not included any estimate of possible savings relating to this.
6. The SoS and others initial claim for loss and damages was £90 million. The settlement value itself will most likely be different from the claim amount. Claims for compensation were also brought against RB by other parties, including certain generic manufacturers and suppliers. We have not reviewed all of the information from these claims in preparing this evaluation, but note that these claims conflict in some aspects with the SoS claim.

Appendix D: Key literature on the impact of generic competition in the UK

Summary of key studies on the impact of generic competition in the UK

Study	Data	Findings			
		<i>Number of generic entrants</i>	<i>Market share after patent expires</i>	<i>Prices/cost after patent expires</i>	<i>Other</i>
DH/ABPI (2002)*	137 chemical entities, which were identified as having lost patent protection in the UK between 1990 and 2000. Source: NHS information centre statistics	Varied significantly by product. For only 47 out of the 137 products was there any generic entry but for some products there were up to 16 generic entrants.	Of the 28 products in the High NIC category four experienced generic erosion by 2000 of 40% or more, six between 20% and 40% and 14 less than 20% (remaining 4 excluded as patent had only just expired).	High NIC (>£10m per year) – Average 25% reduction in cost by year 2000. Mid NIC (>£3m, <£10 per year) – 2% reduction. Low NIC (<£3m) – 0.3% reduction.	Study found that the impact of generic savings tended to vary significantly with the number of generic entrants and that this was influenced by a number of factors such as market size, form of product (tablet, liquid), etc.
EU Pharmaceutical Sector Inquiry (2009)†	128 molecules that faced loss of exclusivity over the period 2000–2007. International non proprietary names (INNs) likely to be representative of the EU as a whole. The resulting list comprised 128 INNs for which the Commission subsequently requested information from each of the 27 EU Member States. 84 of these molecules were relevant to the UK.	After two years on average eight companies were active in each INN. Figures provided just for the UK suggest there were also eight active companies on average with around two being manufacturers of originator drugs. Over the sample period 66% of all INNs where the patent expired faced generic entry.	The market share (in volume terms) of the generic companies was about 30% at the end of the first year and 45% after two years.	Price of generic medicines during the first year after loss of exclusivity was, on average, 25% lower than the price of the originator medicines prior to the loss of exclusivity. Two years after entry, prices of generic medicines were on average 40% below the former originator price. Also the prices of originator products appear to drop following generic entry (by 15% on average).	Often generic entry occurs later than could be expected on the basis of the statutory loss of exclusivity of the originator product. The average time gap between the date on which the originator medicines lost exclusivity and the date of first generic entry was more than seven months (on a weighted average basis for the whole sample). Also for the highest selling medicines, for which rapid entry matters most, it took about four months on average before market entry
Kanavos (2014)‡	Proprietary data from Intercontinental Medical Statistics (IMS). The data covered the period from the last quarter of 1998 (Q4, 1998) to the last quarter of 2010 (Q4, 2010)	For the UK on average two generic competitors were observed across all molecules in 12 months after patent expiry with 2.4 competitors on average after 24 months after patent	For the UK where there was at least one generic entrant the markets shares by volume of the combined generics were on average 15.5% after 3 months, 35.8% after 12 months and 46.5% after 24	For the UK on average prices of generic competitors observed 12 months after patent expiry were 60.6% of the originator price at expiry and after 24 months	In the UK 24 months after patent expiry a generic had been launched for 46.7% of molecules. These molecules accounted for 88.6% of sales.

Study	Data	Findings			
		<i>Number of generic entrants</i>	<i>Market share after patent expires</i>	<i>Prices/cost after patent expires</i>	<i>Other</i>
	for a total of 101 molecules (originator brands and generics) and their combinations, which lost patent protection between January 2000 to December 2008 individually across 12 EU member states. For the UK 90 molecules were part of the study.	expiry (the 12 and 24 month average for molecules that were in the bottom 10% by sales by value were 1.4 and 1.6 respectively)	months. For the bottom decile the 3, 12 and 24 month figures were 13.9%, 36.5% and 43.4% respectively. For the top decile the 3, 12 and 24 month figure were 25.4%, 35% and 46.6% respectively.	30.6% of this price. The 12 and 24 month average for molecules that were in the bottom 10% (by sales) were 76.7% and 56.5% respectively For the top decile the values were 54.3% and 26.5% In the UK, where there had been at least one generic entrant, originator prices 12 and 24 months after patent expiry were 99.1% and 96.9% respectively of the price at time of patent expiry.	

Sources:

*PPRS: [The Study into the Extent of Competition in the Supply of Branded Medicines to the NHS, Department of Health and ABPI.](#)

†[Pharmaceutical Sector Inquiry, European Commission \(2009\)](#). A more condensed version looking mainly at the impact of generic entry can be found in [Glowicka et al \(July 2008\), Generic entry in prescription medicines in the EU: main characteristics, determinants and effects](#). All of the authors were members of the Chief Economist Team of DG Comp.

‡Kanavos P. Measuring performance in off-patent drug markets: A methodological framework and empirical evidence from twelve EU Member States. Health Policy 2014.

Appendix E: Selection of the case studies

1. In our search for relevant case studies we sought advice from the stakeholders that we interviewed during the evaluation and we also sought the help of experts from the Centre for Medicines Optimisation (CMO) at Keele University and from the Regional Drug & Therapeutics Centre (RDTC). These organisations, among other things, provide advice and support on cost effective prescribing for GPs via clinical commissioning groups (CCGs). Their work includes the use of comparators for purposes similar to our intended use of case studies in this evaluation.
2. Based on our literature review and some initial discussions with stakeholders we drew up a list of criteria that we would like from an ideal case study. The criteria were as follows:
 - (a) be a liquid;
 - (b) be a well-known brand with a large off-prescription advertising budget;
 - (c) have a similar market size to the AA by prescription market: approximately £10–£30 million a year;
 - (d) have alternatives which are therapeutically relevant but not necessarily identical;
 - (e) be sold both over the counter and via prescription; and
 - (f) have gone off patent recently and (unlike Gaviscon) faced relatively unimpeded generic competition.
3. At the time we considered these criteria the most relevant. The criteria were intended to cover both demand side (treatment, brand awareness, possible substitutes, dosage form) and supply side (dosage form) factors. We intended it to be an informal prompt to consider factors which have similar sales markets to the AA by prescription market, not a strict set of criteria for an eligible case study. We were aware that no product would match all the criteria and asked contributors to use their discretion to decide which criteria could be dropped for the purposes of finding a feasible case study. Our discussions with the CMO and RDTC suggested that there would be only be a limited number of drugs that would meet most of our criteria. The following drugs were suggested:
 - (a) Omeprazole, a proton pump inhibitor tablet taken as a treatment for GORD.

- (b) Ranitidine, a histamine H₂-receptor antagonist tablet taken as a treatment for GORD.
 - (c) Maalox, which is a liquid antacid taken as a treatment for GORD.
 - (d) Fluticasone, a liquid nasal spray taken as a treatment for hayfever.
 - (e) Levocetirizine/ cetirizine and desloratadine/loratadine which are antihistamine tablets for allergy relief.
4. Further conversations with drug manufacturers suggested that the primary distinctive feature which affects the supply of a drug is its dosage form rather than the therapeutic class (see paragraph 4.49). This is because solid dose drugs are produced internationally on a very large scale. However, liquids are more sensitive to heat conditions and transportation and so tend to be produced closer to the UK in smaller quantities. Fewer firms have the facilities to produce liquids and so potential entry into generic liquid drug markets is constrained by the ability of companies to supply the product. The discussions also yielded a further potential case study: fluoxetine hydrochloride or liquid Prozac.
5. Following the comments from drug manufacturers we limited our selection to the three liquid products (Maalox, Prozac and Flutiscsone) before dropping Maalox because of a concern that it may fall within the same market as Gaviscon (defined as 'no greater than the market for antacids and alginates by prescription'). If so, Maalox should not be used as a case study since it may be affected by the abuse of dominance and so could not be used to estimate market changes if the abuse had not occurred.

Appendix F: Sensitivity of the estimated possible savings to alternative assumptions

1. In this section we present analysis of the sensitivity of the estimated possible savings set out in Table 6.1 to alternative assumptions to those set out in paragraphs 6.51 and 6.54. In particular we make alternative assumptions about:
 - the growth of the volumes of GA dispensed absent the Withdrawal; and
 - the price of generic equivalents of GL absent the Withdrawal and subsequent to the assigning of the generic name ARFOS.

Sensitivity to alternative assumptions about GA growth

2. The estimates of the possible savings to the NHS presented in Table 6.1 assume that the rate of growth in the market share achieved by GA between 2006 and 2016 to be approximately that observed between 2002 and 2005 (5% a year). In Tables 1 and 2 below we present alternative estimates of the possible savings based on the assumption that: (a) items of GA dispensed from 2006 remained at their 2005 level; and (b) items of GA dispensed after 2005 grew at 10% a year.

Table 1: NPV of estimated savings assuming items dispensed of GA from 2006 remained at their 2005 level

Scenario	<i>£ million</i>		
	<i>NPV of estimated cost to NHS between 2006 and 2016 at 2005 prices</i>	<i>NPV of actual cost to NHS between 2006 and 2016 at 2005 prices</i>	<i>NPV of estimated possible savings to NHS between 2006 and 2016 at 2005 prices</i>
Kanavos – lower decile	229.6	183.8	45.8
Kanavos – median	229.6	183.6	46.0
Kanavos – upper decile	229.6	181.8	47.8
EC Sector	229.6	185.4	44.2
Fluoxetine	229.6	157.1	72.5
Fluticasone	229.6	184.6	44.9

Source: CMA analysis

Table 2: NPV of estimated possible savings assuming items dispensed of GA after 2006 remained at their 2005 level

Scenario	£ million		
	NPV of estimated cost to NHS between 2006 and 2016 at 2005 prices	NPV of actual cost to NHS between 2006 and 2016 at 2005 prices	NPV of estimated possible savings to NHS between 2006 and 2016 at 2005 prices
Kanavos – lower decile	229.6	206.6	23.0
Kanavos – median	229.6	206.6	23.0
Kanavos – upper decile	229.6	206.1	23.5
EC Sector	229.6	206.8	22.7
Fluoxetine	229.6	192.2	37.3
Fluticasone	229.6	206.2	23.4

Source: CMA analysis

Sensitivity to alternative assumptions about the price of generic versions of GL

3. The estimates of the possible savings to the NHS presented in Table 6.1 assume the price of generic equivalents to GL is the same price as Peptac was between 2005 and 2013, then at the 2013 Peptac price from 2013 until 2016. In Table 4 below we present estimates of the saving based on alternative estimates of the price of generic equivalents of GA. These assumptions are based on evidence from the economic literature and our two case studies on the price path (as a proportion of the originator drug price) followed by generic entrants after loss of patent by originator drugs. The assumed price paths are set out in Table 3.

Table 3: Assumed price paths for generic versions of GL as a proportion of GL*

	Price of generic equivalents of GL as a % of the price of GL									
	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Kanavos (2014) – lower decile	77	57	57	57	57	57	57	57	57	57
Kanavos(2014) – median	61	31	31	31	31	31	31	31	31	31
Kanavos (2014) – upper decile	54	27	27	27	27	27	27	27	27	27
EC sector study (2009)	75	60	60	60	60	60	60	60	60	60
Fluoxetine case	74	68	62	66	83	80	65	39	33	26
Fluticasone case	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Source: CMA analysis.

*We do not include an assumed price path for generic Fluticasone relative to the originator drug as most of the impact on average prices in this market appears to have been due to the presence of a secondary originator drug, Avamys.

4. In Table 4 we present estimates of the possible savings using these alternative assumptions about the relative price of generic equivalents of GL and the price of GL. The estimates are calculated in same way as those presented in Table 6.3 except for change to the assumed price of generic equivalents of GL. The price of generic equivalents of GL in each year is the price of GL as set out in Table 6.2 multiplied by the percentage set out in Table 3.

Table 4: NPV of estimated savings assuming alternative price paths for generic equivalents of GL

Scenario	£ million		
	<i>NPV of estimated cost to NHS between 2006 and 2016 at 2005 prices</i>	<i>NPV of actual cost to NHS between 2006 and 2016 at 2005 prices</i>	<i>NPV of estimated possible savings to NHS between 2006 and 2016 at 2005 prices</i>
Kanavos – lower decile	229.6	184.2	34.1
Kanavos – median	229.6	187.2	42.4
Kanavos – upper decile	229.6	183.5	46.1
EC Sector	229.6	195.7	33.9
Fluoxetine	229.6	172.6	56.9
Fluticasone	229.6	197.4*	32.1

Source: CMA analysis.

*Based on the assumption that after the assigning of the generic name ARFOS **average** prices in the AA by prescription market followed the same path as the average prices in the Fluticasone market following generic entry into that market.