Provisional decision on one and conclusions on two Enterprise Act 2002 merger remedies

5 January 2017

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Introduction

1. In its 2015/16 Annual Plan, the Competition and Markets Authority (CMA) committed to commence a programme of work systematically to review our existing remedies to seek to remove measures that are no longer necessary. As part of this, in April 2015, the CMA launched reviews of 71 structural merger remedies that had been put in place before 2005. These reviews resulted in 51 remedies subsequently being removed.

2. In its 2016/17 Annual Plan, the CMA noted that it would build on this work in the coming year, launching further reviews of existing mergers or market remedies. On 14 June 2016 and 31 August 2016, the CMA launched further reviews of merger remedies put in place before 1 January 2006.

3. This notice concerns three merger remedies under the Enterprise Act 2002. Two of these remedies have been found to have lapsed and the CMA is consulting on a provisional decision concerning one remedy.

Jurisdiction

4. The CMA has a statutory duty in Schedule 24 of the Enterprise Act 2002 to keep under review undertakings and orders. From time to time, the CMA must consider whether, by reason of a change in circumstances:

   (a) undertakings are no longer appropriate and need to be varied, superseded or released; or

(b) an order is no longer appropriate and needs to be varied or revoked.

5. Responsibility for deciding on variation or termination of Orders lies with the CMA.

Undertakings that have lapsed

6. The CMA has found that two of the undertakings have lapsed. Both of these are due to the undertakings having become time-expired. These cases are Coloplast A/S / SSL International plc (2002) and Dräger Medical AG & Co KGaA / Hillenbrand Industries, Inc (2004). The CMA will remove both of these sets of undertakings from its register of Orders and Undertakings.

Provisional decision on the remaining remedy

7. The CMA's provisional decision in relation to the merger remedy that has not been found to have lapsed is set out in the annex described in Table 1 below. Our provisional decision is to retain the undertakings.

Table 1: Undertakings on which the CMA has reached provisional decisions

Purchaser	*Target business*	*Provisional decision*	*Annex*
Ivax International GmbH	3M Company	Retain	1

Consultation on the CMA's provisional decision

8. The CMA is consulting on its provisional decision in the case where the undertakings have not lapsed, as described above and in the annex below.

9. This consultation will close on **3 February 2017**. If you wish to respond to this consultation, please contact the CMA as follows:

Nancy Race
6th Floor
Competition and Markets Authority
Victoria House
37 Southampton Row
London WC1B 4AD

Email: remedies.reviews@cma.gsi.gov.uk

10. Following this consultation, the CMA will consider the responses received and the evidence and views presented and will assess the impact of these responses on its provisional decision before reaching its final decision.

Annex 1 – Ivax International GmbH / 3M Company

Undertakings given by

1. Ivax International GmbH (Ivax).

Jurisdiction

2. Enterprise Act 2002.

Details of the transaction

3. On 1 October 2003, Ivax acquired 3M Company's distribution business for certain asthma treatments operating in the UK, Ireland, Germany, France Netherlands, Norway, Sweden, Finland and Denmark.

Undertakings in lieu of a reference to the Competition Commission (CC)

4. Undertakings in lieu of a reference to the CC were given on 9 January 2004.

The market concerned

5. The supply of asthma treatments. The parties overlapped in the supply of salbutamol, a molecule used in relief products (rather than preventative products) for asthma. The parties indicated to the OFT that there were other molecules that are clinically substitutable, however the OFT considered that the price of these products meant that it was unclear to what extent these act as effective substitutes in practice.

6. At the time of the original transaction there were a number of different methods of delivery of the active molecule, including chlorofluorocarbon (CFC) inhalers and hydrofluoroalkane (HFA) metered dose inhalers, as well as breath actuated CFC and HFA inhalers and dry powder inhalers, although the OFT noted that not all combinations were commercially available at the time.

7. The evidence available at the time did not, 'enable us to conclude with any certainty that dry powder inhalers or metered dose inhalers with spacers are demand side substitutes for breath actuated inhalers.'[1]

[1] Completed acquisition by IVAX International GmbH of 3M Company's distribution business for certain asthma products, OFT, 20 October 2003.

8. Consequently, the OFT took the cautious view that the appropriate frame of reference appeared to it to be salbutamol HFA breath actuated inhalers in the UK.

Theory of harm

9. Potential loss of competition in the supply of salbutamol HFA breath actuated asthma relief products.

Description of the undertakings in lieu of reference

10. The undertakings imposed price caps of £6.02 per 100mcg/200 dose in relation to Airomir Inhalers,[2] and £6.30 per 100mcg/200 dose in relation to Salamol Inhalers.[3]

11. Based on the OFT's cautious conclusions on the level of substitution, the undertakings described one change in circumstances that the OFT considered would warrant the release of the undertakings. This was in the event that a new product that was clinically substitutable for two branded salbutamol HFA breath actuated inhalers (Airomir and Salamol) and not produced or distributed by Ivax or any connected company, entered the market and had been available in the UK for at least 6 months.[4]

History of the companies since the undertakings were given

12. Ivax is still active[5] and was purchased by Teva Pharmaceutical Industries Ltd in 2006.

Response to the CMA's consultation

13. The CMA received one submission, from Teva UK Ltd (Teva), in response to its consultation. Teva observed that since 2004 new products have entered the market, though none of these are breath actuated inhalers. Teva also observed that the NHS list price of branded products is constrained by the Pharmaceutical Price Regulation Scheme.

Change of circumstances

14. The CMA notes that there have been a number of changes since the undertakings were agreed in January 2004. While the OFT's analysis refers to inhalers using CFC propellants, these items are no longer available due to

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[2] Specified in the undertakings as the product marketed as 'Airomir Autohaler'.
[3] Specified in the undertakings as the product marketed as 'Salamol Easi-Breathe'.
[4] See the full text of the undertakings for details.
[5] See http://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapId=222954013

CFCs having been phased out due to their environmental impact. In some applications, hydrofluorocarbon or other propellants have been used as a replacement for CFCs.

15. More specifically, in relation to medical products used to treat asthma and with salbutamol as an active ingredient, the Medicines and Healthcare products Regulatory Agency (MHRA) provided the CMA with details of new products authorised since the undertakings were agreed. These are listed below:

Table 1: Salbutamol asthma products authorised since 2004

Authorisation holder	*Product birth date*	*Licensed product name*	*Pharm type*	*Drug substance*
Chiesi Ltd	01/03/2004	Pulvinal Salbutamol 200mcg/metered dose inhalation powder	Inhalation powder	Salbutamol
Focus Pharmaceuticals Ltd	04/10/2004	Salbutamol 2.5mg inhalation solution	Inhalation solution	Salbutamol Sulphate
Focus Pharmaceuticals Ltd	04/10/2004	Salbutamol 5.0mg inhalation solution	Inhalation solution	Salbutamol Sulphate
Fannin (UK) Ltd	13/07/2006	Salbutamol 1mg/ml nebuliser solution	Nebuliser solution	Salbutamol Sulphate
Fannin (UK) Ltd	13/07/2006	Salbutamol 2mg/ml nebuliser solution	Nebuliser solution	Salbutamol Sulphate
Meda Pharmaceuticals Ltd	03/01/2008	Salbulin MDPI Novolizer 100 micrograms / dose inhalation powder	Inhalation powder	Salbutamol Sulphate
Sandoz Ltd	17/06/2009	AirSalb CFC-free inhaler 100 microgram/dose	Pressurised inhalation, suspension	Salbutamol Sulphate
Fannin (UK) Ltd	03/07/2009	Asmavent CFC-free inhaler 100 micrograms	Pressurised inhalation, suspension	Salbutamol
	06/08/2010	Respigen 100 micrograms per actuation pressurised inhalation suspension	Pressurised inhalation, suspension	Salbutamol Sulphate
Cipla (EU) Ltd	06/06/2011	Salbutamol 1mg/ml nebuliser solution	Nebuliser solution	Salbutamol Sulphate
Cipla (EU) Ltd	06/06/2011	Salbutamol 2mg/ml nebuliser solution	Nebuliser solution	Salbutamol Sulphate
Cipla (EU) Ltd	30/06/2011	Salbutamol Sulphate 100 micrograms inhaler	Pressurised inhalation, suspension	Salbutamol Sulphate

Source: MHRA.

16. In relation to the table above, the MHRA stated that the only breath actuated inhalers are those produced by the parties, and the CMA notes that none of the new products listed above are HFA breath actuated asthma relief

products. The products listed above include metered dose inhalers and powder inhalers, as well as nebulisers.[6]

17. In relation to the use of different types of inhaler, the CMA notes that the National Institute for Health and Care Excellence (NICE) describes the options as follows:

> A pressurised metered-dose inhaler is an effective method of drug administration in mild to moderate chronic asthma; to deliver the drug effectively, a spacer device should also be used (see also NICE guidance, below). By the age of 3 years, a child can usually be taught to use a spacer device without a mask. As soon as a child is able to use the mouthpiece, then this is the preferred delivery system.
>
> Dry powder inhalers may be useful in children over 5 years, who are unwilling or unable to use a pressurised metered-dose inhaler with a spacer device; breath-actuated inhalers may be useful in older children if they are able to use the device effectively.[7]

18. The CMA highlights that Asthma UK describes breath actuated inhalers as follows:

> Breath actuated MDIs are usually given to people who have difficulty using a standard 'puffer'. These inhalers are activated by your breath so that when you breathe in normally through the mouthpiece, it releases medicine in a fine spray form. With this inhaler you don't have to push the canister to release a dose.[8]

19. The CMA notes that guidance in this area indicates that metered dose inhalers are the standard method for delivering salbutamol, however, it is clear from the guidance that education and some degree of co-ordination are necessary in order for these to be operated correctly and deliver the dose required. These can be used more easily with spacers to make their use easier. As NICE notes above, it is possible in some cases for those with difficulties using metered dose inhalers to use alternatives, including powder inhalers and breath actuated inhalers.

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[6] Nebulisers are products designed typically for patients suffering with severe asthma attacks, and the product converts the liquid active ingredient into a fine mist which is then inhaled through a mask or mouthpiece. They are typically designed for use in hospitals or in ambulances rather than for being prescribed directly to consumers. The National Institute for Health and Care Excellence notes that 'Nebuliser (or respirator) solutions of salbutamol and terbutaline are used for the treatment of severe acute asthma both in hospital'. See NICE website for details.
[7] See NICE website for details.
[8] See Asthma UK website for details

20. Consequently, while the CMA has found evidence of a number of changes in this sector since the undertakings were agreed, including a significant number of new salbutamol inhalers having been introduced by manufacturers other than IVAX and its related companies, the CMA does not have any evidence on whether (and the extent to which) these new products are placing a competitive constraint on the production and pricing of salbutamol HFA breath actuated inhalers, nor any evidence to allow it to assess the relative scale of the use of these products.

21. Consequently, and in the absence of relevant evidence of significant changes, the CMA is unable to conclude that there are changes of circumstance relevant to the undertakings given by IVAX.

Provisional decision

22. Based on the information available, the CMA's provisional decision is to retain the undertakings.