

Annexe B

Related OFT work

December 2007

OFT967b

© **Crown copyright 2007**

This publication (excluding the OFT logo) may be reproduced free of charge in any format or medium provided that it is reproduced accurately and not used in a misleading context. The material must be acknowledged as crown copyright and the title of the publication specified.

INTRODUCTION

1.1. This Annexe presents information in relation to the following studies and investigations carried out by the OFT relating to the medicines sector:

- **Section A** : The PPRS market study
- **Section B** : The Report into the Control of Entry Regulations and Retail Pharmacy Services in the UK
- **Section C** : OFT merger decisions
- **Section D** : Competition Act 1998 decisions

SECTION A : THE PPRS MARKET STUDY

Introduction

- 1.2. On 20 February 2007 the OFT published the results of its market study into the PPRS. The study was launched on 13 September 2005 with its remit being to assess how effective the current PPRS is in meeting its high level objectives.

OFT's assessment of the PPRS

- 1.3. The PPRS report noted that many pharmaceutical companies viewed the PPRS positively, considering it a relatively stable regime that affords, over its five-year term, some insulation from opportunistic behaviour by government. However, many companies also noted that this stability has been undermined to some extent by the increasing price cuts implemented at the beginning of each new PPRS. Pharmaceutical companies were typically content that the PPRS allows new medicines to be launched more quickly than in some other countries, due to the broad freedom of pricing under the profit cap and consequent absence of price negotiations for new products. However, some observed that as a corollary of this, NHS uptake of new medicines is often slow by international standards.
- 1.4. From the point of view of the NHS, the PPRS price cuts deliver substantial savings in primary care, although such savings are eroded over time as new medicines enter the market, with initial prices not being controlled by the PPRS. The benefit of the PPRS price cuts for secondary care is less clear, as hospitals do not typically purchase medicines at prices based on the PPRS list price.
- 1.5. The OFT's overriding concern with the PPRS is that neither the profit cap nor the price cut help to secure prices which reflect the therapeutic value of the medicines used within the NHS. Given that the high level objectives of the PPRS include providing value for money for the NHS, as well as incentives for beneficial investment by companies, this was perceived to be a major shortcoming.

Recommendations to reform the PPRS

- 1.6. The OFT report considers there to be a compelling case for reform of the PPRS towards a value-based pricing scheme with the prices of medicines determined by their therapeutic benefits compared to existing alternative treatments, if available.

- 1.7. The report provides substantial detail on how this could be achieved and identifies two broad options in relation to patent protected branded medicines, ex post value-based pricing and ex ante value-based pricing.
- 1.8. Ex post value-based pricing would involve pharmaceutical companies maintaining their freedom to set the initial price of a new medicine. Instead of the current price cuts and the profit control, there would be a number of ex post reviews of the cost effectiveness of individual medicines or classes of medicines. Such reviews would be able to set a maximum price for medicines to accord with the clinical benefit provided for patients. The principles of when such reviews would take place could be set out in an agreement between the DH and the ABPI.
- 1.9. Ex ante value-based pricing would involve a swift initial assessment of the cost effectiveness of a new medicine. Where data is sufficient, a maximum price could be determined, again reflecting the clinical benefit for patients. Where data was not sufficient for such an assessment, a risk sharing contract could be adopted. This would mean that the price paid by the NHS would be determined by the evidence on the cost effectiveness of the medicine, with the evidence gathered over time as the medicine is used in practice.
- 1.10. Both of the above approaches would allow for greater flexibility in pricing. This could be beneficial where medicines have different cost effectiveness in different applications. Overall, the OFT recommended that an ex ante approach to value-based pricing would provide the best long-term arrangement for the UK.
- 1.11. The report also covers off-patent branded medicines. In this case, where the off-patent originator branded medicine has an exact generic equivalent, the benefits of a value-based pricing system are particularly clear. The report recommended that off-patent branded medicines should also be included in the principles of value-based pricing, while noting that it was important to maintain the incentives for generic prescribing. To ensure this, the OFT recommended that off-patent originator branded medicines should be reimbursed up to 25 per cent above the generic price.

Government's response to the PPRS market study report

- 1.12. The Government response to the PPRS is being co-ordinated by the Department of Business, Enterprise and Regulatory Reform (BERR). BERR

published an interim response on 2 August welcoming the study. This contained the following statements:

'To ensure that patients realise the full benefits of developments in this industry, we agree with the OFT that it is time to develop a pricing system which is fit for purpose for the twenty first century.'

'The OFT report contained a number of detailed proposals as to how a future pricing regime would work. We are undertaking a continuing programme of detailed analysis of the OFT report's proposals, and will discuss this analysis with the industry, taking into account their strong concerns about a number of the proposals.'

'We will take this work forward over the coming months and will discuss proposals with industry. We will then aim to make further proposals as part of the renegotiation of the PPRS.'

'We are grateful to OFT for this report and will ensure that any future pricing scheme delivers value, rewards innovation and ensures a fair deal for the NHS. This will mean that NHS patients will get the drugs they need at a fair price to the public purse and the pharmaceutical industry will continue to be encouraged to develop important new medicines.'¹

Coverage of the PPRS market study and this report

- 1.13. The principal area of overlap between the PPRS market study and this report relate to the reimbursement to pharmacies for dispensing medicines.
- 1.14. Part of this report is considering the methods by which the DH and the relevant devolved bodies can control the costs of the medicines they purchase from the pharmaceutical industry. Clearly, there is an overlap here between the PPRS market study and this report, as the PPRS study recommended changes to the way in which the prices of medicines are set.
- 1.15. The recommendations from this study (see Chapter 6) and that of the PPRS do not conflict as while the PPRS study recommended changes to reimbursement, this was concerned principally with a move to value-based

¹ BERR Interim Government Response to the Office of Fair Trading (OFT) market study on PPRS, August 2007, URN 07/1247. See BERR website for further details (www.berr.gov.uk).

prices to provide better value-for-money for the NHS and clearer investment incentives for the pharmaceutical industry.

- 1.16. The recommendations as a result of this study concerning medicine prices are related to the mechanisms by which pharmaceutical companies are paid for the medicines they supply, rather than whether the prices paid to pharmaceutical companies reflect the therapeutic value of the medicines supplied.

SECTION B : THE REPORT INTO THE CONTROL OF ENTRY REGULATIONS AND RETAIL PHARMACY SERVICES IN THE UK

- 1.17. The control of entry regulations were introduced in England and Wales, Scotland and Northern Ireland 1987 in order to contain the escalating cost to the NHS which arose from a pharmacy reimbursement system intended to address the decline of pharmacy numbers. Under the control of entry regulations, any pharmacy in the UK wishing to obtain an NHS contract to dispense NHS prescriptions must satisfy the local Primary Care Organisation that it is 'necessary' or 'desirable' to grant the application to secure the adequate provision of pharmaceutical services in a particular neighbourhood.
- 1.18. In January 2003, the OFT published a report of a market study: 'The control of entry regulations and retail pharmacy services in the UK'.² The report examined the provision of retail pharmaceutical services in the UK. In particular, it examined whether the interests of consumers are best served by the control of entry regulations, which place restrictions on how and where contracts to dispense NHS prescriptions in the UK are awarded.
- 1.19. The OFT report concluded that removing the restrictions on entry to the community pharmacy market would give consumers greater choice, benefits from greater competition and better access to pharmacy services. There would also be large regulatory cost savings for business and government. The OFT report recommended that regulations controlling entry to the industry should be lifted to allow any registered pharmacy with qualified staff to dispense NHS prescriptions. Based on its research, the OFT was not convinced that regulation of entry could be justified on the basis of public interest.
- 1.20. The OFT found that the regulations controlling entry to the industry :
- restrict consumer choice and convenience in terms of location of pharmacies and opening hours;
 - restrict access to lower priced OTC medicines resulting in consumers paying around £30m a year more than in a deregulated market;
 - reduced incentives for pharmacies to compete on additional customer services;
 - cost businesses an estimated £16m in compliance costs every year;
 - cost the NHS approximately £10m a year in administration costs; and

² The Control of Entry Regulations and Retail Pharmacy Services in the UK. OFT report, January 2003. OFT609.

- hold back innovation and responsiveness to changing and growing consumer needs.
- 1.21. The OFT found that effectively, the regulations have blocked entry by new pharmacy businesses.
- 1.22. The government responded cautiously to the OFT recommendations. The government's written statement to the House of Commons on 17 July 2003 announced a package of measures to raise the quality of services offered by pharmacists and boost local access. On 18 August 2004, the government announced the implementation of the package, which included secondary legislation to introduce new criteria in assessing the adequacy of local service provision, exemption of shopping developments over 15,000 square meters (excluding developments in town centres) from the control of entry regulations and exemptions for consortia wishing to establish new one stop primary care centres providing a regular and comprehensive range of services and serving a substantial population.
- 1.23. The new package was introduced in April 2005, including a revised test and four complete exemptions to the entry test (provided certain criteria are met):
- pharmacies open for at least 100 hours per week
 - in designated out-of-town large shopping centres
 - in new one-stop primary care centres, and
 - internet-based and wholly-mail order pharmacies.
- 1.24. Some streamlining of applications and decision-making was also introduced.
- 1.25. The Department of Health report of its review of the reforms³ has found that they had had a modest impact and uneven impact on promoting more choice and competition, though access had improved where new 100-hour pharmacies opened. In announcing the Department of Health report on 11 January 2007, Andrew Burnham MP, the Minister of State for Delivery and Reform, commissioned Ann Galbraith to review NHS pharmaceutical contractual arrangements with the aim of informing formal consultation on how best arrangements should be developed or reformed. The review included examining again the control of entry regulations. The publication of the 'Galbraith review' is awaited.

³ www.dh.gov.uk/en/Consultations/Responsestoconsultations/Borwsable/DH_0644.

1.26. The OFT remains of the view that the entry restrictions operate against the interest of consumers and that the government modifications have not been sufficient to remove the concerns raised by the 2003 report. Market deregulation with contestability for enhanced services would drive up standards. This view has been re-enforced by the OFT's ongoing review of markets including review under the Enterprise Act of qualifying mergers.

SECTION C : MERGER DECISIONS

Anticipated merger between Co-operative Group (CWS) Limited and United Co-Operatives Limited – OFT decision of 23 July 2007

- 1.27. Co-Operative Group (CWS)_ Limited (CGL) was the UK's largest co-operative with approximately 3.9 million members. It was active in a number of diverse sectors, including pharmacy. United Co-operatives Limited (United) was a regional co-operative society, based primarily in the North of England and the Midlands. It also was active in a number of diverse sectors, including pharmacy. The merger brought together the 473 retail pharmacies operated across the UK on behalf of CGL with United's 229 pharmacy stores in the north of England and the Midlands. In relation to pharmacy services, the OFT applied the method of analysis used in its previous merger decisions of Boots / Alliance UniChem⁴ and Lloyds / IPCC and found no reason to depart from that approach. On this basis, the OFT identified two local areas within a one-mile radius that resulted in a substantial lessening of competition.
- 1.28. The Decision of the OFT⁵ concluded that, on the evidence available, it is or may be the case that the merger may be expected to result in a substantial lessening of competition in the supply of a number of services, including pharmacy, in certain overlap areas across the UK. Undertakings in lieu of a reference to the Competition Commission were offered by CGL⁶ which, in relation to pharmacy services, consisted of the divestment of specific businesses in particular areas of overlap. The OFT has decided to accept the undertakings offered by CGL as they addressed all of the competition concerns identified in the Decision.

Anticipated acquisition by Lloyds Pharmacy Limited of Independent Pharmacy Care Centres plc – OFT decision of 8 June 2007

- 1.29. The merger brought together the 1,574 pharmacies throughout the UK operated by Admenta Holdings Limited, an intermediate holding company of Lloyds Pharmacy Limited (Lloyds) and a subsidiary of Celesio AG (as also is the pharmaceutical wholesaler AAH) with the 34 retail pharmacies of Independent Pharmacy Care Centres plc (IPCC).

⁴ Boots / Alliance UniChem and Lloyds / IPCC – see below

⁵ www.offt.gov.uk/shared_offt/mergers_ea02/361227/Co-op.pdf

⁶ www.offt.gov.uk/shared_offt/mergers_ea02/undertakings2007/CoopUnitedUIL.pdf

- 1.30. The OFT applied the method of analysis used in its previous merger decisions and found no evidence to depart from that approach. The OFT concluded⁷ that at the local level, on the basis of a one mile radius, there were five areas where the merger would result in a three to two reduction in the number of competing pharmacies. On the evidence available to the OFT, including the persistence of regulation as a barrier to entry, it was concluded that there was a realistic prospect of a substantial lessening of competition in four of those five areas, post merger. The OFT found, however, that as only 34 pharmacies were involved in the transaction, no national, regional or vertical competition concerns arose.
- 1.31. Undertakings in lieu of a reference to the Competition Commission were offered by Lloyds⁸ and accepted by the OFT. Those undertakings consisted of divestments in the localities identified by the OFT as ones of concern.

Anticipated acquisition by Phoenix Healthcare Distribution Limited (Phoenix) of East Anglian Pharmaceuticals Limited (EAP) – OFT decision of 29 June 2005

- 1.32. Phoenix is part of the Phoenix Group which is active in pharmaceutical wholesaling and retailing throughout Europe. Phoenix itself is a pharmaceutical wholesaler to retail pharmacies and dispensing doctors in Great Britain. It also operated a small chain of retail pharmacies but, as found by the OFT at the time, had no outlets in the East Anglia area. The principal activity of EAP is the wholesale supply of pharmaceuticals to retail pharmacies, dispensing doctors and hospitals through a single distribution depot in Norwich.
- 1.33. The OFT found at the time that the merged entity would be the second largest full-line supplier of ethical pharmaceuticals and that, at the regional level, the number of competing full-line wholesalers would effectively be reduced from four to three. The merger was cleared however on the basis of the existence of competitive constraints. The OFT recognised that in certain circumstances, short-liners would be able to provide some competitive constraint on the parties. Competition was, however, expected to come from other full-liners operating in the region, namely AAH and UniChem, whom

⁷ http://oft.gov.uk/shared_oft/mergers_ea02/361227/Lloyds.pdf

⁸ http://oft.gov.uk/shared_oft/mergers_ea02/undertakings2007/LloydsUIL2.pdf

the OFT considered well placed to compete for additional custom in the region.⁹

- 1.34. As a consequence, the OFT did not believe that it was or may be the case that the merger may be expected to result in a substantial lessening of competition.

Anticipated acquisition by Boots Group plc (Boots) of Alliance UniChem plc (UniChem) – OFT decision of 25 May 2006

- 1.35. Merger bringing together Boots' 1,350 retail pharmacies with UniChem's pharmaceutical wholesaling business and chain of 958 pharmacies (trading under the name Moss but to be re-branded Alliance Pharmacy).
- 1.36. In its analysis of the merger, the OFT drew on the findings of its 2003 report on the control of entry regulations,¹⁰ which found that 78 per cent of consumers travel less than one mile to get to a pharmacy, and 96 per cent travel less than three miles. The decision noted the parties' internal documents which clearly showed that there is some competitive interaction between different retail pharmacies. Both Boots and UniChem monitored a number of different price and service quality variables and compared themselves to competitors. Possible aspects of competition mentioned in Boots' consumer research documents included product availability, store layout, ease of shopping and shopping environment. At a local level, waiting times for obtaining a prescription and the provision of deliveries seemed to be a key measure of competition. The OFT found that though locality appeared to be the main factor determining customers' choice of pharmacy, there was nevertheless some evidence to suggest that a reduction in the number of competing pharmacies ('fascias') could bring about a reduction in competition, whether by lowering service / quality levels, by reducing choice (on a quality level) or, less so, affecting prices.

⁹ As explained in paragraph 84 of the decision, the original merger decision was remitted back to the OFT by the Competition Appeals Tribunal to consider the additional evidence presented by UniChem relevant to its ability to provide an effective competitive constraint on the merging parties. The OFT carefully considered all of the evidence provided by UniChem and as explained in the decision, did not accept that UniChem lacked the ability and the incentive to compete for the merged entity's customers in the area.

¹⁰ The control of entry regulations and retail pharmacy services in the UK. OFT report, January 2003. OFT609.

- 1.37. The OFT found that on a local basis of a one mile radius around both Boots and UniChem pharmacies, there were 38 areas where the merger would result in a two-to-one reduction in the number of fascias which was expected to result a substantial lessening of competition (SLC), given the high barriers to entry as a result of the control of entry regulations. The SLC could take the form of reductions in quality of the level of service provided (over and above the levels stipulated in the NHS Pharmacy Contract).¹¹
- 1.38. There OFT examined potential vertical issues arising from the merger by way of:
- The creation of incentive or ability to cross-subsidise wholesale operations by retail operations
 - whether Boots' retail competitors would, post-merger, be unwilling to use UniChem as a full-liner because of information flows between the wholesale and retail arms in the new company, and
 - whether the new company would be unwilling to supply its main competitors (either nationally or locally) on a wholesale level, or may increase prices / reduce wholesale service levels, which could have the effect of raising (retail) rivals' costs, or foreclosing them in certain areas of the country.
- 1.39. The OFT found that these hypothetical vertical concerns were not backed by evidence.
- 1.40. Boots offered to the OFT undertakings to address the horizontal retail overlap competition concerns, in lieu of a reference of the anticipated merger to the Competition Commission (CC). The undertakings were revised following consultation and consisted, essentially, of Boots divesting one of either a Boots or UniChem pharmacy in each of the overlap areas, to a purchaser or purchasers to be approved by the OFT. Those sales were to be by way of a number of packages of pharmacies, for which acquisitions Boots was

¹¹ On 9 May 2006, the Competition Appeal Tribunal (the 'CAT) dismissed an application by Celesio AG for review of the OFT decision not to refer the merger to the CC. The CAT dismissed Celesio's claim that the OFT's decision did not support its conclusions in relation to the absence of an SLC on certain local markets.

permitted to offer assistance by way of finance. The OFT accepted undertakings from Boots.¹²

¹² These can be found at www.offt.gov.uk/advice_and_resources/resource_base/Mergers_home/2006/boots

SECTION D: COMPETITION ACT 1998 DECISIONS

2003 Competition Act 1998 decision re Genzyme

- 1.41. In March 2003 Genzyme Limited was fined £3 million by the OFT¹³ (reduced on appeal to the Competition Appeal Tribunal¹⁴ in March 2004 from a higher, original figure) for exclusionary pricing behaviour in breach of the Chapter II prohibition of the Competition Act 1998.
- 1.42. Genzyme supplies a drug called Cerezyme, which had, until a short time before the decision, been the only treatment for the rare inherited disorder Gaucher disease.
- 1.43. Genzyme held a dominant position in the market for the supply of drugs for the treatment of Gaucher disease. Genzyme was found to have abused its dominant position by:
- charging the NHS a price for Cerezyme which included the price of home delivery of Cerezyme and provision of homecare services, thereby effectively ensuring only Genzyme (or an undertaking acting under contract for Genzyme) could provide such services; and
 - precluding viable competition by charging independent third party homecare service providers a price for Cerezyme that allowed them no possible margin.
- 1.44. The OFT found that Genzyme's behaviour:
- prevented existing competitors in the home delivery of Cerezyme and provision of homecare services from operating viably and ensured that no new competitors could begin to offer such services viably;
 - deprived the NHS and patients of a choice of delivery/homecare services provider; and
 - raised barriers to entry into the market for the supply of drugs for the treatment of Gaucher disease.
- 1.45. In addition to the penalty, the OFT also issued directions requiring that Genzyme:
- ends its exclusionary pricing and subsequently refrains from repeating the infringement;
 - thereafter refrains from adopting any measures having an equivalent effect;

¹³ The OFT press release can be found at www.of.gov.uk/news/press/2003/pn_31-03

¹⁴ www.catribunal.org.uk/documents/Jdg1016Genzy110304.pdf

- offers to supply Cerezyme to the NHS at a stand-alone price for the drug only, i.e. exclusive of any home delivery of Cerezyme and homecare services that may be provided; and
- supplies Cerezyme to third parties at a price no higher than the stand-alone price for the drug only, as agreed between Genzyme and the Department of Health.

1.46. The Competition Appeal Tribunal found that Genzyme had abused its position by allowing no margin to competing homecare providers but did not find that Genzyme's bundling of homecare services and Cerezyme was an abuse. In September 2005 it gave a direction¹⁵ that Genzyme must terminate its margin squeeze and must supply Cerezyme to any bona fide provider of homecare services at a discount from the prevailing NHS list price of not less than 20 pence per unit (which was 7.2 per cent of the then NHS list price).

2001 Competition Act 1998 decision re Napp

- 1.47. The OFT ruled in March 2001 that Napp Pharmaceuticals had abused its dominant position and Napp was fined £2.2 million (reduced on appeal to the Competition Appeal Tribunal from a higher figure). Napp had supplied a drug used by cancer patients, sustained release morphine (trade name MST), to patients in the community at excessively high prices while supplying hospitals at discount levels that blocked competitors. Napp had offered discounts of well over 90 per cent when tendering for hospital contracts. During this period at least one competitor withdrew from the market as a result of Napp having targeted its discounts for hospitals at other sustained release morphine products produced by competitors.
- 1.48. Napp was found to have been able to retain a high share of the much larger community market because the prescribing practices of GPs were found to be strongly influenced by the brands used in hospitals. Community prices were typically more than ten times higher than Napp's hospital prices and up to six times the export price of MST.
- 1.49. Napp's conduct was judged to have infringed Chapter II of the Competition Act 1998, which prohibits abuse of a dominant position in a market if it may affect trade within the UK.
- 1.50. The Competition Appeal Tribunal, in January 2002¹⁶, reduced the penalty originally imposed by the OFT and reinstated a direction made in May 2001 by the OFT requiring Napp to bring the infringements to an end, in particular by:

¹⁵ www.catribunal.org.uk/documents/Jdg1016Genzyme290905.pdf

¹⁶ www.catribunal.org.uk/documents/JdgNapp150102.pdf

- reducing the price of MST tablets to the community; and
- limiting the extent to which discounts can be offered to hospitals.