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GENERIC PHARMACEUTICALS

-- Note by the United Kingdom --

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This document reproduces a written contribution from the United Kingdom submitted for Item VI of the 121st meeting of OECD Competition Committee on 18-19 June 2014.

More documents related to this discussion can be found at <http://www.oecd.org/daf/competition/generic-pharmaceuticals-competition.htm>.

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1. Introduction

1. This contribution focuses on UK developments in competition issues between originator and generic companies in the pharmaceutical sector since the previous OECD Competition Committee roundtable discussion on generic pharmaceuticals in 2009. Matters pertaining to regulation and competition affecting the distribution chain in this sector are not dealt with in this contribution.

2. The following developments in enforcement concerning generic pharmaceuticals are based on the recent experience of the Competition and Markets Authority (CMA) and its predecessor organisations, the Office of Fair Trading (OFT) and the Competition Commission (CC).¹

3. The contribution highlights recent² cases undertaken which are most relevant to the issue of competition concerning generic pharmaceuticals, in particular the following OFT cases: *Reckitt Benckiser*; the 2011 evaluation of the 2001 *Napp Pharmaceuticals* case; and the ongoing *Pay for delay* investigations now being carried out by the CMA.

2. Pharmaceutical companies' practices under competition scrutiny

2.1 Unilateral practices

2.1.1 *Reckitt Benckiser*³

4. This case concerned the strategic withdrawal of a product that was facing the introduction of generic competition in order to move patients onto a product that was still patent protected, thereby preventing the establishment of effective generic competition.

a) The OFT Decision and Early Resolution Agreement

5. In 2008, the OFT launched an investigation into allegations that Reckitt Benckiser Healthcare (UK) Limited and Reckitt Benckiser Group plc (Reckitt Benckiser) had abused a dominant position in the market for the UK National Health Service (NHS) supply of alginate and antacid heartburn medicines in breach of the Chapter II prohibition of the Competition Act 1998 and Article 102 of the Treaty on the Functioning of the European Union. The allegations of anticompetitive behaviour were brought to the OFT's attention by a report on the BBC's Newsnight television programme.

6. Following the issue of its Statement of Objections (SO),⁴ the OFT reported in October 2010 that it had reached an Early Resolution Agreement (ERA) with Reckitt Benckiser. Reckitt Benckiser admitted infringing competition law under the terms of the ERA and agreed to pay a penalty of £10.2 million. The

¹ The CMA was created by the Enterprise and Regulatory Reform Act 2013. The CMA has been in shadow form since 1 October 2013 and was formally established on 1 April 2014, taking over most of the functions of the OFT and the CC – both of which were abolished on 31 March 2014

² Cases prior to 2009, for instance the 2003 abuse of dominance case in the market for the supply of drugs for the treatment of Gaucher disease in the UK (Genzyme Limited, available at: http://www.offt.gov.uk/shared_offt/ca98_public_register/decisions/genzyme.pdf) have not been referred to in the contribution

³ Decision No. CA98/02/2011, Case CE/8931/08 dated 12 April 2011. The non-confidential version of the decision is available at http://www.offt.gov.uk/shared_offt/ca-and-cartels/rb-decision.pdf

⁴ The SO was issued on 23 February 2010

OFT's decision was issued on 13 April 2011, imposing the fine and concluding the OFT's investigation (the Decision). The text of the ERA can be found at Annexe A of the Decision.

7. Gaviscon products are alginate based compounds used to treat acid reflux, gastro-oesophageal reflux disease and dyspepsia. Reckitt Benckiser supplied Gaviscon products in packs for prescription and over the counter sales channels. The OFT considered the relevant market⁵ to be no wider than the supply of alginates and antacids in the prescription channel. Reckitt Benckiser retained a market share of over 80% in the relevant market.

8. In its Decision, the OFT found that Reckitt Benckiser withdrew one of its products, Gaviscon Original Liquid (GL), with the intention of limiting pharmacy choice and hindering competition from suppliers of generic medicines.

9. GL was launched in 1977 and its patent expired in 1997. Another product, Gaviscon Advanced Liquid (GA), was launched in 1997 and was patented until 2016. The withdrawal of GL took place in 2005, in advance of the publication of a generic name relevant to GL. The OFT considered the publication of a generic name was necessary to facilitate full generic competition in relation to prescription medicines:⁶

- Where a generic name does not exist, GPs (general practitioners) write prescriptions that refer to the brand name of their chosen product (a 'closed script'). On receipt of a closed script, pharmacies must dispense the branded product and are not able to substitute a generic equivalent. This inhibits the ability of pharmaceutical manufacturers to use price as a means of persuading pharmacies to purchase their products.
- Where a generic name exists, GPs can refer to that name on prescriptions (an 'open' script). On receipt of an open script, pharmacies can dispense any manufacturer's product that satisfies the requirements of that generic name. This choice fosters price competition between pharmaceutical manufacturers which have a strong incentive to compete on price to persuade pharmacies to choose their products.

10. The OFT found that Reckitt Benckiser's decision to withdraw and delist NHS packs of GL was motivated by a desire to hinder the development of full generic competition following the publication of a generic name relevant to GL. Reckitt Benckiser sought to switch patients to its patent protected product, GA, which would not be covered by the generic name corresponding to GL and not therefore subject to full generic competition.⁷ The withdrawal took place in the context of a long term intention to delay the onset of full generic competition⁸ and would have been loss making, were it not for the prospect of using the withdrawal to hinder the development of full generic competition.

b) Private Damages Claims

11. Following the OFT's Decision, the NHS, represented by the UK's Department of Health and various regional and local health authorities, commenced proceedings against Reckitt Benckiser for

⁵ The relevant market was considered in section 4 of the Decision

⁶ Section 2.G of the Decision relates to the process and benefits of generic competition

⁷ Further details as to the decision to withdraw GL NHS packs are set out in paragraphs 2.161 and following of the Decision

⁸ As set out in paragraphs 2.17 and 2.18 of the Decision

damages following the abusive conduct. By May 2014, these claims across England, Wales, Scotland and Northern Ireland had been settled.⁹

2.1.2 *Napp Pharmaceuticals Case Evaluation*

12. In 2001, the OFT fined Napp Pharmaceutical Holdings Limited (Napp) for abuse of dominance under the Competition Act 1998¹⁰. The OFT found Napp to be supplying sustained release morphine (SRM)¹¹ to patients in the community at excessively high prices while supplying to hospitals at high discount levels with the effect of eliminating competition in the relevant market. By offering high discounts to hospitals, Napp had been able to win hospital contracts and also had been able to retain a high share of the larger community market because the prescribing practices of GPs were found to be strongly influenced by the brands used in hospitals. On 15 January 2002, the Competition Appeal Tribunal substantially upheld the OFT's decision on liability but reduced the fine payable by Napp¹².

13. In 2011, the OFT conducted an evaluation of its case against Napp¹³. The aim was to understand the extent to which the SRM market had changed as a result of the 2001 decision and to estimate the impact of the OFT's intervention in terms of monetary savings to the NHS. The evaluation was carried out by OFT economists and independently reviewed by Professor Stephen Davies of the University of East Anglia.

14. The evaluation found that the 2001 intervention stimulated competition in the market, as demonstrated by a reduction in Napp's market share in both hospital and community segments. Napp's market share in the hospital segment fell from approximately 95 per cent to 50 per cent and in the community segment from 95 per cent to 65 per cent. Further, Napp removed its exclusionary discounts in the hospital segment and reduced its prices to the community.

15. The impact of the OFT's 2001 intervention has potentially been enhanced by the increase in generic prescribing of SRM¹⁴. For the purposes of the evaluation, the conservative savings estimate did not claim impact for the increase in generic prescribing of SRM.

16. The report (Evaluating the impact of the OFT's 2001 abuse of dominance case against Napp Pharmaceuticals) can be found on the OFT website¹⁵.

⁹ On the launch of proceedings, see for example: <http://www.theguardian.com/business/2011/apr/17/reckitt-gaviscon-lawsuit> and <http://www.independent.co.uk/news/business/news/nhs-sues-reckitt-for-16389m-over-gaviscon-supply-2269383.html>. The claim in connection to supply in England was settled in February 2014 (see Department of Health press release <https://www.gov.uk/government/news/department-of-health-and-rb-settlement>); the remaining claims were settled in May 2014 (see <http://app.parr-global.com/intelligence/view/1111640>)

¹⁰ No. CA98/2D/2001, available at: http://www.of.gov.uk/shared_of/ca98_public_register/decisions/napp.pdf

¹¹ SRM is used to manage severe pain and is commonly used in the treatment of cancer related pain.

¹² A copy of the judgment is available at the following link: <http://www.catribunal.org.uk/237-565/1001-1-1-01-Napp-Pharmaceutical-Holdings-Limited-and-Subsidiaries.html>

¹³ http://www.of.gov.uk/news-and-updates/press/2011/63-11#_U3naCV6aBSU

¹⁴ As noted in paragraph 1.16 of the evaluation, the Department of Health has proactively sought to influence the way in which GPs prescribe, particularly encouraging generic prescribing. There has been a sharp increase in generic prescribing of SRM products since 2004

3. Anticompetitive agreements

3.1 *Pay for delay*

17. On 19 April 2013, the OFT issued a Statement of Objections to certain pharmaceutical companies alleging that they had acted to delay effective competition in the UK supply of paroxetine. Paroxetine is an antidepressant medicine used in the treatment of disorders such as depression and anxiety disorder.

18. The investigation concerns certain patent dispute settlement agreements relating to paroxetine. The OFT's provisional view was that the agreements included substantial payments from the branded manufacturer to the generic companies in return for their commitment to delay their plans to supply paroxetine independently. The OFT also alleged abuse of a dominant position by the branded manufacturer in the supply of paroxetine in the UK.

19. The CMA is presently continuing the investigation commenced by the OFT and is currently considering the written and oral representations received in response to the Statement of Objections. The CMA has not made any findings of infringement of competition law and no assumption should be made at this stage that there has been an infringement of competition law. The outcome of the investigation will be determined in due course.

¹⁵

At the following link: http://www.of.gov.uk/shared_of/ca-and-cartels/OFT1332.pdf