



Neutral citation [2005] CAT 32

**IN THE COMPETITION**  
**APPEAL TRIBUNAL**

Case No: 1016/1/1/03

Victoria House  
Bloomsbury Place  
London WC1A 2EB

29 September 2005

Before:

Sir Christopher Bellamy (President)  
Professor Peter Grinyer  
Mr Graham Mather

Sitting as a Tribunal in England and Wales

**BETWEEN:**

**GENZYME LIMITED**

Appellant

-v-

**THE OFFICE OF FAIR TRADING**

Respondent

supported by

**HEALTHCARE AT HOME LIMITED**

Intervener

**JUDGMENT: REMEDY**  
**(Non-Confidential version)**

Mr David Vaughan CBE QC, Mr Christopher Vajda QC and Mr Aidan Robertson (instructed by Taylor Vinters, Cambridge) appeared for the Applicants

Mr Rhodri Thompson QC and Mr Jon Turner (instructed by the Treasury Solicitor) appeared for the Respondent

Mr Euan Burrows (of Ashurst) appeared for the Intervener

Note: Excisions to this judgment marked “[...][C]” relate to commercial confidential information: paragraph 1 of Schedule 4 to the Enterprise Act 2002

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## I INTRODUCTION

1. This judgment concerns the remedy to be imposed following the appeal by Genzyme Limited (“Genzyme”) against decision no. CA98/3/03, taken by the Office of Fair Trading (“OFT”) on 27 March 2003<sup>1</sup>. A shortened version of this judgment, identical save for the omission of background material set out in sections III to VIII, will be published on the Tribunal’s website at the same time as this judgment.
2. The OFT found in its decision that Genzyme had abused a dominant position by bundling the price of its drug, Cerezyme, at a price to the NHS which included not only the supply of the drug but the supply of Homecare Services, as defined in the decision. The OFT also found that Genzyme had abused a dominant position by providing Cerezyme to third party providers of Homecare Services only at the NHS List Price, thereby denying a margin to any such third party provider.
3. The Tribunal gave its judgment on the merits of Genzyme’s appeal on 11 March 2004 [2004] CAT 4. In our judgment we decided, inter alia, that Genzyme had abused a dominant position in the period from 7 May 2001 contrary to the Chapter II prohibition by, without objective justification, adopting a pricing policy which resulted in a margin squeeze, with the effect of foreclosing the supply of Homecare Services to Gaucher patients. The OFT’s finding in the decision that Genzyme’s practice of bundling Homecare Services in the NHS List Price for Cerezyme was a separate abuse, was set aside by the Tribunal. However, the Tribunal found that Genzyme’s practice of bundling had facilitated the margin squeeze abuse. The Tribunal imposed a penalty of £3 million on Genzyme in substitution for the penalty of some £6.8 million imposed by the decision.
4. The background facts, including, inter alia, as to the relevant markets, Gaucher disease and arrangements for its treatment in the United Kingdom, the OFT’s investigation of Genzyme’s practices and the relevant regulatory regimes and NHS mechanisms applicable are set out in our judgment on the merits. Defined terms used in our earlier judgment have been adopted in this judgment.

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<sup>1</sup> Although the Decision was in fact taken by the Director General of Fair Trading all his functions were assumed by the OFT from 1 April 2003 under the Enterprise Act 2002.

5. The decision, at paragraphs 390 to 396, contained a direction to Genzyme intended to bring both of the abuses identified by the OFT to an end. Paragraph 396 of the decision set out the direction in these terms:

- “1. Genzyme shall
- 1.1. within fifteen working days from the date of this Decision bring to an end the infringement referred to at paragraph 386 above;
  - 1.2. thereafter, refrain from repeating the infringement referred to at paragraph 386 above; and
  - 1.3. with effect from the date of this Decision, refrain from adopting any measures having an equivalent effect.
2. In particular, within fifteen working days from the date of this Decision
- 2.1. the price at which Genzyme supplies Cerezyme and Ceredase to the National Health Service shall be, in respect of each drug, a stand-alone price for the drug only that is exclusive of any Homecare Services that may be provided; and
  - 2.2. the price at which Genzyme supplies Cerezyme and Ceredase to third parties shall be, in respect of each drug, no higher than the stand-alone price for the drug only as agreed between Genzyme and the Department of Health.
3. The term ‘Homecare Services’ in paragraph 2.1 means, in respect of each of Cerezyme and Ceredase, the delivery of the drug to a patient’s home and the provision of homecare services (including, but not limited to, basic stock check, supply of and monitoring of the need for accessories such as fridges and syringes, waste removal, dispensing the drug, training on how to infuse the drug, infusing the drug, providing an emergency helpline, respite care and full nursing support).”

6. The direction is currently suspended following the President’s judgment of 6 May 2003 on certain terms pending the determination of this appeal or until further order: see [2003] CAT 8.

7. As to the appropriate remedy in this case we decided in our judgment on the merits to adjourn the matter for six weeks to enable negotiations to take place: see paragraphs [654] to [679] of that judgment.

## **II PROCEDURE FOLLOWING THE TRIBUNAL'S JUDGMENT**

8. Since the handing down of our judgment in March 2004 we have, however, been provided with extensive further submissions on remedy from all parties running to hundreds of pages. We express our regret that, notwithstanding indications on the part of Genzyme that it felt it would be possible to reach an agreed solution, for a prolonged period Genzyme adopted a position which, in our view, precluded any reasonable negotiated settlement. That approach involved the OFT in many hours of extra work.
9. While this judgment was being prepared, the Tribunal was informed by letter of 8 July 2005 that Genzyme Homecare (now renamed Careology) had been sold by Genzyme by means of a management buy-out. With effect from 1 July 2005, Cerezyme was to be supplied by Genzyme to all healthcare providers, including Healthcare at Home, at a discount of 6.5 per cent from the new NHS List Price of £2.767 per unit. In a letter to Healthcare at Home dated 4 July 2005 Genzyme said that:

“The discount of 6.5% on Cerezyme is a voluntary unbundling offer made in the interim until a final direction has been given by the CAT”.

10. The OFT was informed by Genzyme by letter of 8 July 2005 that:

“the former homecare division of Genzyme [Careology] will now be trading on an arms length basis and on the same discount/credit terms as its competitors in the homecare services markets”.

11. The more significant steps in the procedure since March 2004 are summarised below and, where necessary, considered in more detail later in this judgment. The recent developments mentioned above have reduced the scope of the matters the Tribunal has to decide. Nonetheless, it is important to set the matter in context.

*Genzyme's instruction of experts*

12. Following the Tribunal's judgment of 11 March 2004 Genzyme did not immediately begin to make arrangements for negotiations with the DoH and hospital purchasers as envisaged by the Tribunal but instead, as evidenced by a letter from Genzyme's solicitors to the Treasury Solicitor dated 31 March 2004, instructed Professor Appleyard, ICAEW Northern Society Professor of Accounting and Finance at the University of Newcastle Business School, to prepare a report for submission to the OFT. Genzyme envisaged that following completion of Professor Appleyard's report, discussions should take place between Professor Appleyard and Professor Yarrow on behalf of Genzyme and economists from the OFT. Professor Yarrow had previously been instructed by Genzyme and gave evidence before the Tribunal in the main proceedings: see paragraphs 179 et seq of our judgment on the merits.

13. In response to Genzyme's letter dated 31 March 2004 the Treasury Solicitor, on behalf of the OFT, wrote to Genzyme in the following terms:

"We are surprised by the approach which you have unilaterally adopted, and would point out:

- (1) It was clearly envisaged by the Tribunal that the parties should adopt a co-operative approach to this exercise; and
- (2) The Tribunal has stated that, based on the information already available, the average cost of homecare appears to lie within a relatively narrow range of between 8%-11% of the NHS list price (see paragraphs 673-678 of the judgment). It should be noted that the Tribunal did not consider that formulating a precise direction to terminate the margin squeeze would be a difficult exercise based on the amount of information already available (see paragraph 672 of the judgment)

(...)

In these circumstances and in view of the limited time available before the need arises to file reports with the Tribunal, please inform us by return of (a) the substance of the instructions; and (b) the full extent of the information which you have given to Professor Appleyard."

14. The Registrar of the Tribunal wrote to the parties on 19 April 2004 setting the date on which the parties were required to file and serve reports as to the result of negotiations no later than 5pm on 20 May 2004.

15. On 19 May 2004 the Treasury Solicitor wrote to the Tribunal referring to the Registrar's letter dated 19 April 2004 and stating that whereas, at that time, the parties had thought it possible that a negotiated settlement could be reached by 20 May 2004

it had since become clear that further work was required, including a study of Healthcare at Home's costs.

16. As a result the Tribunal decided to hold a directions hearing on 27 May 2004.

*The directions hearing on 27 May 2004*

17. The OFT explained that Genzyme had served Professor Appleyard's report by cover of a letter dated 8 April 2004 and that, with Genzyme's consent, the OFT had passed that report to Healthcare at Home and to Mr Farrell of the Royal Free Hospital for comment. On 20 April 2004 the OFT obtained proposals from Genzyme that the appropriate discount per unit to reflect normal competitive conditions in this case was 2.6p per unit or just under 1 per cent. The OFT did not agree with Genzyme's proposal and submitted that the most appropriate way forward was for the OFT to produce its own report. The OFT was concerned about the commercial reality of what had been proposed by Genzyme, given the history of the case and of Genzyme's market power.

18. Genzyme submitted that negotiations were then at an advanced stage and Genzyme was confident that a negotiated solution could be achieved which would obviate the need for the Tribunal to issue a direction in this case.

19. Genzyme reported that a meeting had taken place on 1 April 2004 with the Department of Health. Genzyme then had a meeting with the OFT on 6 April 2004. Genzyme then had four meetings with NHS pharmacists at the four specialist centres where Gaucher patients are treated, including with Mr John Farrell of the Royal Free Hospital and Ms Sue Patey, Deputy Chief Pharmacist at Great Ormond Street Hospital. Those meetings had taken place between 7 April 2004 and 5 May 2004. Genzyme had had meetings with two of the consultants treating Gaucher patients, Dr Atul Mehta of the Royal Free Hospital and Professor Cox at Addenbrooke's Hospital. A meeting had also been held with the Gaucher Patients' Association on 27 March 2004.

20. The Tribunal noted that the resolution of issues concerning the direction had been taking rather more time than the Tribunal had anticipated. The Tribunal directed:

- (a) that the OFT submit to the Tribunal by 7 June 2004 a draft consent order concerning the establishment of a confidentiality ring of identified people to whom commercially sensitive information could be disclosed in relation to a possible direction in this case.
- (b) that the OFT submit a report by 14 July 2004 setting out the state of progress reached in relation to the negotiations regarding the price of Cerezyme and Homecare Services as required by the Tribunal's judgment of 11 March 2004; and
- (c) that a further hearing be listed for 29 July 2004.

21. A confidentiality ring was established by the Tribunal's order of 14 June 2004.

*The Progress Report dated 14 July 2004*

22. On 14 July 2004 the OFT submitted a "Report setting out the state of progress reached in relation to the negotiations regarding the pricing of Cerezyme and Homecare Services" (the "Progress Report"). According to the Progress Report, a submission had been received by the OFT from Healthcare at Home on 17 June 2004 and this had led to a further information request from the OFT on 23 June 2004, to which Healthcare at Home had responded on 1 July 2004. Further information had been requested by the OFT from Healthcare at Home by letter dated 7 July 2004 regarding the level of nursing, Healthcare at Home's allocation of delivery costs and profit margins. The OFT had held a meeting with Central Homecare on 7 June 2004 which also provided cost information on 28 and 30 June 2004. Further information had been sought by the OFT from Clinovia, by email dated 16 June 2004 and a response was expected by 19 July 2004. The information sought from Central Homecare and Clinovia concerned the approach those companies would take to pricing the Cerezyme Homecare Services if they were to tender to supply, including what direct costs would

be incurred, the contribution they would expect towards fixed overheads and the margin they would expect to earn on such business.

23. According to the Progress Report a meeting was to be held between the OFT and Mr Farrell of the Royal Free Hospital. The OFT hoped to have completed the drafting of its report by 26 July 2004. A meeting with Genzyme's experts had provisionally been planned for 28 and 29 July 2004 to discuss the report.

*The OFT's Costs Report of 23 July 2004*

24. On 23 July 2004 the OFT submitted a "Report on the Cost of Homecare Services for Gaucher Patients and the Discount Necessary for Genzyme to Bring the Margin Squeeze Abuse to an End" (the "OFT Costs Report"). The OFT Costs Report concluded that the appropriate discount from the NHS List Price required to remove the margin squeeze lay at the higher end of the range of 6.4 to 8 per cent of the then list price of £2.975 per unit.
25. In response to the OFT Costs Report, Genzyme submitted further written reports from Professor Yarrow (dated 6 August 2004 and 24 September 2004, respectively) and Professor Appleyard (24 September 2004). Healthcare at Home provided detailed submissions responding to the OFT Costs Report on 14 September 2004.

*The OFT's Supplementary Report of 13 September 2004*

26. On 13 September 2004 the OFT submitted a "Supplementary Report on the Cost of Homecare Services for Gaucher Patients and the Discount Necessary for Genzyme to Bring the Margin Squeeze Abuse to an End" (the "Supplementary Report"). In the Supplementary Report the OFT slightly revised its initial proposal made in the OFT Costs Report to the effect that an appropriate margin lay towards the higher end of the range of 5.1 to 7.3 per cent of the then NHS list price of £2.975 per unit.
27. On 14 September 2004 Healthcare at Home applied to the Tribunal for permission to intervene in the proceedings. A case management conference was held on 17 September 2004 at which Healthcare at Home was granted permission to intervene.

28. On 6 October 2004 Genzyme's solicitors made an application for specific disclosure of various documents from the OFT and from Healthcare at Home.

*The hearing on 13 October 2004*

29. A hearing was held on 13 October 2004. At the start of the hearing Genzyme made further proposals to the Tribunal and in particular made an unconditional offer, for the future, to "unbundle" the price of Cerezyme from the price of Homecare Services. The other parties had not had prior notice of Genzyme's intention to make such a proposal.
30. During the hearing the Tribunal discussed with the experts present various aspects of the OFT Report and Supplementary Report.

*Events following the hearing of 13 October 2004*

31. Following the hearing of 13 October 2004, Genzyme informed the Tribunal that it had commenced further negotiations with representatives of the Department of Health and of pharmacists under the auspices of the OFT.
32. On 28 October 2004 the Department of Health issued an announcement to inter alia Chief Executives of Primary Care Trusts, NHS Trusts, Foundation Trusts and Strategic Health Authorities that for a period of two years from April 2005 to March 2007 six centres will be nationally designated and funded by the Department of Health under the auspices of the National Specialised Commissioning Advisory Group ("NSCAG") to provide a service for patients with lysosomal storage disorders including Gaucher's disease. The announcement explained that the cost of such drug treatments would be funded on a national basis, although some funding responsibility for local patients would apparently remain with the PCTs. The six NHS Trusts concerned are: Great Ormond Street, Manchester Children's, the Royal Free, Addenbrooke's, University College and Hope Hospitals.

33. It appears that Genzyme wrote to the OFT on 19 November 2004 proposing a reduction of the NHS list price of 15 pence to give a new list price of £2.825 per unit. The OFT responded to Genzyme on 24 November 2004 and expressed the view that Genzyme's offer was insufficient as it did not fall within the range identified in the Supplementary Report (15 pence represented a discount of 5 per cent from the then NHS list price of £2.975 per unit).
34. The OFT met Healthcare at Home on 6 December 2004. The latter submitted a memorandum to the OFT on 21 December 2004.
35. It appears that representatives of Genzyme stated at a meeting with the OFT on 13 December 2004 that it was intended to close Genzyme Homecare. The stated reason for the closure of Genzyme Homecare was that Genzyme no longer considered that Genzyme Homecare would be able to obtain the minimum margin of 5 or 6 per cent it requires in order to be viable once the market is opened up to competition.
36. Following the meeting on 13 December 2004, Genzyme wrote to the OFT with a revised offer. At this stage a notable matter was that the NHS list price for Cerezyme was to be reduced by 7 per cent as a result of industry-wide negotiations regarding the 2005 PPRS. For the future that list price was to be £2.767 per unit instead of £2.975 per unit. Genzyme offered to reduce the new NHS list price by 18 pence per unit (or 6.5 per cent of the new NHS list price) to give a bulk pharmacy price of £2.587.
37. On 27 January 2005, following confirmation of Genzyme's intentions, the OFT notified relevant pharmacists and homecare providers of Genzyme's intention to close Genzyme Homecare and requested their observations on Genzyme's latest proposals. Notwithstanding Genzyme's decision to close Genzyme Homecare, the OFT considered it still necessary for the Tribunal to issue a ruling.
38. On 27 January 2005 the OFT also informed the Tribunal that the PPRS had required a 7 per cent reduction in the NHS list price for Cerezyme for 2005 onwards, thereby reducing the NHS list price for Cerezyme to £2.767 per unit.

39. On 27 January 2005 the Registrar invited all parties to submit written observations to the Tribunal by 8 February 2005 on the implications of Genzyme's decision to close Genzyme Homecare and on the PPRS reduction in the Cerezyme list price.
40. Genzyme then wrote to the OFT on 28 January 2005 stating that it was not, in fact, proposing to unbundle the NHS list price of Cerezyme. The NHS List price would, according to its proposal, remain at the new bundled price of £2.767 per unit but there would be a discounted "bulk pharmacy" price that would apply to providers of Homecare Services and hospitals.
41. On 8 February 2005 the OFT submitted a report on progress since the hearing on 13 October 2004 (the "February 2005 Progress Report"). The OFT maintained that nothing new had emerged to persuade it to alter the views set out in its Supplementary Report.
42. Healthcare at Home (on 4 February 2005 and 25 February 2005) and Genzyme (10 and 11 February 2005 and 25 February 2005) also provided further detailed submissions. Further correspondence between the parties, to which the Tribunal was copied, was sent during February and March 2005.
43. On 9 March 2005 Genzyme's solicitors informed the OFT that instead of closing Genzyme Homecare, work was then in progress on a management buy-out of Genzyme Homecare Division from Genzyme. It was envisaged that there would be no cross-subsidy by Genzyme of the new company created by the management buy-out. The new company would be financially independent. Genzyme's intention was that the process would be completed so that the handover of patients to the new company could take place by the end of May 2005.
44. On 18 May 2005 Genzyme informed the OFT that there had been a delay in the establishment of the management buy-out of Genzyme Homecare. Completion of the project had been delayed until 1 July 2005.
45. On 8 July 2005 Genzyme informed the OFT and the Tribunal that the management buyout of Genzyme Homecare (now renamed "Careology Limited") was completed

that day. Genzyme has stated that the consequence of the management buyout is that the former homecare division of Genzyme will now be trading on an arm's length basis on the same terms as its competitors in the Homecare Services market.

46. We understand that with effect from 1 July 2005 Genzyme has made Cerezyme available to healthcare providers such as Healthcare at Home at a discount of 6.5 per cent from the list price of the drug.
47. On 14 September 2005, at the Tribunal's request, Genzyme submitted further representations on the disclosure application it had previously made in October 2004.

### **III THE OFT COSTS REPORT OF 23 JULY 2004**

#### *The OFT's general approach to costs calculation*

48. As mentioned above, the OFT Costs Report was submitted to the Tribunal on 23 July 2004. The OFT Costs Report, comprising fifty-five pages of analysis supported by ten annexes, sets out the OFT's reasoned view of what ex-manufacturer price for Cerezyme would enable a reasonably efficient homecare provider to supply its services to Gaucher patients in competition with Genzyme Homecare and in doing so earn a competitive return.
49. The OFT Costs Report notes that in its BSKyB Decision (Case CA98/20/2002, *BSkyB investigation: alleged infringement of the Chapter II prohibition*, 17 December 2002), the OFT had considered whether BSKyB's notional "downstream company" could earn a reasonable return. The test applied in that case was whether an undertaking as efficient as BSKyB can earn a normal profit when paying the wholesale price charged by BSKyB to its distributors and that this should be tested by reference to BSKyB's own costs of transformation.
50. In this case, the OFT Costs Report notes that, unlike the BSKyB case, Genzyme Homecare was effectively a "start-up" operation. The OFT therefore considered that in this case it is inappropriate to base its determination as to the appropriate remedy entirely upon the current cost structure of Genzyme Homecare which, at the time,

provided homecare services to approximately 15 Cerezyme patients and some Fabrazyme patients.

51. The approach adopted in the OFT Costs Report is therefore to consider the costs incurred by Healthcare at Home in supplying homecare to Cerezyme patients. In reaching its conclusions the OFT Costs Report also considered evidence of Genzyme Homecare's own budgeted costs and the price at which competing homecare providers would be prepared to provide the service.
52. The OFT Costs Report considered the information provided in Professor Appleyard's reports of 5 and 8 April 2004. In those reports Professor Appleyard considered that the correct approach to the issue is to calculate the avoidable resources required by Healthcare at Home to provide the Homecare Services and adopted two approaches to estimating avoidable costs, each ultimately based on the resources required by Healthcare at Home. The first approach adopted by Professor Appleyard involved "estimating costs from accounting information available from current homecare providers" and the second approach was to "'model' the resources necessary for the efficient provision of the homecare service".
53. The OFT Costs Report noted that during the course of the OFT's investigation Genzyme had commissioned the Dixon Wilson Report in relation to financial issues that arose in the context of the OFT's investigation, including the "pricing of Cerezyme", the "profile of Cerezyme sales and distribution" and the "terms of trade between Genzyme and Healthcare at Home".
54. In preparing the OFT Costs Report the OFT had had regard to the Dixon Wilson Report which considered the costs that Genzyme had budgeted to incur with respect to Homecare Services in 2002. The resulting analysis, which compared Cerezyme revenues to direct and indirect costs, was designed to indicate the financial profile of Cerezyme in the United Kingdom. The figures in the Dixon Wilson Report suggested that the costs of providing Homecare Services including overheads were around 10 per cent of the list price of Cerezyme.

55. In addition, the OFT Costs Report noted that Healthcare at Home considered that the correct approach to the remedy in this case is to consider the price paid by Genzyme to Healthcare at Home before the margin squeeze abuse began since this represented a “competitive price”. This price, submitted Healthcare at Home, was “inherently conservative” given that Healthcare at Home’s contract with Genzyme was exclusive, and that homecare costs have risen since that contract was concluded in 1998.
56. Healthcare at Home provided the OFT with an account of the costs that Healthcare at Home considered are incurred in providing Cerezyme homecare services to the approximately 150 patients served by it. Its analysis included the direct costs incurred exclusively in respect of its Cerezyme business and Healthcare at Home’s view of how shared costs should reasonably be allocated to this service. In particular, Healthcare at Home identified two operational areas within that business, “Nursing” and “Home Delivery”.
57. Additional information was obtained by the OFT from two competitors to Healthcare at Home and Genzyme Homecare: Central Homecare and Clinovia. At the OFT’s request, those competitors had considered the price at which they would tender for the Homecare Services in question. Central Homecare’s approach involved calculating the direct costs that would be incurred, as well as the share of indirect costs Central Homecare would expect such business to cover. Central Homecare also explained to the OFT the level of profit margin that it would require, given the level of risk Central Homecare anticipated would be involved in the provision of homecare to Cerezyme patients. In preparing its information Central Homecare had had regard to the protocols set out on the Gaucher Association website which provide a detailed explanation of what is required of providers of homecare services to Gaucher patients.
58. Central Homecare’s analysis suggested that a per unit margin of [...] [C] per cent (or [...] [C] per cent with supply of the Sidekick infusion device) would be sufficient to enable it to provide Homecare Services to Cerezyme patients.
59. Clinovia also submitted an outline of the costs that it would include in a “typical proposal” for the provision of Homecare Services for Cerezyme patients. Clinovia considered the various fees that it would expect to charge for the service and, making

assumptions about the level of nursing care required, suggested a price per delivery plus a further fee to cover working capital and trade risk.

60. In addition, the OFT Costs Report considered the evidence prepared on behalf of Genzyme by Mr Richard Williams, who used the invoices raised by Healthcare at Home to Genzyme for the calendar year 2000 to compare the economic cost of the service provided by Healthcare at Home and the service provided by Genzyme when Genzyme had brought the service “back in-house”.
61. The OFT in its Costs Report did not consider that only the avoidable costs of the provision of the homecare service should be taken into consideration. In the OFT’s view, such an approach would provide no incentive for a reasonably efficient homecare provider to offer the service. In the OFT’s view the appropriate margin needs to take account of the firm’s fixed overhead costs. The OFT considered that a company whose pricing reflected only the avoidable cost of each of its activities would be loss-making and unsustainable. The OFT therefore chose to apply a “fully distributed costs” or “FDC” approach to any shared overheads.
62. The OFT also considered that it was required to consider whether the margin between the “upstream” and “downstream” prices allowed an efficient undertaking to earn a “normal profit”. The OFT stated that it would typically consider an undertaking’s cost of capital as a basis for ensuring that an efficient undertaking could earn a reasonable return in the relevant market. However, in its Costs Report, the OFT noted that in this case there are difficulties involved in correctly valuing and allocating capital between lines of business. Further, a cost of capital analysis based on the value of tangible capital recorded in homecare providers’ published financial statements could lead to a significant undervalue of the required rate of return.
63. The OFT therefore instead considered information from Healthcare at Home and others on the profit margins typically earned by homecare providers (in particular from Healthcare at Home, Genzyme (Professor Appleyard), Clinovia and Central Homecare). The OFT Costs Report did not accept Professor Appleyard’s view as his reports had been based on avoidable costs only which, in the OFT’s view, represented only a fraction of the investment required to provide Cerezyme homecare services.

Healthcare at Home had considered [...] per cent to be the minimum net margin whereas Central Homecare considered [...] per cent to be the minimum. The OFT noted that Healthcare at Home and Central Homecare treated working capital differently and that this might account for some of the difference between them.

#### *Nursing costs*

64. The OFT noted that the average cost of the Cerezyme Homecare Service depends on the costs of both delivery and nursing. In contrast to delivery costs, which are more or less equal for each patient not all patients require nursing and the number that do require nursing may vary over time. The OFT therefore attempted to establish the level of nursing required by the population of Cerezyme homecare patients receiving homecare in order to calculate the costs of providing this part of the service. The OFT noted that according to the first witness statement of Gareth Jones, 37 out of 154 Healthcare at Home patients required nursing assistance. According to the second witness statement of Dominic Moreland, Genzyme Homecare had 16 patients, of whom 5 required nursing assistance. This evidence suggested to the OFT that approximately 25 per cent of Gaucher patients require nursing support.
65. Professor Appleyard's report on behalf on Genzyme had used information submitted by Healthcare at Home to the OFT in the interim measures proceedings dated 23 March 2001 (see [2003] CAT 8) which estimated that the direct costs associated with the Genzyme business included [...] full-time nurses. With regard to that evidence, Healthcare at Home submitted to the OFT that this was an initial estimate of the notional number of full-time nurse equivalents which had assumed perfect efficiencies which are not present in practice. Healthcare at Home had since revised its submission on the basis of more up-to-date information and estimated that around [...] nurse visits are in fact required per month requiring at least [...] full-time equivalent nurses in practice and [...] full-time nurses being the number prudently required to provide the necessary level of cover.
66. The OFT noted that Healthcare at Home's later estimates of nursing resources were in line with Genzyme Homecare's own estimated costs of nursing as set out in the Dixon Wilson Report. Genzyme had estimated that Genzyme Homecare would employ 9

nurses (including a Head Nurse) and that 93.6 per cent of their cost would be attributable to Homecare Services for Cerezyme patients rather than other activities (equivalent to 8.4 full-time equivalent nurses for Cerezyme patients).

67. The OFT also took account of other sources of evidence on the number of nurse visits required to provide homecare to all Gaucher patients including:

(a) the second witness statement of Charles Walsh submitted to the Tribunal in relation to interim measures which analysed Healthcare at Home's costs in the period November 2002 to March 2003 on the basis of [...] [C] nursing visits per month (see paragraph 76 of [2003] CAT 8) ; and

(b) evidence submitted by Genzyme to the PPRS which showed the amounts paid to Healthcare at Home in the first nine months of 1999 under the terms of Genzyme's original contract with Healthcare at Home, from which it could be deduced that Genzyme paid Healthcare at Home for [...] [C] nurse visits in nine months or [...] [C] visits per month (although, at the time those payments were made there were fewer Gaucher patients receiving treatment at home than currently).

68. In addition the OFT had asked Healthcare at Home to provide details of the actual number of nurse visits made to Gaucher patients in the years to October 2000, 2001 and 2002. As Healthcare at Home did not hold this information electronically and submitted that to provide the information from paper records would have involved a great deal of work, Healthcare at Home instead produced information on the actual number of nurse visits in the month of March in each of those years. That evidence suggested to the OFT a true level of nurse visits some way below Healthcare at Home's initial estimate of [...] [C] visits per month. The OFT noted that there had been some pressure on Healthcare at Home to cut costs and that it had lost some patients to Genzyme Homecare which may explain the lower number of visits in recent years. Therefore the OFT considered that although Healthcare at Home's estimate of nursing resources was consistent with the analysis of Genzyme Homecare's costs in the Dixon Wilson Report, the OFT was unable to reconcile

Healthcare at Home's evidence on nursing resources with the actual number of nurse visits it has undertaken in recent years.

69. Taking into account all the evidence before it, the OFT considered that the most appropriate approach was to calculate nursing costs for 150 patients on two different bases:

- (a) an estimate based on evidence from Healthcare at Home and from the Royal Free and Addenbrooke's hospitals suggesting [...] [C] visits per month or [...] [C] full-time equivalent nurses (which the OFT rounded up to [...] [C] to reflect possible inefficiencies in utilising nurses); and
- (b) an estimate based on the number of nurse visits in March 2000, increased to take account of the lower numbers of patients at that time. This suggested [...] [C] nurse visits per month or [...] [C] full-time equivalent nurses, increased to 4.5 to reflect any inefficiencies in utilising nurses.

#### *Delivery costs*

70. In particular, in the OFT's view, Professor Appleyard had allocated costs inappropriately on the basis of full-time equivalent employee numbers. However, the figures in Healthcare at Home's Annual Reports are not full-time equivalents but actual staff numbers, in contrast to the estimate of staff numbers used by Professor Appleyard in his calculations. The OFT therefore considered that Professor Appleyard's analysis understated the true costs of Cerezyme staffing. Professor Appleyard's approach was also, in the OFT's view, inconsistent with the report of Genzyme's other expert, Professor Yarrow, who had noted that there are difficulties and costs in "consolidating" the distribution of Cerezyme with the great majority of drugs that are packaged in more standardised ways and that, in the past, Cerezyme had been distributed via specialist arrangements lying outside the normal wholesaling/distribution process.

71. The OFT Costs Report noted that Healthcare at Home had produced a complexity weighting or quotient for each of the costs items Healthcare at Home had identified as falling within its home delivery operations. Healthcare at Home had submitted to the OFT that the complexity ratings it had applied related to the estimated time, resource and seniority of the personnel required to complete a particular task. The OFT noted in the Costs Report that it had some concerns as to the validity of Healthcare at Home's complexity quotient analysis. Whilst the OFT accepted Healthcare at Home's contention that basing a costs allocation purely on the number of deliveries would lead to an under allocation of costs for Cerezyme, given the more complex nature of the homecare service provided for that drug, the OFT was not convinced that the complexity quotient analysis provided by Healthcare at Home was sufficiently linked to costs to justify allocating costs on that basis.
72. As regards other treatments, the representatives of the Royal Free Hospital had confirmed to the OFT that there are important differences between the service provided for haemophilia patients and that provided for Cerezyme patients, but it was not clear to the OFT that those differences implied a 50 per cent higher cost as Healthcare at Home's complexity quotient analysis indicated. The OFT Costs Report therefore noted that the OFT had asked Healthcare at Home for more information on the complexity quotient analysis and asked it to illustrate how a higher complexity rating is linked to proportionately higher costs.
73. Given that the OFT was not in a position to verify Healthcare at Home's complexity quotients or to determine alternative quotients, the OFT decided to adopt a "sensitivity analysis," taking Healthcare at Home's figures as an upper bound but also calculating a lower bound allocating delivery costs purely on the basis of the number of deliveries. The OFT considered that the true allocation of costs lay between those two limits.

*Central overheads*

74. With regard to central overheads, the OFT did not consider turnover or drug value to be a sound basis on which to allocate the central overhead costs items described by Healthcare at Home. Given the expense of Cerezyme, the OFT considered that an

allocation based on Cerezyme turnover would overstate the costs properly attributable to the provision of Homecare Services. For this reason, the OFT revised the proportion of finance and IT costs allocated by Healthcare at Home to Cerezyme. The OFT considered that allocation by the number of transactions represented a more objective and meaningful method of determining how finance costs should be allocated between Healthcare at Home's activities. The OFT therefore allocated 100 per cent of such costs on the basis of "transactional levels".

75. As regards the costs of directors, the OFT used an estimate of directors' time but modified the allocation that Healthcare at Home had made with respect to the time each of its directors devoted to the Cerezyme activity. In particular the OFT disregarded any costs resulting from the OFT's investigation and subsequent appeal to the Tribunal. As regards retail costs, the OFT Costs Report stated that Healthcare at Home had provided no evidence to the OFT as to why the workload involved in tracking FP10 prescriptions will vary according to value. Therefore the OFT allocated [...] [C] per cent of retail costs to Homecare Services, which reflected the mid-point of the volume of FP10s Healthcare at Home estimated were due to Cerezyme.
76. The OFT noted that the Dixon Wilson Report prepared for Genzyme had allocated common costs in proportion to revenue. However, the OFT considered that Genzyme's budget for common costs, as reflected in the Dixon Wilson Report, did not provide a sound benchmark by which to assess the reasonableness of the corresponding costs incurred by Healthcare at Home, as Genzyme Homecare's budgeted costs were those of a start-up operation. In the OFT's view, it was therefore unsurprising that the central costs allocated to Homecare Services in the Dixon Wilson Report were higher than those allocated to Healthcare at Home's Homecare Services business.

#### *Working capital*

77. Healthcare at Home calculated its working capital required on the basis of Healthcare at Home receiving no credit from Genzyme. However, Genzyme had suggested that it will in future offer normal credit terms. Therefore for the purposes of the OFT Costs

Report the OFT had adopted a working assumption that more conventional credit arrangements would be put in place between Genzyme and homecare providers in the future. The OFT noted that Professor Appleyard had assumed in his report that demand for Cerezyme is sufficiently predictable such that virtually no stock would be required. However, the OFT's consultations with the representatives of the Royal Free Hospital suggested to it that to hold less than one week's worth of stock would be unrealistic. The OFT did not therefore accept Professor Appleyard's view that virtually no stock is required and considered it appropriate to accept Healthcare at Home's evidence that two week's stock should be held.

#### *Other issues*

78. The OFT Costs Report noted that one possible indicator of a competitive price for homecare is the price that Genzyme had agreed to pay Healthcare at Home when Healthcare at Home was awarded the homecare contract in 1998. This involved a 2.5 per cent management fee, a separate payment for nurse visits and a scale of homecare charges based on patient categories. Based on the payments made to Healthcare at Home in the first nine months of 1999 this fee structure resulted in total payments worth 33.9p per unit or 11 per cent. Healthcare at Home submitted to the OFT that the appropriate level of discount is one which "returns the market to a situation of undistorted competition" and viewed the 1998 price as the "market price" absent the abuse, since that price had been based on an "industry-wide competitive tender". Healthcare at Home had also suggested that the price it offered in 1998 "was sufficiently competitive to displace the incumbent provider, Caremark". Genzyme submitted to the OFT that the 1998 price had been agreed when homecare for Cerezyme was a relatively undeveloped business. Genzyme wished to replace Caremark and there were few other companies able to provide such a service in 1998. Genzyme submitted that it had had little option but to accept the fees proposed by Healthcare at Home.
79. In the Costs Report the OFT did not agree with Healthcare at Home that the 1998 position can simply be assumed to be one of undistorted competition or that the price that it was paid by Genzyme in 1998 necessarily represented a competitive price. There was, in the OFT's view, some credibility to Genzyme's argument that the price

in 1998 was not truly competitive given the relative lack of choice of homecare provider available to Genzyme at the time. The contract with Healthcare at Home was not put out to an industry-wide tender nor did Healthcare at Home face strong competition from Caremark whom Genzyme were seeking to replace.

80. However, the OFT also noted that by 1998 Genzyme had already been purchasing homecare for five years and was not a naïve purchaser. The OFT noted that after Genzyme had been required to reduce the list price of Cerezyme in 1999, Genzyme renegotiated the contract with Healthcare at Home to reduce its homecare costs, which suggested to the OFT that there was a degree of market power on both sides at that time and the renegotiated price was, at the very least, a relevant fact in indicating the competitive level of discount, although it should be treated with a degree of caution. The re-negotiated price paid by Genzyme to Healthcare at Home in 2000 amounted to 28.4p per unit or 9.5 per cent. Genzyme had now suggested that that the total cost of Homecare Services is around 1 per cent of the Cerezyme list price. In the circumstances the OFT found it difficult to accept that, even where it faced a relatively limited choice of homecare provider, Genzyme would have agreed to pay very significantly more than the amount that was justified for Homecare Services, particularly since the negotiations with Healthcare at Home had been conducted on an “open-book” basis.
81. The OFT Costs Report noted that the service provided to patients is not a homogeneous service, particularly with regard to nursing. Some patients require little or no nursing on an on-going basis, although this need may vary over time if their circumstances change, while other patients require continuous nursing assistance. In particular, the OFT noted that third-party homecare providers may be over-compensated or under-compensated depending on the precise composition of the patient groups that they serve at any particular time.
82. In the OFT’s view, to the extent that in the future there is competition between third-party homecare providers, any over-compensation would not lead to customers paying excessive prices since any excess would be competed away by homecare providers offering their services for lower prices. On the other hand, in the OFT’s view, under-compensation would, in this case, be more problematic since it would be difficult for

hospitals to find homecare companies willing to take on their patients if they are more costly than average.

83. The OFT also considered that the cost of providing Homecare Services depends on the quality of the service provided. Given the high level of patient and hospital satisfaction with the service provided by Healthcare at Home, demonstrated by the decision of most hospitals to keep their patients with Healthcare at Home even after Genzyme had ended its contract, the OFT took the view that the level of service offered by Healthcare at Home at the time the margin squeeze began provided “a base quality threshold”. The OFT did not think it appropriate to build any contingency into the costs calculation for increased quality of service in the future. The OFT’s view was that the appropriate remedy should be based on the quality of service being provided by Healthcare at Home when the margin squeeze was introduced.
84. According to the OFT Costs Report the approach adopted by the OFT was to treat Healthcare at Home as a “reasonably efficient provider,” while using information from other providers, notably Central Homecare and Clinovia, to provide a cross-check.
85. The OFT noted that where Cerezyme is prescribed on an FP10 prescription the homecare company is reimbursed by the PPA rather than the hospital and receives the list price of Cerezyme and a 2 per cent Expensive Prescription Fee (“EPF”). At the time of the interim relief hearing approximately 40 per cent of Cerezyme prescriptions were by way of FP10, the remainder being private hospital prescriptions for which no EPF is made. Genzyme had submitted that EPF payments should be taken into account when calculating the average cost of homecare since this income is a significant contribution to meeting those costs. The OFT noted that the use of FP10s is concentrated in particular hospitals and that of the four national Gaucher centres in the United Kingdom only Addenbrooke’s Hospital used FP10s, the other hospitals using private prescriptions. If a homecare company were to win a contract with a hospital that did not use FP10s but the remedy had been calculated to take account of EPF income, then the homecare company would find the discounted price insufficient to meet its costs of providing the service. Where a homecare company wins a contract with a hospital that does use FP10s the discount that did not reflect EPFs

would over-compensate it. However the OFT would expect to see any such over-compensation being passed back to customers in some way by homecare companies offering lower prices, higher quality or additional services if the homecare market is competitive.

86. The OFT also noted that the current pattern of FP10 usage may change significantly in the future and that Addenbrooke's in particular had stated to the OFT that it was devising a homecare policy and, in the light of that, reviewing its use of FP10s. If, in the future, Addenbrooke's puts the Gaucher homecare service out to competitive tender then it will use hospital prescriptions and not FP10s. This suggested to the OFT that any discount that reflected EPF income was likely quickly to become out of date. For all those reasons the OFT did not consider it appropriate to take account of EPF income in calculating the level of discount in this case.

*The OFT's conclusions in the Costs Report*

87. Healthcare at Home had submitted to the OFT that it incurred homecare costs of £[...] [C] per unit of Cerezyme (equivalent to [...] [C] per cent of the then list price). Healthcare at Home's analysis had included no estimate of its required rate of return. The OFT had made a series of adjustments to Healthcare at Home's analysis in those instances where the OFT considered there to be objective evidence to suggest that an alternative approach to the calculation of costs was more appropriate. The OFT applied sensitivity analyses to Healthcare at Home's use of the complexity quotient and nursing resources, as the OFT considered that although Healthcare at Home had failed to fully justify its own treatment of those items in its calculations, there was insufficient objective evidence to determine precisely an alternative treatment. The resulting discounts, depending on whether the complexity quotient is applied, and whether [...] [C] or [...] [C] nurses were taken into account, were in the range £[...] [C] per unit ([...] [C] per cent of the list price £2.975) to [...] [C] per unit ([...] [C] per cent of that list price).
88. In addition, the OFT had regard to the evidence of Clinovia and Central Homecare. The percentage reductions in list price indicated by the information obtained from those companies was between [...] [C] per cent and [...] [C] per cent of the list price of

£2.975 per unit (Central Homecare) or between [...] per cent and [...] per cent (Clinovia). The OFT noted that the approximately [...] per cent difference suggested by the information from Clinovia and Central Homecare was significant. According to the OFT Costs Report it had not been possible in the time available to the OFT to verify that each company had produced a hypothetical tender for a service of the same quality as that currently provided by Healthcare at Home. The OFT noted that Clinovia does not currently provide homecare services to any Gaucher patients at all and that when it had done so previously (as Caremark) the quality of its service had been a matter of concern that had eventually resulted in its replacement by Healthcare at Home. The OFT noted that Central Homecare does currently provide a homecare service, if only to 1 Gaucher patient. The OFT therefore had more confidence in the information submitted from Central Homecare, which also more closely matched the information obtained from Healthcare at Home, and for those reasons considered that in a real tender process some of the items in Clinovia's analysis might need to be revised upwards.

89. The conclusion of the OFT Costs Report was that the appropriate level of discount required to remove the margin squeeze abuse lay in the range 6.4 per cent to 8 per cent of the list price of Cerezyme of £2.975 per unit. As to where in that range the correct discount lay, in the OFT's view, a discount of 6.4 per cent would be likely to underestimate costs as it made no allowance for Cerezyme delivery being more complex than other services provided in respect of other drug treatments and accordingly the appropriate discount in this case was, in the OFT's view, nearer the middle to top end of the OFT's range.

#### **IV THE OFT SUPPLEMENTARY REPORT OF 10 SEPTEMBER 2004**

90. Following submission of the OFT Costs Report on 23 July 2004 and its service on Genzyme's advisers the OFT held a meeting with Genzyme's experts, Professors Appleyard and Yarrow, on 28 July 2004. Following that meeting, Professor Yarrow submitted a note to the OFT outlining his response to the OFT Costs Report. Professor Yarrow disagreed with the OFT's conclusions in the OFT Costs Report in a number of respects and submitted that the correct level of discount required was in the

range of 1-2 per cent. The main issues between the OFT and Professor Yarrow at that stage were:

- (a) the apportionment of overheads and direct costs to calculate the costs of delivery of Cerezyme;
- (b) the amount of nursing assistance required by Gaucher patients; and
- (c) the amount of the profit margin element in the OFT's calculations.

91. The OFT then sent further requests for information to Healthcare at Home, Clinovia and Central Homecare to which responses were received during August 2004. Healthcare at Home also submitted observations on the OFT Costs Report. The OFT also sought information from Sheffield Teaching Hospitals regarding certain tenders to which no response was received. Further information was provided to the OFT by John Farrell of the Royal Free Hospital and the nursing agency, "24 Ambition". A further meeting was held with Genzyme's experts on 7 September 2004.

92. Having considered the responses of Genzyme and Healthcare at Home to the OFT Costs Report the OFT considered that adjustments were required to its original analysis in the OFT Costs Report. The OFT served a Supplementary Report on the advisers to Genzyme and Healthcare at Home on 10 September 2004. The revised conclusion of the OFT in the Supplementary Report was that the range of discount required, in the OFT's view, to remove the margin squeeze abuse in this case lay in the range 5.1 per cent to 7.3 per cent of the Cerezyme list price of £2.975 per unit. In particular the OFT's Supplementary Report considered the following matters:

- (a) Cost allocation: The OFT Supplementary Report rejected Professor Yarrow's assertion that central overheads are fully allocated in Professor Appleyard's model. According to the OFT no proportion of certain of Healthcare at Home's central overheads were allocated to Cerezyme homecare. No proportion of HR, IT or retail staff time was included in the Cerezyme staff requirement in Professor Appleyard's report and an analysis based on each activity's direct resources would

mean that such costs are not recovered by any given Healthcare at Home activity. The OFT remained of the view that the costs of Homecare Services should be calculated on a fully distributed basis, taking account of central and fixed costs in assessing the overall costs of a homecare provider providing its services to Gaucher patients.

- (b) Delivery costs: Professor Yarrow's view was that direct and indirect delivery costs should be allocated solely on the basis of delivery numbers. Professor Yarrow also criticised the OFT's figures for delivery charges because he suggested that they resulted in much higher charges per delivery than actual market rates. The OFT rejected Professor Yarrow's criticisms and continued to accept Healthcare at Home's view that Cerezyme is relatively more complex than other services provided by Healthcare at Home. The OFT remained of the view that allocating all costs pro rata on the basis of deliveries would understate the true costs of providing Homecare Services.
- (c) The OFT considered that in his submissions on the OFT Costs Report Professor Yarrow had, in the OFT's view, contradicted his own earlier statements to the Tribunal. The OFT referred in particular to page 17 of the Report of Professor Yarrow which stated:

"The fact that the Cerezyme must be consistently kept at a low temperature for the entirety of its own movement along the supply chain, coupled with the relatively small number of patients who use the medicine, the geographic distribution of those patients, the bulkiness of the packaging (arising from the temperature requirements) and the relative infrequency of deliveries, implies that there are difficulties and costs in "consolidating" its distribution and delivery with the great majority of drugs that are packaged in more standardized ways. It is certainly the case that, in practice, Cerezyme has been distributed via specialist arrangements, lying outside the normal wholesaling/distribution process".

The OFT agreed with Professor Yarrow's description which, in the OFT's view, correctly noted that the delivery of Cerezyme is more complex than other products. In the OFT's view therefore the allocation of delivery costs on the basis of delivery numbers, as

advocated by Professor Yarrow's later submissions, would be incorrect.

- (d) Directors: In the OFT Costs Report the OFT had allocated directors' costs on the basis of Healthcare at Home's estimate of the time each director spent working on the Cerezyme contract, adjusted to remove time spent on the OFT's investigation and the appeal to the Tribunal. The OFT Supplementary Report stated that Professors Yarrow and Appleyard had not disputed that, in principle, an allocation based on directors' time is reasonable. However, the Professors did not consider the time allocations put forward by Healthcare at Home to be credible. According to Healthcare at Home's estimates, approximately [...] [C] per cent of directors' time has been spent working on the Cerezyme contract. This calculation was made on the basis of the sum of the proportion of total directors' costs allocated to each director and dividing by the total cost of directors apportioned to delivery and on the assumption that all directors are paid comparable salaries. The OFT agreed that Healthcare at Home's allocation appeared high given the number of contracts held by Healthcare at Home. In contrast, the OFT considered that it should bear in mind that the proportion of time spent on the Cerezyme contract between 2000 and 2002 would underestimate the time spent on the contract when first secured by Healthcare at Home and that the Cerezyme contract has distinct complexities. However, the OFT Supplementary Report concluded that the alternative approach suggested by Professor Yarrow, which treated the costs of the directors as non-avoidable cost, would result in the continuation of the margin squeeze. Therefore, in exercise of its judgment, the OFT considered in its Supplementary Report that it would not be appropriate to adjust the time allocation put forward by Healthcare at Home in respect of Director's costs.
- (e) Retail costs: The OFT Supplementary Report considered it appropriate to adjust the OFT's earlier calculation in the Costs Report of retail costs to reflect the fact that the OFT now considered the use of FP10s

to be declining and that a costs allocation taking account of the processing of FP10s would not be representative of the future discount required with respect to Homecare Services.

- (f) Ancillaries: The OFT Supplementary Report considered that amendments should be made to the calculations in the OFT Costs Report to include the cost of ancillaries which the OFT had come to understand are included in Healthcare at Home's cost of sales and were therefore not included in the cost of Homecare Services that the OFT had determined in the OFT Costs Report.
  
- (g) Market rates: Professor Yarrow had cast doubts on the validity of the delivery figures put forward in the OFT Costs Report because he considered them to be out of line with "market rates", namely the Healthcare at Home tender for haemophilia of £[...][C] per delivery. The OFT asked Healthcare at Home to provide further information on charges per delivery for a range of contracts for different treatments (Neorecormon, Etanercept, Bosentan, Trepstinil, Immunoglobulin, Pulmozyme). The information provided to the OFT demonstrated that charges per delivery in practice do vary with the value of the drug and the level of service that is being offered. While the OFT acknowledged that the per-delivery figures for Cerezyme in the OFT Costs Report were higher than some delivery prices charged by Healthcare at Home in respect of some other treatments, there were other examples of contracts with similar or higher delivery charges to the delivery charge in the OFT Costs Report. In addition, the OFT had sought information from Healthcare at Home on its haemophilia contract with the Royal Free Hospital. Healthcare at Home explained that competition in that market is distorted by the presence of vertically integrated manufacturers who are able to bid very low prices. Healthcare at Home submitted that the current level of remuneration under the haemophilia contract is such that Healthcare at Home is considering withdrawing from that market altogether. The OFT also had regard to the hypothetical tenders submitted to the OFT by

Clinovia and Central Homecare. With regard to delivery charges, the figure put forward by Clinovia in its hypothetical tender was similar or higher than that in the OFT Costs Report while Central Homecare's figure for delivery charges was significantly above the OFT's figure. On the basis of all the evidence the OFT did not therefore consider it appropriate to revise its figure for delivery charges which the OFT does not, contrary to Professor Yarrow's view, consider to be out of step with market evidence.

- (h) Nursing: The OFT Costs Report used two different assumptions for the required number of nursing visits (resulting in full-time equivalent nurse numbers of [...] or [...] compared with Healthcare at Home's estimate of [...]). Clinovia and Central Homecare provided information to the OFT on the amount that they charge for nursing by the hour and the OFT therefore used these assumptions, on the further assumption that a nurse visit to a Gaucher patient, including travelling time, takes approximately 4 hours, to calculate the price that would be bid by those companies in respect of nursing. Professor Yarrow accepted that a nurse visit to a Gaucher patient takes around 4 hours. His approach had been to work out the cost of a nurse hour and use this number to calculate total nurse costs based on the number of visits made over the course of a year. Healthcare at Home estimated the average salary of a nurse as £[...] which suggested to the OFT that Healthcare at Home employs [...] full-time equivalent nurses. Professor Yarrow found it difficult to accept Healthcare at Home's figure for average salary and suggested that there were likely to be a number of low paid and/or part-time staff in the business. Professor Yarrow also made detailed criticisms of the OFT's nursing calculations and produced his own calculations, based on figures from March 2002. Healthcare at Home had also criticised the OFT's nursing figures and submitted that in reaching those figures the OFT had assumed perfect efficiencies which cannot possibly exist in practice. The OFT noted that Professor Yarrow had assumed that all 7.5 hours per working day of a nurse's time was chargeable and therefore that there was near

perfect efficiency in nurse utilisation. The OFT's view was that as Healthcare at Home employs nearly all its nurses on a full-time basis it will, in the OFT's view, inevitably have some nurse capacity for which it cannot charge. Healthcare at Home's own information supported its assumption that the average number of nurse visits, across all treatments, is [...] per day. The OFT considered that Professor Yarrow's approach was unrealistic. The OFT's approach implied that nurses can be charged out for around two-thirds of their available time (around 5 hours) per day. Healthcare at Home had suggested that this rate of utilisation was realistic and it was consistent with the evidence Healthcare at Home provided to the OFT on the number of nurse visits achieved per day.

The OFT took the view in the Supplementary Report that even if the number of nurse visits suggested by Professor Yarrow was correct, the costs involved in providing that level of visits would be higher than he had suggested because it would require [...] full-time equivalent nurses to provide it. The OFT considered that the March 2002 figure for nurse visits used by Professor Yarrow in his calculations was likely to underestimate the number of nurse visits that would take place in the absence of the margin squeeze. The OFT did not agree with Professor Yarrow that the March 2000 figures which it had used were likely to be inflated either because of the switch from Ceredase to Cerezyme or because of the rate of growth in homecare patients. The OFT did not accept Healthcare at Home's criticism that it had assumed perfect efficiency in nurse utilisation in its Costs Report. The OFT noted that Healthcare at Home has [...] nurses that have been specifically trained to treat Gaucher patients that cannot be fully utilised elsewhere, but considered that the nurse utilisation resulting from using Healthcare at Home's figure of [...] full-time equivalent nurses ([...] per cent and [...] per cent, respectively) was high and would overstate nursing costs, even for a new entrant provider.

Professor Yarrow highlighted the significant difference between Healthcare at Home's estimated nurse cost per-visit compared with the hypothetical charges that had been quoted to the OFT by Central Homecare and Clinovia. In response, the OFT sought further evidence from Central Homecare and Clinovia. The OFT noted that the business model used by Clinovia and Central Homecare was very different to that of Healthcare at Home as those companies placed heavy reliance on the use of agency nurses rather than directly-employed staff. Central Homecare informed the OFT that it employs no nurses directly and uses all agency nursing staff. The cost of nursing is then passed on to Central Homecare's customer directly with no profit element. The OFT had then further discussed that issue with representatives of hospitals. Evidence submitted from Mr Farrell of the Royal Free Hospital was that it would be totally unacceptable for a Cerezyme homecare provider to use agency nurses and that hospitals would expect nurses to be employed directly by the homecare company. This was considered to be an issue of critical importance by hospitals. Homecare already involved passing responsibility for patient care from the hospital to a third party and hospitals did not regard it as acceptable for that responsibility to be further delegated to another third party. In the light of that further information the OFT took the view that comparisons between the nursing rates of Central Homecare and Clinovia on the one hand and Healthcare at Home on the other hand needed to be treated with some caution. In the light of all the evidence before it the OFT did not therefore consider it necessary to alter the nursing assumptions contained in its analysis of Healthcare at Home's costs in the OFT Costs Report.

- (i) Profit margin: In the OFT Costs Report the OFT had used Healthcare at Home's minimum target net margin of [...] [C] per cent to calculate the required discount. Professor Yarrow had submitted that this rate of return was excessive and resulted in discriminatory pricing. Professor Yarrow considered that although Healthcare at Home's capital employed number did look very low, the fixed asset figure appeared to

be in a reasonable range for a business of this type. Professor Yarrow applied the ROCE ratio of 30 per cent (the rate applied under the PPRS) to Healthcare at Home's fixed assets to determine his estimate of Healthcare at Home's required rate of return. In response to Professor Yarrow's criticisms the OFT submitted that Professor Yarrow's approach applied an entirely arbitrary ROCE ratio to Healthcare at Home's accounting capital employed. The OFT considered that the 30 per cent upper limit applied by the PPRS has been derived with manufacturing companies in mind. Homecare providers such as Healthcare at Home have wholly different capital structures to manufacturing companies. In the OFT's view the limited value of a homecare provider's accounting capital as a measure of its economic capital is clearly illustrated by the price that had been paid by the acquirers of Clinovia. Whereas Clinovia's fixed assets were £[...][C] million as at 30 September 2003 the purchaser of the company paid £[...][C] million for the Clinovia Group in August 2003. Clinovia's market value that a willing purchaser was prepared to pay was therefore apparently over 12 times the value of its fixed assets and it was clear, in the OFT's view, that applying a cost of capital of 30 per cent of Healthcare at Home's accounting fixed assets could drastically underestimate Healthcare at Home's required rate of return. Furthermore, in the OFT's view, Professor Yarrow's approach produced an estimate that bore no relation to the rates of return typically observed in the market.

The OFT therefore considered the evidence of Healthcare at Home, Clinovia and Central Homecare as to the level of profit margin required. The profit margin suggested by Clinovia was [...][C] per cent of the end price to cover trade risk as well as a standard "on cost" margin of [...][C] per cent. Central Homecare suggested that its profit margin would be [...][C] per cent of the end price. Healthcare at Home assumed a minimum margin of [...][C] per cent of end price, although this must also contribute to certain costs. In the light of the further information obtained by the OFT since it had produced the OFT

Costs Report the OFT now considered it appropriate to take [...] [C] margin of [...] [C] per cent as an upper bound and to adopt [...] [C] per cent as the lower limit (the level implied by [...] [C]'s approach).

(j) Conclusion: The OFT in its Supplementary Report therefore considered it appropriate to make certain adjustments to the figures put forward in the OFT Costs Report, as follows:

- (i) as regards delivery costs, to allocate retail costs on the basis of transactions and to include ancillaries; and
- (ii) as regards profit margin to adopt a [...] [C] per cent upper limit and a [...] [C] per cent lower limit.

93. The effect of the above changes in the Supplementary Report was to reduce the OFT's view of the range of required discount in this case to the range 5.1 per cent to 7.3 per cent of Cerezyme's then list price.

## **V THE PARTIES' SUBMISSIONS FOR THE HEARING ON 13 OCTOBER 2004**

### *Genzyme's submissions*

94. Genzyme submitted that the methodology for calculating the required discount to eliminate the abuse in this case had been broadly agreed between the OFT and Professors Appleyard and Yarrow. The discount which is ordered must, in Genzyme's view, be established with a sufficient degree of certainty and is not an exercise in re-establishing historic prices applicable in a completely different situation. It should not be used as a mechanism to compensate for past injury.

95. Genzyme submitted that there are three principal "heads" of the cost of the Cerezyme homecare service which fall to be determined in calculating the required discount in this case: (i) cost of delivery; (ii) cost of nursing; and (iii) profit margin.

96. Genzyme submitted that the differences that continue to exist between the OFT and Professors Appleyard and Yarrow arise in applying the agreed principles to the facts. In Genzyme's submission, if the views of Professor Appleyard or Yarrow as to the application of the principles to the facts are disputed by the OFT then the OFT must produce evidence to demonstrate that they are wrong. According to Genzyme, the OFT and Genzyme faced significant problems in obtaining the best evidence upon which to determine delivery costs, nursing costs and profit margin in this case. Those evidential problems arose from Healthcare at Home's refusal to supply detailed figures or documents.
97. Genzyme submitted that Healthcare at Home had failed to supply information to the OFT regarding successful tenders in late 2002 for contracts awarded by the Birmingham Children's Hospital NHS Trust for home delivery of pharmaceuticals and nursing or its successful tenders in 2002, 2003 and 2004 for contracts awarded by the University of Leicester NHS Trust for various homecare delivery and/or nursing services.
98. Genzyme submitted that the price for homecare services cannot vary according to the value of the drug as contended by Healthcare at Home. The figures supplied by Healthcare at Home to the OFT in support of its contention that homecare prices vary according to drug value were tenders won by Healthcare at Home or renewed contracts. The original documentation upon which the figures in the OFT supplementary report were based was not disclosed to Genzyme and therefore cannot be accepted by the Tribunal. Genzyme submitted that there was no evidence upon which to compare and explain the differences in price for delivery for each of those contracts. For certain of the other products mentioned in the Supplementary Report, (Neorecormon and Etanercept) the charges per delivery were similar to those calculated by Professors Appleyard and Yarrow. For other products the charge for delivery was different and may reflect a wholesaler discount or a relationship with VAT. In Genzyme's submission it was impossible for the OFT to draw any conclusions from those figures.
99. In Genzyme's submission the haemophilia contract referred to in the OFT's Supplementary Report is comparable to the delivery of Cerezyme, as Factor VIII

treatment like Cerezyme treatment involves reconstitution of a powder in vials for infusion at home. Genzyme submitted that the same result as that calculated by Professors Appleyard and Yarrow would have been obtained by the OFT if the OFT had examined prices obtained in comparable tenders.

100. In particular, Genzyme submitted that the OFT should have examined various tenders issued by hospitals for what Genzyme said were comparable services, four of which had been awarded to Healthcare at Home:

- (a) University Hospitals of Leicester for the supply of blood coagulants and associated consumables to patients in their homes – 25 August 2001;
- (b) Birmingham Children’s Hospital NHS Trust for the supply of high-tech home care packages including a range of pharmaceuticals and nursing care to patients in their homes – 6 September 2001;
- (c) University of Leicester NHS Trust for the supply of clotting factor concentrates recombinant and plasma-derived and associated consumables for delivery to patients in their homes – 20 December 2002;
- (d) University Hospitals of Leicester for a home delivery service providing disease modifying agents for the treatment of multiple sclerosis – 18 August 2003; and
- (e) Sheffield Teaching Hospitals NHS Trust for delivery service covering prescription drugs and consumables to patients at home including supply and maintenance of storage facilities in patients’ homes – 12 May 2004.

Healthcare at Home had been awarded a contract under the first four of these tenders.

101. According to Genzyme its experts had calculated the delivery cost element in this case as £103 per delivery. This calculation is consistent with information in the first and second witness statements of Charles Walsh prepared in April and May 2003 in relation to the interim measures proceedings and consistent with information provided to Genzyme from Mrs Sue Patey, the Head of Pharmacy at Great Ormond Street Hospital and the former pharmacy service manager for the University of Birmingham NHS Trust, Mr Steve Potter (now employed by Genzyme as a Therapy Liaison Officer). Mr Potter provided a witness statement which explained that cold-chain delivery of Cerezyme is broadly comparable to delivery of other cold chain delivery drugs and there was no good reason why the cost of delivery of Cerezyme should be more costly than delivery of those drugs.
102. As regards nursing costs, Genzyme submitted that Professors Appleyard and Yarrow calculated the nursing cost element for Cerezyme homecare as £120 per visit, with an allowance for profit. Genzyme submitted that this figure was consistent with the information in the first and second witness statements of Charles Walsh and information provided by Mrs Patey and Mr Potter. There is no reason to accept Healthcare at Home's submission that homecare nursing for Gaucher patients is more costly or complex than other types of homecare nursing. According to Genzyme there are other treatments such as haemophilia, multiple sclerosis, HIV and pulmonary hypertension which are comparable types of homecare nursing and there is no case for saying that Cerezyme homecare requires a different level of resource to those treatments.
103. Genzyme submitted that the largest divergence of approach between the OFT and its experts arose in relation to the required element of profit margin. The OFT had rejected what Genzyme describes as the "standard approach" of estimating the required profit margin in a competitive market by focusing on the cost of capital. The OFT had instead adopted an entirely incorrect approach. Genzyme submitted further that allocating central overheads by reference to turnover or drug value, as had been done in the first and second witness statements of Charles Walsh, would give rise to a perverse result and would be circular. The only rational approach for the OFT to take was the approach that had been adopted by Professor Yarrow who had concluded that central overheads should be allocated equi-proportionately.

104. In conclusion Genzyme submitted that the analysis of Professors Appleyard and Yarrow had demonstrated that the price required to end the margin squeeze in this case is no more than 6p per unit. If that conclusion is to be disputed or challenged then the burden of proof is on the OFT and/or Healthcare at Home to demonstrate that the conclusions of Professors Appleyard and Yarrow are incorrect and they have not discharged that burden.
105. It was now obvious, in Genzyme's submission, that the process of engaging economic experts and testing the available evidence has proved to be a critically important exercise particularly as the OFT's own position changed in the light of the expert evidence submitted by Genzyme and discussions between the OFT and Genzyme's experts. It was now clear to Genzyme that the correct margin figure is well below the range initially indicated by the Tribunal in its judgment of March 2004. Genzyme submitted that it would not be appropriate for Genzyme to "settle" the issue of the remedy in this case on the basis of the OFT's proposals in the Costs Report (as refined in the Supplementary Report) as vital required evidence had not been produced and because there are important differences between the OFT and Genzyme's experts as to the calculation of the remedy.
106. Genzyme submitted that, in contrast to the evidence submitted by the OFT and Healthcare at Home, the evidence of Professors Appleyard and Yarrow is clear and cogent and the criticisms of it by the OFT are unfounded.
107. As regards delivery charges, Genzyme did not accept that there are any relevant differences in the delivery process between Cerezyme delivery and haemophilia. Genzyme disputed the evidence of Mr Farrell and Ms McDonald relied on by the OFT but not disclosed to Genzyme. The OFT did not particularise what the differences are supposed to be. If anything the haemophilia service appeared to be slightly more complex as tender documents for haemophilia refer to "on demand" therapy whereas this did not apply in the case of Cerezyme.
108. As regards the complexity quotient applied by Healthcare at Home the OFT has accepted in the Costs Report that it has not been able to verify this quotient. The

figures relating to other treatments supplied by Healthcare at Home in the Supplementary Report are impossible to accept and need to be verified by a comparison with underlying documents.

109. Historical information, and in particular information relating to the price agreed between Genzyme and Healthcare at Home in 1998 cannot be relevant in the different market conditions prevailing now.

*OFT's submissions*

110. The OFT submitted that the Tribunal, in its judgment of 11 March 2004, had concluded that one method of eliminating the margin squeeze identified in the judgment was for Genzyme to offer an ex-manufacturer price to independent providers of Homecare Services that would reflect the fact that Genzyme would not be incurring the costs of providing such service. The Tribunal had noted in its judgment, from a provisional analysis of the historical information, that the appropriate level for an ex-manufacturer price at first sight appeared to lie within a relatively narrow range between 8 per cent and 12.5 per cent.
111. Following the Tribunal's invitation to the parties to see whether it would be possible to negotiate the remedy in the light of the Tribunal's judgment, Genzyme had taken the view that rather than seeking to negotiate with its customers it should seek to quantify, by the process of the preparation of expert evidence, the appropriate level of discount from Genzyme's current list price. The outcome of the process had not been negotiation, as envisaged by the Tribunal, but the preparation of a sequence of reports by Professors Appleyard and Yarrow on behalf of Genzyme and two reports on the costs of the Cerezyme homecare service by the OFT. The OFT's Supplementary Report dated 10 September 2004 had concluded that the discount required to remove the abuse lies in the range of 5.1 to 7.3 per cent of the list price of £2.975, or 15p to 22p per unit. By contrast, Genzyme's submissions, based on the reports of Professors Appleyard and Yarrow, concluded that the price reduction required to remove the margin squeeze abuse is no more than 6p or 2 per cent.

112. The OFT considered that if the outcome of the exercise is a range of possible discounts (as the OFT had concluded in both of its reports) then there is no presumption or rule of law that the lowest possible figure must be adopted. It is equally undesirable, in the OFT's view, to set a discount that is too low as one that is too high. The OFT submitted that the remedy in this case must be effective. Genzyme's approach, based on the work of Professors Appleyard and Yarrow, was to attempt to calculate the minimum cost of homecare services based on a perfectly efficient homecare provider and without taking account of central costs or any specific requirements of a provider of services to Gaucher patients. Professor Yarrow sought to allocate costs without taking into account the relative complexities of providing homecare to Gaucher patients and his approach was therefore inappropriate. In addition, the OFT submitted that there is a marked tendency in the reports submitted on behalf of Genzyme to resolve any conflicts or uncertainties by adopting the lowest possible figures.
113. The OFT's view was that Genzyme's approach results in a level of discount that is too low. The OFT, on the other hand, had adopted an approach aimed at reflecting the average costs of Cerezyme homecare as accurately as possible, while not erring on the low side, with the risk that the remedy will be ineffective.
114. The OFT rejected Genzyme's submission that there is a presumption that the Tribunal should accept the analysis of Professors Appleyard and Yarrow. There is no presumption that the evidence or analysis put forward by Genzyme is correct. The OFT submitted that evaluation of the available evidence is a matter for the Tribunal and the Tribunal is able to take account of any inadequacies in the available evidence and the analyses put forward by Genzyme and Healthcare at Home as well as the OFT, in reaching its view as to the appropriate remedy to be imposed.
115. The OFT did not agree with Genzyme that the price for the Homecare Services cannot vary according to the value of the drug. The OFT had stated that it did not consider turnover or drug value to be a sound basis on which to allocate certain central overheads. However, this does not mean that the price for Cerezyme homecare is entirely independent of the value of the drug as Genzyme sought to suggest. The OFT submitted that some cost items naturally vary with drug value and it may be

appropriate for the profit margin to be linked to drug value because the risk involved in a business concerned with higher value drugs are likely to be greater. The OFT's view was therefore that some relevant factors will be linked to drug value and this was supported by the evidence provided to the OFT from Healthcare at Home, Clinovia and Central Homecare.

116. As regards Genzyme's submission in response to the Supplementary Report that the delivery figures put forward by Professor Yarrow are supported by "market rates", in particular Healthcare at Home delivery charges for [...] [C] and [...] [C] and the charge made for haemophilia deliveries, Genzyme had either overlooked or rejected other evidence of significantly higher delivery charges for other drugs because, it submitted, it had not seen documentary evidence justifying any price differences. The OFT emphasised, as Professor Yarrow had pointed out, that it is important to ensure that the services involved in each case are comparable. This means looking at all aspects of the service provided for the drug concerned and not just the pure delivery component. The "delivery" costs element for the purposes of the calculations in the OFT Costs Report and Supplementary Report encompasses customer care, co-ordination with treatment centres (chasing-up prescriptions, liaising with physicians etc.) pharmacy and warehousing as well as the physical transportation of the product to the patient.

117. Genzyme's comparison of different drugs had looked only at the physical transportation element of the "delivery" costs component and finding low delivery prices for two or three other drugs, had sought to deduce that the price for delivery of Cerezyme should be in the same range. However, the OFT submitted that it is necessary to make allowance for all aspects of the delivery service provided by Healthcare at Home when providing the Homecare Services, rather than solely the transportation of the product. This is the logic behind Healthcare at Home's "complexity quotient" analysis which had attempted to rank the various treatments according to their relative complexity across the different aspects of the delivery service. The OFT had not been able to verify Healthcare at Home's complexity quotients but did accept that Cerezyme homecare is a relatively complex service. This was supported by evidence to the OFT from the Mr Farrell of the Royal Free

Hospital which confirmed that the haemophilia service is less complex than the Cerezyme service.

118. Genzyme had also submitted a witness statement from Sue Patey at Great Ormond Street Hospital and Steve Potter of Genzyme (previously of University Hospital Birmingham) who had provided their views as to what they would expect to pay for “home delivery of a drug”. Each of those witnesses had provided a price range for the delivery element, although neither witness had given any specific examples of contracts with which they had been involved where such delivery charges had actually been made or the specific factors that would be taken into account in pricing such a service. Ms Patey had noted the price ranges she quoted were dependent on requirements and indicated that Great Ormond Street Hospital did not intend to tender for homecare services “for a year or so”.
119. Genzyme had not made any reference in its submissions to the evidence from Clinovia and Central Homecare, who are actual or potential competitors, as to what they might bid to win the Cerezyme business which was in line with Healthcare at Home’s figures and considerably above the figures put forward by Genzyme. Accordingly the OFT remained of the view that its analysis of delivery charges in its Costs Report and Supplementary Report was valid.
120. As regards nursing costs, the OFT reiterated its views in the Supplementary Report. The OFT submitted that the figures put forward by Professor Yarrow assume complete nursing efficiency which the OFT does not consider to be realistic. The OFT took a different view to Professor Yarrow regarding nurse numbers, as explained in its Supplementary Report. Further evidence had been provided from Ms Patey and Mr Potter who stated what they would expect to pay for nursing. However the OFT submitted that Ms Patey and Mr Potter had not provided specific evidence on their experience of purchasing homecare to support their figures. The OFT noted that with regard to nursing costs the OFT was concerned that the information supplied to it by Central Homecare and Clinovia may not be reliable as those companies did not employ many (if any) nurses directly and it is necessary to do so in order to provide the Homecare Services for Cerezyme patients. Mr Potter had stated in his witness statement that it is not for a hospital pharmacist to say whether nurses should be

directly employed or agency nurses. The OFT submitted that that comment was surprising as, in the OFT's view, it seemed perfectly proper to the OFT for the purchaser of a service to specify how that service should be provided. Mr Potter's evidence directly contradicted the evidence of Mr Farrell who considered that it was not acceptable for the provider of the Cerezyme homecare service to employ agency nurses.

121. The OFT noted that the Dixon Wilson Report prepared for Genzyme Homecare had not envisaged using any agency nurses, even though Genzyme Homecare had very low patient numbers, and the use of agency nurses would almost certainly have been cheaper than employing nurses directly. The Dixon Wilson Report, on the contrary, was prepared on the basis that Genzyme Homecare would employ nurses directly. The OFT therefore maintained its approach to nursing costs adopted in the Supplementary Report.
122. Genzyme, supported by Professor Yarrow, submitted that historical prices, in particular the price negotiated in 1998 are irrelevant to the current exercise. The OFT's view was that the discount required to remove the margin squeeze should be based on current cost figures. However, the OFT did consider the price agreed in 1998 to be a relevant factor. The OFT considered Genzyme's submissions to be unconvincing given Genzyme's market position at that time, and the evidence of Charles Walsh concerning the original negotiations.
123. On the other hand, the OFT did not accept Healthcare at Home's submission that the 1998 figures should be taken as the starting point for calculating the discount in this case and increased to take account of increases in costs over recent years. However, the OFT considers that the 1998 price is a relevant piece of background evidence to be taken into account in reaching an overall assessment of a realistic appraisal of the appropriate remedy in this case.
124. The OFT noted that it is neutral as between unbundling or setting an ex-manufacturer price, but submitted that the "unbundling route" does not remove the need to calculate the cost of Homecare Services. If the difference between the unbundled price and the old bundled price is not sufficient to cover the cost of Cerezyme homecare, then the

extent to which Genzyme could truly be said to have unbundled the two prices would be questionable.

*Healthcare at Home's submissions*

125. Healthcare at Home submitted that the legal test for margin squeeze is to be found in the European Commission's Decisions in *National Carbonising Company* and *Napier Brown/British Sugar*, cited in the Tribunal's earlier judgment in this case.
126. The test has the purpose of ensuring that a reasonably efficient competitor can survive in the long run and is not based on ensuring that the most efficient competitor can survive or requiring survival to be conditional on the competitor supplying almost all of the market. Accordingly, Healthcare at Home submitted that a market opening price in this case is not the lowest price that the most efficient, largest scale competitor can sustain.
127. Healthcare at Home submitted that it was striking that the OFT now, in its Costs Report and Supplementary Report, suggested that the appropriate remedy involves a substantially lower margin than that which had been suggested by the Tribunal in its judgment "at first sight" of between 8 per cent and 12½ per cent. The OFT now proposed in the Supplementary Report that the correct level of margin was between 5.1 per cent and 7.3 per cent. The OFT's analysis had focused primarily on Healthcare at Home's costs. This approach is wrong as a matter of law. The requirement on the OFT is to identify the costs of a reasonably efficient provider. The adoption of an erroneous approach focused on Healthcare at Home's costs rather than Genzyme's costs led the OFT to underestimate the costs of Homecare Services in the OFT Costs Report and Supplementary Report, as Healthcare at Home is the incumbent provider and may be presumed to be more efficient than the average provider.
128. The OFT Report and Supplementary Report only provide information on those activities the OFT has been able to identify and often only those that Healthcare at Home has been able to provide proof for. This cautious approach, while understandable, leads to a further under-estimation of the true level of the cost of

providing the service. There are particular difficulties for a business whose assets are largely intangible and where expertise is of a specialist nature and where Healthcare at Home has to budget for the cost of taking on the responsibility of providing homecare with its full supply chain, service complexity and risks.

129. Healthcare at Home concurred with the OFT's analysis that the costing model needs to be based on fully allocated costs in this case, which includes director's costs, central overheads, HR, IT and retail staff time. Basing the cost model solely on incremental costs, which would require other business activities to fund all common costs, cannot be a sustainable benchmark for a reasonably efficient competitor as it would preclude any competitor not willing or able to cross-subsidise entry to the market on the basis of profits derived from other businesses.
  
130. Healthcare at Home emphasised that winning the Genzyme contract in 1998 had involved a very substantial scaling up of its business and an increase in the costs incurred by the business as a whole. Initially, the Genzyme contract had quadrupled Healthcare at Home's turnover in relation to a complex homecare service for a small number of patients which required substantial management input. It is fanciful to suggest, as Genzyme submitted, that this did not require a step-change in common costs and that a reasonably efficient competitor would not need to recover similar costs to have a sustainable business. Healthcare at Home won the contract with Genzyme from an incumbent supplier by offering a lower price and on the basis of "open book" costings. Those costings had included the recovery of common costs and a profit element and Genzyme had signed the contract with Healthcare at Home on that basis.
  
131. As regards delivery costs, the OFT Supplementary Report had accepted that it is inappropriate to allocate delivery costs simply on the basis of the number of deliveries since delivery costs depend, inter alia, on the complexity of the total supply chain, which varies between products. Healthcare at Home submitted that the complexity of the supply chain for Cerezyme is not typical for a wide range of drugs as Cerezyme requires temperature-controlled warehousing, high security levels, insurance, and computerised inventory control and batch tracking; a complex pharmacy function for prescribing the drug and dosages; temperature controlled drug picking and packing;

and temperature controlled delivery to a small number of homecare customers (150 patients) widely distributed throughout the United Kingdom.

132. These various factors have been taken into account as objectively as possible in Healthcare at Home's complexity quotient analysis and other allocations suggested by Healthcare at Home which had been analysed, adjusted and benchmarked by the OFT in the time available to ensure that it is within broadly reasonable parameters.

133. As regards nursing costs Healthcare at Home submitted that the OFT's estimate of [...] [C] to [...] [C] full-time equivalent nurses fails to take sufficient account of the operational flexibility that has to be budgeted for in order to provide a safe Cerezyme nursing service. Healthcare at Home submitted that Genzyme Homecare had itself considered that it would require 8.4 full-time equivalent nurses which would be "sufficient to provide an effective support service for all Gaucher patients, their families and healthcare providers" (see Dixon Wilson Report, paragraph 8.7). The OFT has been unable to reconcile Genzyme's estimations with its own calculations. Healthcare at Home submitted the reasons for this are:

(a) Gaucher nursing visits, lasting for some [...] [C] hours, take longer than the average nurse visit. Neither Healthcare at Home nor the OFT have ever studied or observed the average number of Gaucher visits made per day. Nevertheless, it is clear as a matter of arithmetic that any over-estimate of the number of nurse visits per day has dramatic consequences for the final estimate. Healthcare at Home did not consider that the OFT's adjustment of half a nurse to reflect that risk is sufficient.

(b) The OFT failed to take account of the overall Gaucher nursing capacity and flexibility that is required and has to be budgeted for to cope with the overall provision of reasonably local access to a safe national service. There is a degree of flexibility that has to be estimated as a matter of safe practice and built into the Gaucher nursing resource which is difficult to assess. In those circumstances the OFT ought to have placed more weight on Genzyme Homecare's original assessment

of how many full-time equivalent nurses it would need to take responsibility for patient care safely.

- (c) Healthcare at Home's specialist nursing resource is larger and carries greater scope for efficiencies than its competitors. Whilst this was acknowledged by the OFT no adjustment was made to the resulting figures. In particular the OFT's figures are produced on the basis of [...] full-time nurses which serve Gaucher patients out of a total of [...] full-time equivalent nurses employed by Healthcare at Home and on the basis of Healthcare at Home serving a high proportion of Gaucher patients. Any calculation of nursing efficiency is critically dependent upon the size of geographical area served by the nurses and the service levels provided and Healthcare at Home's nurses will have considerably lower drive times than any other actual or potential competitor due to its larger network. Healthcare at Home submitted that fewer than [...] Gaucher-trained nurses simply could not cover the entire country adequately or provide a proper level of service (including emergency call outs, sickness cover etc.) Therefore, a reasonably efficient competitor could not operate using the number of full-time equivalent nurses indicated by the OFT.

134. Healthcare at Home submitted, with regard to the profit element, that it is important to appreciate that Cerezyme is a disproportionately demanding product in terms of the management resources and focus of the company with this being reflected by the allocation of directors' time and the complexity quotient analysis. Moreover, in service industries return on capital employed (ROCE) is not regarded as a meaningful profitability measure. In such circumstances Healthcare at Home considers it wholly reasonable that the profit figure is linked to the turnover of the product.

135. Healthcare at Home objected to the OFT's decision in the Supplementary Report to reduce the net profit margin identified in the first OFT Costs Report. Healthcare at Home submitted that this late but extremely significant reduction made by the OFT was flawed as:

- (a) The figure of [...] per cent used by the OFT in the Supplementary Report as a “lower level” is based on a level suggested by [...]’s approach. The “upper level” is based on [...]’s approach. However, no significant weight should be given to these assessments when it is quite clear that both companies failed to appreciate important characteristics of the project under consideration. This is evident from the fact that both companies prepared their estimates on the basis of using agency nurses when it is clear that this would be totally unacceptable to hospitals (see the evidence of Mr Farrell).
  
- (b) The OFT’s reasons for rejecting Healthcare at Home’s minimum margin of [...] per cent in the Supplementary Report are flawed as it is derived from information in a short telephone call with Healthcare at Home’s Finance Director, Mr Graham White. Healthcare at Home had provided evidence to the OFT in the form of a five year business plan and a minuted statement to the Board of Healthcare at Home by the Chief Executive that the Board of Healthcare at Home will ensure that the company achieves at least a minimum net margin of [...] per cent.

136. Although the OFT had concluded that genuine risks do result from holding high value drugs, and that such risks vary with the value of the drugs being handled, it is difficult to understand the subsequent claim made by the OFT in the Supplementary Report that the Cerezyme margin might be disproportionately high. Healthcare at Home submitted that in the light of the evidence its [...] per cent minimum profit figure should be restored.

137. Healthcare at Home submitted that Genzyme’s experts had persisted with their own controversial methodology to find a means to cost the total margin for Cerezyme homecare at between 1 and 2 per cent. Healthcare at Home adopted the criticisms of the OFT of the approach of Professors Appleyard and Yarrow. Healthcare at Home agreed with the OFT that allocation of costs on the basis of directly avoidable resource is inappropriate in this case. Healthcare at Home further submitted that, with regard to the evidence of Charles Walsh prepared for the various interim measures

and interim relief proceedings in this case, that evidence had been prepared upon the identification of directly avoidable resource (i.e. the minimum number of full-time equivalent nurses (assuming perfect efficiencies) that could be sacked if interim relief were not granted. Healthcare at Home had adopted an appropriate and conservative estimate at that time in order to assist the OFT and the Tribunal at the interim measures stage, but this was not the appropriate basis for examining the question of remedy following judgment on the merits of Genzyme's appeal.

138. Healthcare at Home also submitted that there are glaring inconsistencies between the estimates of Professors Yarrow and Appleyard of Cerezyme homecare (less than 6 pence or between 1 per cent and 2 per cent of the Cerezyme list price) with the estimates that Genzyme had itself previously made or commissioned. Healthcare at Home drew the attention of the Tribunal to the following previous estimates by Genzyme of the costs of Cerezyme homecare submitted in evidence before the Tribunal:

- (a) Williams: 18.7 pence or 6.2 per cent;
- (b) Dixon Wilson Report: 29.5 pence or 9.9 per cent
- (c) Genzyme's submissions to Department of Health in 1999: 34 pence or 11 per cent; and
- (d) Genzyme's proposal in November 2000: 21.8 pence or between 6 and 7 per cent.

139. Healthcare at Home submitted that the Tribunal should give particular weight as a reliable benchmark to the initial tender price agreed with Genzyme Limited in 1998 (equating to 11 per cent) as Healthcare at Home submitted that this figure is a reliable guide to a competitive price determined in the market. Healthcare at Home emphasised that the Tribunal should be mindful not to set the level of discount at such a low level as to facilitate market foreclosure. Healthcare at Home submitted that evidence of margins actually achieved in the market is of particular importance in this case.

140. Healthcare at Home also noted that there may be difficulties relating to unbundling the price of Homecare Services from the price of Cerezyme. In particular the potential effects in terms of patient disruption and the possibility of introducing an element of “post code prescribing” as regards Homecare Services are unclear at this stage and the Tribunal should proceed with caution. There are practical difficulties within the NHS in regarding any drug price as something other than a “delivered price” because of the way in which the NHS operates. An unbundled price would be a unique situation in the NHS.

## **VI DISCLOSURE APPLICATION**

141. On 6 October 2004 Genzyme applied to the Tribunal for specific disclosure of certain documents which Genzyme submitted are essential to enable Genzyme properly to exercise its rights of defence. Genzyme submitted that it had repeatedly requested and been denied access to documents upon which the OFT and Healthcare at Home base their case and had first sought specific disclosure at a case management conference on 21 July 2004. Genzyme submitted that the sums at stake are substantial and the difference between the figures put forward by Genzyme’s experts (2 per cent) and Healthcare at Home (11 per cent) would equate to a loss in revenue for Genzyme of approximately £1.9 million per annum. It is inconceivable that an order could be made by the Tribunal in respect of such a sum without Genzyme being able to test the evidence upon which such an Order would be made.

142. Genzyme submitted that its application is limited to those documents which are most directly relevant and was proportionate. In particular Genzyme submitted that the documents are required in order that Genzyme and the Tribunal are able to obtain a proper picture on the market rates for deliveries and to test the evidence on which the OFT relies in reaching its conclusions in its reports. Professors Appleyard and Yarrow, Genzyme’s experts, need to see these documents in order to complete their reports to the Tribunal and there is no reason why the documents should not be disclosed subject to a confidentiality order.

143. Documents sought from the OFT: Genzyme sought documents from the OFT relating to information that Healthcare at Home had provided the OFT concerning its costs and prices for delivery and nursing and to the comparison between haemophilia and Cerezyme treatments. Genzyme submitted that a crucial point of dispute for the purposes of resolving the remedy in this case is whether haemophilia treatment is broadly comparable with Cerezyme and so would not be expected to be less expensive (as had been submitted by the OFT).
144. Documents sought from Healthcare at Home: Genzyme sought documents relating to tenders believed to have been made by Healthcare at Home and contracts awarded to Healthcare at Home which are known to have been put out to competitive tender through publication in the Official Journal of the European Communities. These tenders and contracts in Genzyme's submission, are in respect of "comparable" cold chain delivery of drugs to patients at home. These documents will show, in Genzyme's submission, the actual market price which Healthcare at Home is offering to supply homecare and/or delivery in those contexts. If that evidence were to be supplied, the Tribunal would not need to engage in an exercise of establishing a proxy for a market price as this would be evidenced in the tender documentation. Genzyme also sought contracts relating to Healthcare at Home's deliveries for other drugs mentioned in the Supplementary Report. As the OFT relied on information concerning those contracts it is plain that Genzyme and the Tribunal must be entitled to see all underlying documents relevant to them.

## **VII THE HEARING ON 13 OCTOBER 2004**

145. A hearing was held on 13 October 2004 to consider the parties' submissions as regards remedy outlined above. At the start of that hearing counsel for Genzyme handed up to the Tribunal a draft document entitled "Genzyme, Commitment on Unbundling". The document had not previously been handed to counsel for the OFT or for Healthcare at Home and neither party was aware that Genzyme intended to hand in such a document at the hearing. According to that document Genzyme had taken a decision to offer an unbundled price for Cerezyme which reflected the desire of the Department of Health and the NHS purchasing bodies for transparency in the supply of drugs and for hospitals to be able to invite tenders or enter into contracts for

delivery and nursing. Genzyme offered to undertake full consultation with the Department of Health and the NHS regarding its proposal to unbundle the price of Cerezyme and homecare. That consultation would be done in conjunction with new arrangements for the PPRS. A crucial consideration would be that the NHS does not have to pay more overall than under the present arrangements.

146. According to Genzyme's draft unbundling commitment, Genzyme had had the benefit of the work of Professors Appleyard and Yarrow and further evidence had now been put before the Tribunal. Genzyme was confident that if the OFT had had the evidence which was now before the Tribunal available to it then the OFT Report would have produced a margin figure close or equal to that suggested by Professors Appleyard and Yarrow. Genzyme submitted that it is incumbent on any person challenging Genzyme's understanding of current market prices to produce clear and cogent evidence to the OFT. Over and above the cost price suggested by Professors Appleyard and Yarrow, Genzyme proposed to offer a "safety net" to allow for changes in circumstances and avoid further disputes. The precise level of the safety net would be a matter of appreciation for Genzyme but Genzyme would ensure that in broad terms it would take the margin figure somewhere above the level of the Professors' figures and closer to that of the OFT. Genzyme requested that it be given six weeks in which to implement the commitment offered and to complete the considerable amount of discussion that would be necessary with the relevant health service bodies. Genzyme offered, once it had arrived at a price, to report the new price and its justification to the OFT and to Healthcare at Home by the end of November 2004. The OFT and Healthcare at Home should then be given three weeks to respond with full justification for any dispute of Genzyme's figures backed up with full documentation. If there was agreement between the parties as to Genzyme's proposal then it would not be necessary for Genzyme to make further disclosure applications. However, if there were not full agreement then that would certainly give rise to factual disputes which could only be resolved if further disclosure were given. Counsel for Genzyme took the Tribunal through the note at the outset of the hearing.

147. Upon further questioning from the Tribunal it became clear that Genzyme proposed to abandon the present hospital price, and that the proposed "unbundled price" would be offered to Genzyme Homecare on arms' length terms with no cross-subsidy.

Genzyme had not had the opportunity to have any preliminary discussions with the Department of Health or the NHS concerning its proposals. In discussion with the Tribunal, counsel for Genzyme accepted that at least a transitional arrangement would need to be put in place. Genzyme could not state what the unbundled price would be as the “safety net” element had not yet been worked out.

148. Having heard initial observations from counsel for the OFT and for Healthcare at Home on the proposal that had been read out for the first time by counsel for Genzyme, the Tribunal noted that the unbundling proposal had come somewhat late in the day. Insofar as further negotiations might take place to resolve the matter the Tribunal welcomed any realistic and constructive suggestion. However, in the first instance in the Tribunal’s view it was for Genzyme to satisfy the OFT as to the soundness and reasonableness of any proposals that it put forward. The various individuals in the Department of Health were not, by this stage in the proceedings, necessarily as fully familiar with the detailed issues and arguments in this case as the OFT is. Therefore in the Tribunal’s view it was desirable that any further negotiations that were to take place at that late stage should take place under the auspices of the OFT and the OFT should be associated with and desirably present at any particular meetings so as to avoid misunderstandings occurring as matters progressed.
149. In the time available to the Tribunal at the hearing on 13 October 2004 the Tribunal proposed to raise certain points on the evidence that had been submitted to the Tribunal to date so as to give the parties the opportunity to comment on those points and to indicate the Tribunal’s thinking. The Tribunal noted that it now had a wealth of material before it from a large number of quarters that would enable the Tribunal to decide the remedy in this case.
150. The Tribunal noted that it seemed to it, at that stage, that there are four different approaches to the evidence before the Tribunal in the papers that had been submitted to it from the various parties. The approaches are not necessarily mutually contradictory and to some extent they overlapped. The first approach could be described as a “reverse engineering approach”, to build up a picture of the costs of providing the service, to add a profit margin and to arrive at a figure. That approach involves, among other things, various questions of cost allocation and taking a view

on what is the right way to look at the calculation of a reasonable profit margin in this particular business.

151. A second approach is to examine hypothetical tenders for Gaucher homecare services provided by other providers. That involved looking at the evidence provided to the OFT by Clinovia and Central Homecare as to what price they would charge and how they would calculate that price if submitting a tender for this particular service. That approach had the feature that it relates specifically to Homecare Services for Cerezyme patients but the further feature that it is by definition a hypothetical exercise prepared at short notice by competitors with little recent experience of providing the service.
152. A third approach is to look for comparators, for actual market prices for similar kinds of services. That approach raises as a first question what a suitable comparator is or might be. The Tribunal noted that in this case the Tribunal had had a great deal of evidence and explanation of the care of Gaucher patients and the Gaucher homecare service. Genzyme raised the possibility that other treatments may be suitable comparators, including haemophilia, thalassaemia, HIV, and other diseases. Determining the possible differences between each of those diseases, how they are coped with, the nursing services required, the numbers of patients involved and so forth seemed to the Tribunal at this stage to be a complex exercise. In addition, having identified certain possible comparators, if any, it would still be necessary to determine the implications of relevant differences, such as the number of deliveries required, the frequency of nursing visits and the quality of nursing assistance required. Although that approach appeared to be favoured by Genzyme, the Tribunal noted that it was a particularly complicated approach.
153. A fourth way of looking at the issue is to examine the wealth of historical information already on the Tribunal's file relating to typical costs and margins. Those included the original contract between Genzyme and Healthcare at Home, the figures provided by Genzyme to the Department of Health in 1999, the Genzyme Business Plan from 2000, the Dixon Wilson Report prepared for Genzyme and the evidence of Mr Williams in the main proceedings. Genzyme had invited the Tribunal to reject that historical evidence.

154. With those approaches in mind the Tribunal raised certain issues with the parties from the evidence before it including:

- (a) The approach to cost allocation in this case (avoidable costs or fully distributed costs);
- (b) The approach to the calculation of a profit margin in a business such as this;
- (c) What weight to give to the evidence of Clinovia and Central Homecare?
- (d) Should the Tribunal disregard the historical evidence submitted to it?

155. The Tribunal noted that the OFT Costs Report stated that the OFT did not consider it appropriate to consider only the avoidable costs of providing the Gaucher homecare service and that theme was continued in the Supplementary Report where there was a dispute as to whether various overheads are fully allocated or not. On behalf of Genzyme, Professor Yarrow submitted that this was an important conceptual issue. Fully distributed costs depended on arbitrary accounting conventions and they are not linked to economic decisions. At a practical level, in terms of numbers however, it made little practical difference because it is right to take a long-run approach to costs in this case because it is appropriate to consider whether an efficient competitor can survive over a longer term, and in the long run most costs do tend to fall into the category of avoidable costs. There is a difference of opinion between Genzyme and the OFT concerning directors' costs but it boiled down to very small numbers that should not stand in the way of progress. Both Professor Yarrow and Professor Appleyard agreed that in practical terms for the purposes of the numbers to be used in the cost calculations in this case the issue as to whether "avoidable costs" or "fully distributed costs" should be used to calculate the costs of the homecare fades away.

156. The OFT submitted that it accepted that Professor Yarrow (but not Professor Appleyard) had adopted an allocation of costs, albeit one that was insufficiently

generous. Initially, directors' costs had been left out of the equation altogether and there was still a dispute about quantum between the OFT and Professor Yarrow. On other issues there were disputes as to whether to treat certain items as an average, based on delivery numbers, or whether one needed to have some form of weighting to reflect the complexities involved in Homecare Services, but in principle there was not now a major difference between the OFT and Professor Yarrow as to whether costs are fully allocated.

157. With regard to the complexity of the Gaucher service, Professor Yarrow submitted that having looked at various drugs it seemed to him that Cerezyme delivery and nursing is a simpler service than some and more complex than others. What he had done is to say that those are quite detailed issues, noting that this is a “tiny business” and there are swings and roundabouts as one goes through all the various categories. If one looks at the market a tremendous variation in charges for homecare is observed. The OFT provided a table in the Supplementary Report which showed a variation of about 28 times between the highest and lowest charges. One could see immediately that price discrimination existed in the market which indicated a lack of competition. Furthermore there did not appear to be a direct relationship between the level of charges and whether the contract was for cold-chain delivery or not. If Gaucher homecare moved to a tender system on the basis of an unbundled price then the prices would tend to converge. If one looks at the numbers and at the market evidence for tenders one would see a great deal of convergence. The prices would not be identical as each tender would have slightly different conditions and specifications but there would be a tremendous amount of convergence within a range. This would suggest that although complexity factors almost certainly exist, they are not substantial.
158. Professor Appleyard submitted that from his understanding of the business he had been happy to regard the exercise of determining the costs of homecare service as an accounting exercise as not complex and remained to be convinced by other information in order to change that view.
159. Professor Yarrow also submitted that it also had to be borne in mind that, in relation to pharmaceuticals in general, the market is distorted by the operation of the value added tax system which is a major influence on the way the market has developed

over the past ten years. There is also a Byzantine regulatory system with all sorts of complexities and oddities and there is the complexity of the NHS itself which is one of the largest public service organisations in the world. This is a market which throws up all sorts of odd prices and to unravel this and understand each one would be a very difficult exercise. The market is also very non-transparent. There are no empirical studies and there is a great tendency to keep things secret.

160. Professor Yarrow also suggested that both he and Professor Appleyard had produced a relatively simple accounting exercise. That needed to be cross-checked against the market evidence. Hypothetical exercises, such as those produced by Clinovia and Central Homecare are always inferior. As regards the specific tenders in this case the questions that had been asked of Clinovia and Central Homecare by the OFT were unclear. It was a relatively informal exercise with very little standardisation.
161. In response to the above submissions of Professor Yarrow the OFT submitted that there was essentially a factual issue of appraisal as to the complexity of the Gaucher service between Professor Yarrow and the OFT. Professor Yarrow agreed that Cerezyme delivery and nursing is simpler than some and less simple than others. The OFT had calculated that if no complexity quotient were taken into account at all that would reduce the relevant discount by approximately 1 per cent.
162. The OFT disputed Professor Yarrow's submission that under competitive conditions one would see a great deal of convergence in the rates that are charged for homecare across different markets. First, the OFT had not seen a wealth of evidence which would support that submission. There were traces of evidence, some relating to haemophilia and some remarks by Mrs Patey of Great Ormond Street Hospital which were pitched in general terms. The OFT considered that the specification of the particular service is critical in each case. For example, one of the features that distinguishes haemophilia from Cerezyme is that the haemophilia patients are trained in the hospital and sent home for the homecare service when they are very stable. The homecare operation is therefore very much more straightforward, in the OFT's appreciation, than is the case for Cerezyme. For Cerezyme homecare, after a number of infusions in hospital and while the patient remains somewhat "raw and untrained" they are passed over to the homecare operation. This, in particular, meant that the

level of nursing but also the type of delivery service were different as between haemophilia and Cerezyme. The delivery service for Cerezyme involved a greater amount of customer care, liaison and elements of that kind and is generally more demanding. It would be profoundly wrong to regard the delivery element of Homecare Services as simply a delivery operation because of the importance of the customer service and logistics elements. In the OFT's submission it is very difficult for the Tribunal to go into great detail as regards those types of difference between the various treatments, but they do exist. The OFT for its part accepted the evidence of Healthcare at Home as provider of these different types of services as to this.

163. Although the OFT submitted that it is not practical for the Tribunal to go into great detail as to the differences between different types of treatment at this stage, the OFT stated that to equate the price that is seen in a haemophilia contract at a certain level with that in another service, as Professor Yarrow had done, and say that what one can see is that "competition" viewed in general terms boils it all down to a similar number or range is profoundly misconceived.
164. The OFT submitted that some weight should be attached to the hypothetical tenders prepared by Clinovia and Central Homecare because in preparing the tenders they were competitors who had addressed their minds to the particular demands of the particular service with which the Tribunal is concerned. The OFT was satisfied that in the time available, and taken together with other material, there was sufficient information before the Tribunal to calculate the remedy in this case and that in that context it is appropriate to take account of those hypothetical tenders.
165. Professor Yarrow submitted that it was true that if Genzyme Homecare remained a specialist homecare provider specialising only on one small area it would be at a cost disadvantage because of a failure to obtain economic density because of the small number of patients. Professor Yarrow also submitted that it is key to separately identify the homecare element and to unbundle that from the price of the drug. The bundling of things to drug prices generally in health markets had cost the taxpayer a lot of money over the years in his submission.

166. In Professor Yarrow's view the historical information is less compelling as that information relates to a different set of circumstances and market conditions. The NHS is developing and, in particular with regard to the 1998 information, that applies to very dissimilar circumstances. Professor Yarrow accepted that that criticism is less strong with regard to the later evidence. In Professor Yarrow's view unit costs had been falling with regard to Homecare Services. In his view the price agreed between Genzyme and Healthcare at Home in 1998 was excessive in relation to costs at that time, and costs have fallen since then.
167. The Tribunal noted that the implication of Professor Yarrow's views outlined above, was that the evidence submitted by Genzyme to the Department of Health in 1999 and which formed part of the evidence before the Tribunal in the main proceedings, was misleading. It also suggested that the Dixon Wilson Report before the Tribunal was misleading. Professor Yarrow's response to that was that "misleading" is a strong word but that some information submitted certainly represented "blatant cost padding". Professor Appleyard submitted that times have changed and the costs calculations in the Dixon Wilson Report probably do not represent cost causation and are therefore unreliable. In Professor Appleyard's view the Dixon Wilson Report should be "parked on one side" and no account should be taken of it.
168. The OFT submitted, with regard to the profit element, that Professors Yarrow and Appleyard have reached a very low figure for the profit element in their calculations because they have made no provision for "intangible" capital. Professor Appleyard essentially looked at working capital and fixed assets and applied a very low rate based on the rate used for working capital. Professor Yarrow on the other hand applied a rate used for a quite different purpose under the PPRS and, in the OFT's submission, his calculation in that regard is essentially arbitrary. The OFT submitted that neither the approach of Professor Appleyard nor the approach of Professor Yarrow was satisfactory. Professor Appleyard told the Tribunal that he did consider that there would be intangibles in terms of staffing, but that this would not amount to much. The balance sheet was therefore a good representation of the business. As for "reputation" that, in his view, was a red herring. All firms in business are interested in reputation. Although Healthcare at Home's competitor Clinovia was sold for 13 times its fixed assets that did not alter his view. In particular Professor Appleyard

noted that Clinovia's accounts had been qualified and so that was not a reliable piece of evidence. The OFT pointed out, in that regard, that it had relied on Clinovia's balance sheet and that had not been qualified. The OFT did not accept that Professor Appleyard made a valid criticism with regard to the position of intangibles.

169. The OFT submitted that it was a curious feature of this case that Genzyme has been found to have "bundled" the price of Homecare Services with the price of Cerezyme at the "pre-competitive" price but Genzyme now submits that any "unbundled" price should be calculated as if the market were already competitive. If the submissions of Genzyme's experts were to be approved that would lead to the perverse and unfortunate result, in the OFT's submission, of Genzyme having "bundled-in" the price of Homecare Services at a relatively high margin but "bundled-out" the price of Homecare Services at a low margin. In the OFT's submission that demonstrated the essentially self-serving nature of the arguments that were now being put forward before the Tribunal by Genzyme.
170. The OFT submitted that Professor Yarrow's submissions regarding price discrimination were unclear. In the first place he did not seek to suggest that Healthcare at Home was itself in a dominant position and it is essentially only where a provider is in a dominant position that price discrimination is regarded as a problem in competition law. Further, there may well be justifications for the different prices for different homecare services for other drugs related to the nature of the service provided in each case.
171. As regards the historical information before the Tribunal and the submissions that that should be "parked", the OFT emphasised to the Tribunal that it considers that that information is of some value. In particular even if the criticisms of the 1998 information were to be accepted, in the OFT's submission the information related to the re-negotiation between Genzyme and Healthcare at Home in 2000 is a good indicator of what the market price for the margin needed to perform the Cerezyme Homecare service was at that time. The margin at that time was approximately 9.5 per cent. It is very difficult to suggest that Genzyme were in a "weak negotiating position" as they now sought to do as they were clearly able to extract a significant concession and price reduction from Healthcare at Home at that time in the context of

the new PPRS which reduced the list price for the drug. Further weight should be given to that evidence as it is consistent with the information provided to the OFT by Clinovia and Central Homecare and also in Genzyme Homecare's own business plan. The OFT emphasised that the figures now being put forward by the OFT as a suitable margin are actually lower than the figure negotiated and accepted by Genzyme in 2000. Therefore the historical market evidence, particularly the 2000 figure should be treated as quite strong confirmation that the general approach of the OFT to the question of the margin in this case is in the correct range and that the correct figure is at the higher end of the range identified by the OFT.

### **VIII THE FEBRUARY 2005 PROGRESS REPORT**

172. On 8 February 2005 the OFT submitted a "Report to the Tribunal on progress since 13 October 2004" (the "February 2005 Progress Report"). The main points arising from the February 2005 Progress Report are summarised below.

#### *Matters raised in the February 2005 Progress Report*

173. Following the hearing on 13 October 2004 Genzyme had set up meetings with the OFT, Department of Health and the relevant homecare providers (Healthcare at Home, Clinovia and Central Homecare), pharmacists from the Royal Free, Addenbrooke's and Great Ormond Street. Those meetings took place on 11 and 12 November 2004 and were chaired by the OFT.

174. The main matters arising from those meetings were as follows:

- (a) neither the pharmacists nor the Department of Health envisaged any problem with a mechanism whereby Genzyme unbundled the NHS list price of Cerezyme and Homecare Services were subject to separate negotiation;
- (b) the Department of Health would continue with a list price irrespective of FP10 usage, not least since pharmacists wish to see an NHS list price;

- (c) the pharmacists wanted to know the cost of the drug and anticipated putting Cerezyme homecare out to tender once Cerezyme was available at a drug-only price;
- (d) there was a consensus that transparency of Genzyme's pricing is essential;
- (e) the PPRS does not require modulation of the hospital price but any modulation should be cost neutral for the NHS;
- (f) Healthcare at Home was concerned that it would be much harder to achieve funding for homecare if the NHS list price of Cerezyme was unbundled since PCTs would need to be persuaded to provide funding over and above the costs of the drug;
- (g) The pharmacists had expressed concern over funding for Homecare Services if the list price were to be unbundled. However, this concern is lessened by the fact that NSCAG will be responsible for funding the treatment of lysosomal storage disorders from April 2005 and this will include the funding of Homecare Services;
- (h) Unbundling the price of Cerezyme from the price of Homecare Services fits with the general aim of unbundling homecare which London NHS hospital trusts are seeking to achieve.

175. Further meetings then took place between the OFT and Genzyme on 13 December 2004 and 19 January 2005 and various further submissions were made.

176. The OFT considered that no new evidence had been obtained as to the costs of Homecare Services. Therefore the OFT had no reason to change its view expressed in the Supplementary Report that the discount required to remove the margin squeeze abuse in this case is at the top of the range of 5.1 per cent to 7.3 per cent of the 2004 list price of £2.975.

177. The OFT noted its view that the lowering of the NHS list price for Cerezyme as a result of the 2005 PPRS changes the range of appropriate discount in this case from that identified in the Supplementary Report. The OFT noted that many of the cost items that had been identified in its reports are not a percentage of the drug price but an absolute amount of money and, as a result of the reduction of the list price, those items represent a bigger percentage of the list price than previously. Therefore, the OFT's view is that as a result of the reduction of the list price, the range of an adequate margin for Homecare Services providers is 5.3 per cent to 7.7 per cent. The OFT took the view that an adequate margin is likely to be at the top end of the range.
178. According to the February 2005 Progress Report, Healthcare at Home submitted that the OFT had calculated an overly conservative minimum viable margin. The OFT should take into account that the negotiating process following the hearing on 13 October 2004 allowed Genzyme to influence the views of the pharmacists who now expect to pay very little for homecare for Gaucher patients. Healthcare at Home submitted that restricting the discount to the minimum viable margin would allow no room for competition to emerge and any discount below historical levels effectively allowed Genzyme to increase the price of Cerezyme rather than giving this benefit to the NHS. Healthcare at Home's view is that the most appropriate remedy is to retain a bundled NHS list price, which would protect funding and allow prescribing of Homecare Services on FP10s, and to require Genzyme to offer Cerezyme to all providers of Homecare Services at a 12.5 per cent discount from the bundled NHS list price.
179. In the February 2005 Progress Report, the OFT states that, contrary to Genzyme's earlier proposal to unbundle the price of Cerezyme from Homecare Services, Genzyme now proposes to offer a bulk pharmacy price for Cerezyme in addition to a bundled NHS list price. The OFT submits that, given the commitment offered to the Tribunal at the hearing on 13 October 2004 and the painstaking consultation process that took place under the auspices of the OFT, this change of position by Genzyme appears to mean that relatively little was achieved by the period of negotiation since October 2004. However, the OFT does not consider unbundling to be an essential part of the remedy in this case. What is required, in the OFT's view, is a transparent

drug-only price at which pharmacists can buy the drug independently of the provision of homecare. Whether this drug-only price is the NHS list price for Cerezyme or a bulk pharmacy price makes little difference in practice, in the OFT's view. However, it is clear to the OFT from its meetings with interested parties that there is a preference for unbundling. The main advantages of maintaining a bundled price would be that it allows the continued use of FP10s to cover homecare should pharmacists wish to do so, and it makes it easier to negotiate funding for homecare because it is not seen as representing an "additional" payment over and above the cost of the drug.

180. The OFT noted that all the hospital pharmacists it had consulted expressed a desire to enter into contracts for Homecare Services which will mean abandoning the use of FP10s for prescribing Cerezyme. The funding issue may also be of less concern as lysosomal storage disorders will in future be funded nationally by NSCAG rather than PCTs. Julia Stallibrass of NSCAG had expressed a preference to the OFT for unbundling.
181. Given the preference of hospital pharmacists for unbundling, the OFT believes that an unbundling remedy would be preferable to an ex-manufacturer price. This would also avoid any future complications arising from PPRS price reductions since these would apply simply to the unbundled price. However, the OFT stated that an ex-manufacturer price remedy would, in its view, be equally effective in allowing the emergence of competition for Homecare Services.
182. In response to Healthcare at Home's concerns, outlined above, the OFT stated that it agreed that the required margin needed to be viewed in the context of the historical figures although, unlike Healthcare at Home, the OFT does not consider the historical figures to be determinative of the appropriate margin now.
183. The OFT does not accept that the discount from the NHS list price should be set in excess of the OFT's suggested margin in order to open up the market to competition. If there was absolute certainty as to the required margin, then such an approach would be wrong in principle in the OFT's view because it would be going further than required to remove the margin squeeze. However, for the reasons set out in the OFT

Report and Supplementary Report there is not precise certainty as to the required level of margin in this case, and therefore the OFT has estimated a range. The OFT also takes the view that erring on the side of over-compensation would be preferable in this case to under compensation because the latter would risk a continuation of the abuse whereas competition will result in any over-compensation being competed away. The top end of the OFT's range takes full account of Healthcare at Home's complexity quotient and allows for [...] full-time equivalent nurses allocated to Homecare Services. It also accepts Healthcare at Home's allocations for sales resource, quality assurance and directors' time and applies a profit margin based on the value of the drug. The top end of the OFT's range therefore applies a number of assumptions that, in the OFT's view, are favourable to Healthcare at Home.

184. The OFT does not accept Healthcare at Home's view that transitional restrictions setting minimum homecare prices are required because of the expectations that Genzyme has created as to "the right price" for Homecare Services for Cerezyme patients. The OFT does not consider that Healthcare at Home's concerns justify artificial constraints on pricing and has particular concerns about restricting the pricing freedom of Healthcare at Home's potential competitors in the market for providing Homecare Services.
185. The OFT has some sympathy with Healthcare at Home's view that Genzyme should not be able to set an ex-manufacturer price which results in it effectively charging a higher price for Cerezyme than previously ("bundling out" at a higher price than it formerly "bundled in") but the OFT does not see that this is an essential part of a remedy intended to remove a margin squeeze. Any concern about Genzyme effectively imposing an unauthorised price increase is a matter for the PPRS.
186. With regard to the impact of the then intended closure of Genzyme Homecare, in the OFT's view there were three particular concerns:
  - (a) If Genzyme were simply to close Genzyme Homecare and then make no change to the price at which Cerezyme is sold to third party homecare services providers, this would result in the NHS having to pay an additional amount for such homecare services when previously

they were included in the bundled NHS list price. The NHS would in effect “pay twice” for Homecare Services. Similarly unless the level of discount from the bundled NHS list price offered to homecare services providers adequately reflects the costs of providing those services, then the NHS will have to pay an additional sum above the NHS list price if it wishes to obtain such services from independent suppliers. In either case it would be arguable, in the OFT’s view, that Genzyme’s selling price for Cerezyme in such circumstances would be an illegal excessive price and an abuse for the purposes of section 18 of the 1998 Act. The Tribunal has already expressed the view that the NHS should not have to pay more for the unbundled services offered by Genzyme than it does now for the bundled price.

- (b) In the OFT’s view it is difficult to see the relevance of a bundled NHS list price when there is also a discounted ex-manufacturer price/bulk pharmacy price unless Genzyme is leaving open the possibility of contracting with independent homecare services providers, as it did prior to 2001, and then offering an integrated service to the NHS at the bundled NHS list price. If and when Genzyme chose to take such a course the difference between the bundled NHS list price and the bulk pharmacy price will necessarily represent the margin available to independent homecare services providers to compete for the business. If the margin is insufficient, then exactly the same adverse effects on competition would then exist as resulted from the margin squeeze abuse identified in the Tribunal’s judgment. The possibility of a bundled NHS list price and the offer by Genzyme of a bundled service in conjunction with a third party homecare services provider in circumstances where there was no adequately discounted ex-manufacturer price for third party homecare services providers would continue the abuse, in the OFT’s view.
- (c) From the point of view of hospitals contracting with homecare services providers, the bundled NHS list price for Cerezyme will, in the OFT’s view, act as a strong signal of the appropriate cost of homecare

services and effectively represent the maximum that they will expect to pay for the drug plus homecare services. That can, in itself, be expected to result in continued harm to effective competition in the Homecare Services market as purchasers seek to ensure that homecare services are paid for out of the margin between the bulk pharmacy price and the bundled NHS list price.

187. The OFT noted that Genzyme remains committed to abolishing the hospital price and having a single price for Cerezyme whether it is being sold to a hospital pharmacy or the pharmacy of a homecare services provider. The OFT stated that there is no requirement for this course of action under the PPRS, even if Genzyme were to unbundle. Genzyme had not been able to provide specific details to the OFT as to how it intended the “modulation” of the hospital price to be calculated. In the OFT’s view since Genzyme’s hospital prices did not form part of the OFT’s decision or of the Tribunal’s judgment on liability, it is up to Genzyme what it does about the hospital price. Hospital pharmacists, although not enthusiastic about the removal of the hospital price, were not unduly concerned so long as this were done in a way so as to ensure that the NHS does not “lose out”. In those circumstances the OFT can see no objection to permitting Genzyme to modulate the hospital price in accordance with the rules of the PPRS.

188. The OFT considered that Genzyme’s then decision to close Genzyme Homecare did not remove the need for the Tribunal to rule on the amount of discount required, which was the hypothesis which the OFT was considering, to fund Homecare Services. Genzyme has accepted that the NHS should not be worse off as a result of the remedy and simply closing Genzyme Homecare without a corresponding reduction in the price of Cerezyme to reflect the fact that Homecare Services are no longer included in the price would result, in effect, in an unfair price requiring the NHS to pay for Homecare Services twice. The OFT respectfully submits that the Tribunal should now determine the relevant discount and, on the basis that Genzyme persists in its position that it will not be unbundling the NHS list price, make an order that Genzyme:

- (a) set a bulk pharmacy price that is below the NHS list price by the amount of the discount;
- (b) maintain this differential between the NHS list price and the bulk pharmacy price, following any future changes to the NHS list price of Cerezyme;
- (c) make Cerezyme available to hospitals and their chosen homecare providers at the bulk pharmacy price; and
- (d) ensure that modulation between the hospital and NHS list price is carried out in accordance with the requirements of the PPRS and is cost neutral to the NHS.

*Genzyme's submissions in response to the February 2005 Progress Report*

189. On 25 February 2005 Genzyme made further written submissions in response to the February 2005 Progress Report. Genzyme submitted that substantial progress had been made towards resolving the termination of the abuse found by the Tribunal in its judgment. Genzyme submitted that the closure of Genzyme Homecare by no later than 31 May 2005 and Genzyme's withdrawal from the downstream Homecare Services market would mean that there was no question of Genzyme committing any margin squeeze abuse after that date. It should be understood that Genzyme's withdrawal from downstream Homecare Services for Gaucher patients, either through self-provision or through a contract or contracts with third parties, is permanent.
190. Genzyme submitted that in consequence of the anticipated closure of Genzyme Homecare, it would be difficult to see that there is any basis for the Tribunal to make any further direction under the 1998 Act to eliminate any margin squeeze relating to the future supply of Cerezyme. Genzyme accepts that the Tribunal will wish to satisfy itself that any new price for Cerezyme will satisfy Genzyme's undertaking to the Tribunal through leading counsel on 13 October 2004 in the following terms:

“It is a crucial consideration that the net effect of [Genzyme’s] new unbundled price will not be negative for the NHS, that is to say that when account is taken of tendered and competitive homecare prices, the NHS will never have to pay more than is the case under present arrangements (i.e. not more than that payable under the bundled price of £2.975 pre unit). Indeed it will almost certainly pay less.”

191. Genzyme submitted that in order to comply with its undertaking to the Tribunal there had to be pricing transparency for the supply of Cerezyme and for Homecare Services. With pricing transparency the net effect of the new unbundled price can easily be ascertained by the NHS, which will have full information on what it pays for drugs and Homecare Services. Genzyme submitted that the optimum means of ensuring transparency is for Genzyme to offer Cerezyme for sale to pharmacies at an unbundled drug-only price.

192. As to Homecare Services, Genzyme submitted that such services will in the future be funded by NSCAG which will be responsible for tendering arrangements. Any excessive price for Homecare Services charges by providers of that service will soon be competed away as a result of competitive tendering.

193. Genzyme submitted that the only matters requiring determination by the Tribunal are:

- (a) Whether there would be any purpose served by the retention of a separate NHS List Price for Cerezyme; and
- (b) The precise level of price reduction required for Cerezyme.

194. As to the NHS List Price, Genzyme submits that the OFT and Genzyme are in agreement on the substance of that issue namely that there should be only one unbundled price for Cerezyme delivered to hospitals and homecare service providers (whether or not that price was formally called an “NHS List Price”). The only remaining issue is therefore whether the Tribunal is satisfied that a price reduction in Cerezyme of 6.5 per cent would lead to the NHS not being worse off overall. In Genzyme’s submissions if a price reduction of 6.5 per cent is offered the NHS will be better off, particularly when the transition to NSCAG funded homecare service provision is complete.

195. Genzyme submits that the Tribunal has already had extensive submissions on the appropriate cost of the provision of Homecare Services. Genzyme submitted that the single most significant piece of evidence, relating to a tender by Birmingham Children's Hospital which, in Genzyme's submission, could provide comprehensive evidence for the prices that are actually likely to be paid for the Homecare Services here in issue, has not been made available to the Tribunal. Genzyme reiterated its application for disclosure.
196. Genzyme submits that in the absence of direct evidence from tenders the Tribunal is left to draw on a range of other information before it. First, the expert evidence of Professors Yarrow and Appleyard is that the costs of the Cerezyme Homecare service is up to 6p per unit (or 2.4 per cent of the new list price of £2.767). Secondly, the OFT Report and Supplementary Report which suggest a range of 5.3 per cent to 7.7 per cent of the new list price.
197. Genzyme submits that there is no basis for the OFT's submission that the Tribunal should set the discount at the top end of the range identified by the OFT in the Supplementary Report.
198. Genzyme submitted that its decision to close Genzyme Homecare (at significant cost to Genzyme) was because it needs a margin of 5 per cent to 6 per cent to maintain the viability of Genzyme Homecare for the "Rolls Royce" service that it provides in the very small market in which it operates and that it does not believe that this margin is achievable in a competitive market.
199. Genzyme submits that it wishes to achieve finality in the sense that there will now be unbundling and the closure of Genzyme Homecare. It would be invidious, particularly in the absence of material evidence as to the actual prices charged for comparable services, if a figure were to be imposed on Genzyme Homecare in respect of the discount that is too high simply for safety's sake.
200. Genzyme submits that in order to give the Tribunal comfort that Genzyme will comply with its undertaking not to leave the NHS worse off, Genzyme will undertake

that if a review by NSCAG of the actual prices paid for Homecare Services on competitive tenders indicates that the 6.5 per cent it has offered is not sufficient to meet its undertaking to the NHS that it should not pay more for the separate drug and Homecare Services than it would have paid under the bundled NHS list price, Genzyme will reimburse the NHS accordingly in order to achieve this objective. Genzyme submits that this undertaking is most appropriately given to the Department of Health/NSCAG but the undertaking will be on the record of the Tribunal.

201. In relation to Healthcare at Home's submissions, Genzyme considers that those submissions are made simply for the purpose of denigrating Genzyme rather than furthering the issues before the Tribunal relating to the unbundling and appropriate price at which this should be done. Healthcare at Home's submissions merely repeat their previous submissions and Genzyme does not wish to cover old ground. With regard to Healthcare at Home's submission that the Tribunal should set a "floor price" for Homecare Services, Genzyme submits that this submission is self-serving and that such intervention would obviously be inappropriate.

*Healthcare at Home's submissions in response to the February 2005 Progress Report*

202. Healthcare at Home submits that there are advantages in maintaining an NHS List Price that may provide for Homecare Services in this case. In particular, Healthcare at Home submits that in contrast to a list price which contains no element for homecare services, maintaining the NHS list price will avoid unnecessary interference with the ability of practitioners to use FP10 prescriptions as and when appropriate or required.
203. Healthcare at Home submits that pharmacists, in particular Addenbrookes, had provided evidence that they would not wish to lose the flexibility of their consultants to use FP10s (even if in parallel with the NSCAG system). Healthcare at Home accepts that NSCAG envisages that patients who receive care through the specialist centres funded by NSCAG will not obtain prescriptions through FP10s but it does not follow, in Healthcare at Home's submission, that it will never be necessary in the future to use FP10s for Homecare Services, whether in the case of a consultant in a specialist hospital wishing to retain the flexibility to write FP10s or for prescriptions

written outside non-specialist hospitals. Healthcare at Home noted that in particular that the NSCAG arrangements will provide funding for two years but the regime, if any, to be implemented after that date has yet to be determined.

204. Healthcare at Home submitted that taking the delivery element out of the NHS List Price would take Cerezyme outside conventional principles applied in the NHS under the PPRS and would create a unique situation that would effectively dictate to the NHS that it is unable to use the FP10 prescription for this one drug. Prescribing physicians could not all be expected to be aware that their conventional freedom to prescribe by way of FP10 is curtailed in this one instance. Healthcare at Home also submits that GPs, patients and prescribing consultants, all of whom would be affected by any decision to remove the freedom to use FP10s in the future had not been consulted about the effects of such a remedy.
205. Healthcare at Home submits that, as the OFT recognised in the February 2005 Progress Report, it is not necessary to employ a remedy that interferes with FP10 prescriptions in this case and to do so would be both reckless and disproportionate.
206. Healthcare at Home submits that the approach adopted by the OFT to the amount of the discount it proposes is flawed. The central flaw in the OFT's approach is to subtract the minimum viable margin from the NHS List Price to arrive at the appropriate discount. That approach will restrict competition on price and quality as it would effectively impose an artificial and unprecedented price ceiling on the effective price for Homecare Services.
207. Such a remedy would not be effective and would distort price and quality competition for Homecare Services. Furthermore, the OFT's estimation of the minimum viable margin in this case is simply too low as the OFT continues to fail to take adequate consideration of the available historical evidence of the cost/price of the present level of homecare services and seeks to pre-empt the competitive process. The OFT's approach is also contrary to the "accepted proposition" that prudence requires that the margin should be set on the high side in conjunction with a remedy that will result in any excess remuneration being competed away. The OFT has adopted a methodological approach that is overly conservative, and focussed on Healthcare at

Home's costs rather than those of an ordinary provider, and places insufficient weight upon the overall evidence of the market price that could and should be demanded by a specialist company providing an expert service valued by clinicians and patients.

208. Healthcare at Home submits that if the OFT's approach is accepted it will harm and reduce the quality of Homecare Services currently provided to patients or require the NHS to pay more for homecare than it does presently. Healthcare at Home submits that the NHS List Price is not a market price but is better equated to the maximum price that the NHS is prepared to pay for the drug and the present level of Homecare Services. In those circumstances it is reasonable and proportionate for the Tribunal to have regard to the actual market price for both Homecare Services and the drug only with particular regard to the plethora of historical evidence and to set the ex-manufacturer price accordingly.
209. Healthcare at Home submits that the OFT's conclusion that it has no objection to Genzyme modulating the hospital price in accordance with the rules of the PPRS is premature. Healthcare at Home submits that any modulation that is to take place should not affect the overall cash margin as protected for homecare providers by any order of the Tribunal.
210. Healthcare at Home submits that for a temporary period (up to 12 months) the margin afforded to Homecare Services providers should be protected as exposing the market to open competition on a gradual basis would be prudent, given the product involved, the disruption caused by the proceedings before the OFT and the Tribunal and, in particular, the steps that Healthcare at Home alleges Genzyme has taken which Healthcare at Home submits destroy the perceived value of the service in the eyes of the purchasing market. Healthcare at Home submits that requiring the trusts to persist with a price capable of funding the current standard of Homecare as a safeguard measure merely means that for a limited period the trusts could not reduce the level of funding for homecare below that necessary to provide the current level of service. This would be a wholly prudent step to take particularly in the face of arguments made by Genzyme that the service has a negligible value.

211. Healthcare at Home submits that irrespective of whether the term “margin squeeze” is used or not Genzyme is still able to foreclose Healthcare at Home and/or other third party providers from the homecare market through the manipulation of its ex-manufacturer price for Cerezyme.

## **IX THE TRIBUNAL’S ANALYSIS**

### *Preliminary comments*

212. The margin squeeze abuse in this case began in May 2001. Subsequently, when the OFT intervened, Genzyme contested every aspect of the case, both in the proceedings before the OFT which led to the decision of 27 March 2003, and in the proceedings before the Tribunal, which led to the Tribunal’s judgment on the merits of 11 March 2004. When, following that judgment, the Tribunal adjourned the issue of remedy for six weeks to enable sensible negotiations to take place, we did not expect the turn of events which in fact transpired.

213. Instead of negotiating, Genzyme continued, for a long period, the adversarial posture which it has maintained throughout this case by instructing experts, who arrived at the conclusion that the margin needed by a reasonably efficient provider of Homecare Services to Gaucher patients could be accommodated by a discount of some 1 to 2 per cent of the then NHS list price. That conclusion was contrary to the historical evidence then before the Tribunal.

214. As a result of lengthy interchanges and submissions, the OFT then prepared its Costs Report of 23 July 2004, followed by its Supplementary Report of 13 September 2004, which were extensively commented on by Genzyme and Healthcare at Home. The Tribunal held case management conferences on 27 May 2004, 21 July 2004 and 17 September 2004. The Tribunal finally fixed a remedies hearing for 13 October 2004 on the basis that no negotiated solution was in sight, contrary to earlier assurances by Genzyme that a settlement could be anticipated.

215. At the hearing of 13 October 2004 Genzyme, while pursuing an application for disclosure against the OFT and Healthcare at Home, announced without prior warning

to the OFT that it proposed to “unbundle” the NHS list price so as to separate the Homecare Services element. Genzyme proposed that further negotiations should then take place with NHS representatives and hospital pharmacies as to the implementation of this proposal. At this stage Genzyme, through its experts, was strongly maintaining that an appropriate margin was some 1 to 2 per cent.

216. Negotiations and consultations on “unbundling” then took place up to the end of 2004. However, on 28 January 2005 Genzyme told the OFT that it did not, after all, propose to “unbundle”, but proposed instead to offer a discounted “bulk pharmacy” price. We share the OFT’s view that little, if anything, was achieved during the autumn of 2004 and early 2005, other than further delay.
217. Meanwhile, at a meeting with the OFT on 13 December 2004 Genzyme told the OFT that it proposed to close its homecare operations, on the basis that these operations needed a profit margin of at least some 5 to 6 per cent, which Genzyme did not think was achievable in competitive conditions.
218. That statement by Genzyme management to the effect that Genzyme needed a margin on Homecare Services of some 5 to 6 per cent is in our view inconsistent with Genzyme’s expert evidence that a margin of 1 to 2 per cent would suffice. Indeed Genzyme’s statement to the OFT in December 2004 was more consistent with other evidence that Genzyme had relied on earlier before the Tribunal, such as Genzyme’s internal proposal at the end of 2000, the Dixon Wilson Report and Mr Williams’ evidence, than with Genzyme’s more recent expert evidence.
219. With effect from the beginning of 2005, the NHS list price for Cerezyme was itself reduced by 7 per cent in the context of the PPRS negotiations affecting the pharmaceutical industry as a whole. On 19 January 2005 Genzyme made an offer to the OFT to reduce the new NHS list price of £2.767 by 6.5 per cent (18p per unit). It later transpired that that was the level at which Genzyme proposed to set the new “bulk pharmacy” price. In the OFT’s February 2005 Progress Report the OFT maintained that a discount was required off the new list price towards the top end of the range of 5.3 per cent to 7.7 per cent, as against Genzyme’s offer of 6.5 per cent. Although the gap between the parties has thus narrowed, it is regrettable in our view

that Genzyme was able to delay matters for so long after the Tribunal's judgment of 11 March 2004.

220. The OFT at that stage – February 2005 – was still under the impression that Genzyme proposed to close its Homecare Services operation. However, in March 2005 Genzyme informed the OFT that such was not the case, and that there was to be a management buy-out instead. This was originally to have been completed by the end of May 2005.
221. The Tribunal is informed that completion of the management buy-out took place on 8 July 2005, and that the former Homecare Services Division of Genzyme is now a new company, Careology Limited. We are told that, as from 1 July 2005, Genzyme has made supplies of Cerezyme available to Careology and Healthcare at Home at a discount of 6.5 per cent off the new NHS list price. It is said that Genzyme's dealings with Careology are at arm's length, and that that company will operate independently. Careology appears to be being run by the same operating management and from the same premises as it did when it was part of Genzyme.
222. Looking at the matter broadly, and despite some recent progress, this case has in general been characterised by determined opposition by Genzyme to the OFT's position. Genzyme's approach has, in our view, delayed the resolution of this case. Genzyme has also made a number of statements that turned out to be incorrect, e.g. to the effect that there were good prospects of a settlement in 2004, that the NHS list price was to be unbundled, and that Genzyme Homecare was to be closed, none of which transpired. We are also of the view that Genzyme's management must have known all along that, in commercial terms, Genzyme Homecare required a margin substantially above what its experts said was appropriate.
223. As we pointed out in our judgment on the merits, there is no doubt that both the patients represented through the Gaucher Association, and the hospital pharmacists, wished to see a choice of homecare providers and, in particular, the survival of Healthcare at Home. However, the whole thrust of Genzyme's position had the effect of making it as difficult as possible for Healthcare at Home to remain in the market, contrary to the wishes of many Gaucher sufferers and those who are responsible for

their care. See paragraphs 108 to 119, 254 and 555 to 558 of our judgment on the merits.

224. From March 2001 until the President's interim order of 6 May 2003, Healthcare at Home received no margin at all out of which to fund Homecare Services and remained in the market only in the hope that these proceedings would be favourably resolved. The interim margin ordered by the President in May 2003 was well below the margin of 5 to 6 per cent which Genzyme indicated to the OFT in December 2004 was the minimum commercial margin which it required, and well below the margin of 6.5 per cent which is the basis of the "bulk pharmacy" price that has apparently been offered by Genzyme since 1 July 2005. In these circumstances the effects of a serious infringement of the Chapter II prohibition in fact continued for over 4 years, since March 2001.

225. In all these circumstances we are in no doubt that a direction under section 33 of the Act is called for.

### *Jurisdiction*

226. Section 33 of the Act, as amended, provides:

"33. (1) If the OFT has made a decision that conduct infringes the Chapter II prohibition or that it infringes the prohibition in Article 82 it may give to such person or persons as it considers appropriate such directions as it considers appropriate to bring the infringement to an end.

...

(3) A direction under this section may, in particular, include provision-

(a) requiring the person concerned to modify the conduct in question; or

(b) requiring him to cease that conduct.

(4) A direction under this section must be given in writing.

227. Pursuant to paragraph 3(2) of Schedule 8 of the Act, the Tribunal has the same powers as the OFT. In particular under paragraphs (d) and (e) the Tribunal may “give such directions, or take such other steps, as the OFT could itself have given or taken” or “make any other decision which the OFT could itself have made”.
228. The OFT’s direction, which is currently suspended pursuant to the President’s order of 6 May 2003, is set out at paragraph 5 above. It is common ground that that direction now requires modification.
229. All parties invite the Tribunal to issue a ruling on an appropriate remedy in this case and no party has submitted that these proceedings have become devoid of purpose. Genzyme in particular accepts that that the Tribunal should determine: (a) whether there is any purpose served by the retention of a separate NHS list price for Cerezyme; and (b) the precise level of reduction now required from the price of Cerezyme to provide a margin to providers of Homecare Services.
230. In the present case, the margin squeeze abuse which we found in our judgment occurred in circumstances where Genzyme was both the supplier of the drug, Cerezyme, and the supplier of Homecare Services, through Genzyme Homecare. The abuse consisted of charging independent suppliers of Homecare Services a margin insufficient to enable them to compete in the market. We are now, however, told that the management buy-out, of which as yet we have very limited details, has apparently created two separate entities, Genzyme and Careology Limited. What is said is that Genzyme itself is not now supplying Homecare Services but only the drug Cerezyme. We briefly consider whether these new circumstances affect our jurisdiction.
231. In that regard, in our judgment on the merits at paragraphs [358] to [364] we found, notably, that Genzyme is the only source of supplies of Cerezyme and that third parties are only able, in practice, to provide a homecare service to Gaucher patients if they can obtain supplies of Cerezyme at a price that enables the provision of such services to be economically viable. We found, at paragraphs [528] and [530] of that judgment, that there was no doubt in our minds that Genzyme’s NHS list price for Cerezyme included the cost of Homecare Services, as defined in the decision, and that provision of Homecare Services is an independent economic activity which is separate

from, albeit ancillary to, the supply of the drug Cerezyme (paragraphs [355] to [357] and [532]). At paragraph [533] of our judgment we accepted that the bundling together by a dominant undertaking of separate but ancillary products or services may constitute an abuse where the effect is to eliminate or substantially weaken competition in the supply of those ancillary products or services.

232. Although we accepted that an infringement based on Genzyme's bundling practice was not proved during the period March 2000 to May 2001 (paragraph [548]), we also found, at paragraph [641], that Genzyme's practice of bundling facilitated the margin squeeze abuse which we found to have been proved by the OFT.

233. In our judgment, the power to make a direction under section 33 of the Act includes the power to ensure that an infringement is not repeated, if the OFT in its discretion considers that such a direction is necessary. Moreover, in our view, the power "to bring the infringement to an end" covers conduct closely linked to, or to the like effect as, the infringement found, otherwise section 33 would be ineffective. Similarly, the Tribunal's powers to give such directions or make any decision the OFT could have given or made must, it seems to us, be construed as a power to give a direction that is adapted to the developments that have taken place in the course of the proceedings, provided that the underlying problem to be addressed remains the same or similar. Otherwise, a kind of "catch as catch can" situation could arise in which a dominant undertaking could, by constantly changing its arrangements, keep the competition authorities at bay indefinitely.

234. In the present case it is not yet clear whether there are financial, managerial, physical or other links between Genzyme and Careology such that it would be inappropriate to treat the latter as an entirely independent entity.

235. However, even if we were satisfied that Careology was completely independent, it does not seem to us that the creation of Careology now creates a fundamentally different situation in this case. The underlying vice to which these proceedings are directed is that Genzyme, the dominant supplier of drugs for the treatment of Gaucher disease, has failed or refused to supply such drugs (i.e. Cerezyme) to independent Homecare Services providers at a price such as to enable the latter to operate

competitively in the downstream market for Homecare Services, for which there is a separate demand. The remedy for that abuse is to establish a price for Cerezyme for supply to Homecare Services providers which will enable the latter viably to supply Homecare Services.

236. It is true that, strictly speaking, the expression “margin squeeze” commonly refers to a situation where the dominant undertaking is present in both the upstream and downstream markets. However, it seems to us that, even if Careology is now considered to be an independent provider, rather than part of Genzyme’s “in house” operation, in the circumstances of this case it would still be an abuse for Genzyme to squeeze the margin between the NHS and ex-manufacturer prices to the point at which an efficient Homecare Services provider is unable to compete in the market. Such a strategy on the part of Genzyme would foreseeably lead to the withdrawal of independent Homecare Services providers, thus disrupting the provision of Homecare Services to Gaucher patients and enabling Genzyme to re-enter, and monopolise, the market. This in turn would simply restore the *status quo ante*, in which the only homecare providers would be either those contracted to Genzyme, or Genzyme itself. That was precisely the situation addressed in the OFT’s decision.

237. In addition, as long as the conventional NHS list price for Cerezyme remains, an issue which we discuss below, there would appear to be nothing to prevent Genzyme in the future in fact offering to supply Cerezyme on a bundled basis, including Homecare Services. That would, in turn, again raise the possibility of a classic margin squeeze. Any agreement or understanding between Genzyme and Careology to the effect that Genzyme did not intend to re-enter the market for Homecare Services would not obviate the need for a direction. Private arrangements can be modified, and the future is not foreseeable. Similarly, any unilateral undertakings by Genzyme, even if made in good faith, would not remove the need for a direction: circumstances may change in the future in all kinds of unforeseeable ways.

238. We are therefore of the view that we have jurisdiction to make a direction with a view to ensuring that Genzyme’s infringement of the Chapter II prohibition is terminated, and to prevent that infringement, or any similar infringement, from arising in the

future. Indeed, all parties invite the Tribunal to rule on the outstanding issues between them.

*Maintaining the existing NHS List Price*

239. At various stages in these proceedings it has been suggested that the best solution would be if the existing NHS list price became a “drug only” price, and that the cost of Homecare Services was paid for separately, probably on the basis of tenders put out by the various hospital authorities.
240. We can see the attractions of this solution. In particular, one disadvantage of maintaining the existing NHS list price and introducing a “bulk pharmacy” drug-only price is that competition then has to take place within the parameters set by the NHS list price and the bulk pharmacy price. That could have the effect of constraining the free play of competitive forces in a way which would not occur if there were simply a drug only price, and the price of Homecare Services was left to find its own level in competitive conditions.
241. However, at this stage the administrative and funding complexities of requiring Genzyme’s NHS list price to be a “drug-only” price seem to us to be too great for that to be done by way of a direction under the Act.
242. This aspect of the matter is complicated by the lack of any clear definition of what the “NHS list price” is intended to cover. As explained at length in our earlier judgment, under the NHS system the NHS list price is not an ex-manufacturer price, but the price at which the retail pharmacist is reimbursed, subject to “clawback”, by the Prescription Pricing Authority (PPA) for the supply of the drug. The NHS list price therefore historically includes the wholesaler’s margin. Although the function of the Homecare Services provider is not equivalent to the normal “wholesale” function, the cost of Homecare Services has traditionally been funded out of the NHS list price. In the case of Cerezyme, where Cerezyme has been supplied to the patient pursuant to a hospital prescription, the hospital has reimbursed Healthcare at Home or Genzyme Homecare with the cost of the drug at the NHS list price. When a prescription for Cerezyme is written on a Form FP10 (e.g. by a GP under shared care arrangements or

in some cases by hospital consultants), the homecare provider is reimbursed by the PPA and receives the Expensive Prescription Fee. Again, it is assumed that the cost of Homecare Services will be funded out of the NHS list price for Cerezyme (paragraph [82] of our judgment on the merits).

243. If the NHS list price for Cerezyme were to become a simple ex-manufacturer price we are told that Cerezyme would be the only product to be so treated among the many thousands of products included in the Drug Tariff. We cannot, at present, exclude the possibility that that would cause administrative difficulties, particularly in relation to the funding arrangements for Homecare Services. The evidence before the Tribunal was that a substantial proportion of Healthcare at Home's business was done on FP10s which are reimbursed by the PPA at the NHS list price, which has up to now been treated as including Homecare Services.
244. Gaucher patients are scattered all over the country, from Cornwall to Scotland. Up to now, payment at the NHS list price has been regarded by PCT's as including the cost of Homecare Services. If that were no longer the case, it is not clear to us what the funding mechanisms for Homecare Services would be.
245. It is true that we have been told that funding arrangements for Cerezyme are to be taken over by NSCAG: see Mr Brownlee's email to the OFT of 15 November 2004. However, we have insufficient information about these arrangements to be sure that the present mechanism of funding through the NHS list price can be safely abandoned. In any event, the NSCAG arrangements are apparently only for two years. In addition, any systems of tenders for Homecare Services to Gaucher patients are as yet untried. It is not yet clear to us that any new tendering procedures introduced will automatically replace fully the old funding arrangements which currently involve a number of PCT's up and down the country. In addition, although we are told that the use of FP10s is in decline, we take the view that it is not for the Tribunal to seek to deprive hospitals and doctors of that facility. That is a matter for the NHS to sort out.
246. We are therefore of the view that, at present, Genzyme's existing NHS price, in the conventional sense, of £2.767 should remain, but that a discounted "bulk pharmacy"

price should be introduced. Such a price would introduce transparency, while leaving the NHS free to develop purchasing procedures as it sees fit. There would, however, be nothing to prevent the OFT from modifying the direction at some later date if it were satisfied that changes in NHS funding arrangements and procedures were such as to obviate the need to maintain an NHS list price for Cerezyme in the sense traditionally understood.

247. We turn now to the substantive main issue that arises for consideration: the appropriate level of discount from the NHS list price to arrive at the bulk pharmacy price.

*The appropriate level of discount: general considerations*

248. Genzyme's latest proposal, of a discount of 6.5 per cent off the new list price of £2.767 per unit, although still contested by the OFT and by Healthcare at Home, is in our view much more realistic and constructive than its earlier proposals.

249. In assessing the margin that is required in this case the Tribunal has attempted, on the basis of the information now before it, to consider what ex-manufacturer price for Cerezyme would enable a reasonably efficient homecare services provider to supply its services to Gaucher patients and in so doing earn a competitive return.

250. In dealing with that question the Tribunal now has ample information from three different sources, namely: (a) historical information; (b) indicative estimates by other potential providers, Clinovia and Central Homecare; and (c) detailed information about Healthcare at Home's costs. We consider that this mass of detail is sufficient to enable the Tribunal to make a determination.

251. Genzyme has, however, urged us to obtain further information about allegedly comparable situations involving homecare treatment for other diseases such as haemophilia, thalassaemia, HIV, multiple sclerosis and other treatments. Genzyme seeks disclosure of tenders submitted in the past by Healthcare at Home in relation to these other treatments. Despite Genzyme's arguments, set out earlier in this judgment, and repeated in further submissions dated 14 September 2005, which we

have carefully considered, we are not persuaded that that approach is either necessary or desirable. Moreover, a mass of information has already been disclosed to Genzyme who have had every opportunity to comment on the matters taken into account in this judgment.

252. In our opinion, the gap between the parties' position is now relatively slight, and the Tribunal in our view has sufficient material on which to resolve the remaining dispute. The detailed investigation of allegedly comparable situations was suggested at a time when Genzyme was contending for a margin of 1 to 2 per cent, but matters have since moved on. Genzyme has now acknowledged, de facto, that a margin of at least 6.5 per cent is appropriate.

253. Moreover, it seems to us that a detailed investigation of allegedly comparable situations is not likely to be productive in this case. First, the evidence before us is that there are differences between the various treatments concerned. There are substantial disputes between the parties as to whether a given treatment is or is not comparable with Cerezyme, the complexities of which are set out at paragraphs [325] to [354] of our earlier judgment. There is, for example, already a substantial dispute as to whether homecare provision for haemophilia patients is comparable to homecare provision for Gaucher patients, and there is every indication that the comparability of the treatments for thalassaemia, HIV, multiple sclerosis, and so on would similarly be disputed. In our view, to go in detail into these matters would lead the Tribunal into lengthy collateral disputes on comparability, further adding to costs and delay. Secondly, even if it were established that different treatments were technically comparable, it would be very difficult to know whether the results of particular tenders were or were not comparable with what might be expected in the future for Cerezyme, since so much depends on the particular tender specifications in question, the strategy pursued by the tendering firms, and the characteristics of each of the different markets concerned, all of which may be very different from the factors affecting Homecare Services for Cerezyme. Investigating all these matters would, in our view, be disproportionate, given the narrow issues we now have to decide and the cost and delay involved.

254. We therefore propose to decide the remaining issue on the extensive material that is now before us.
255. We note that the determination of an appropriate margin is necessarily a question of judgment and appreciation. That is particularly so when the Tribunal, as here, is required to deal with markets affected by the intricate operation of the NHS arrangements and regulatory systems more fully described in our earlier judgment. Despite the highly technical nature of the submissions made to us, there are inevitably some areas of uncertainty on matters upon which experts may well take differing views. In those areas the Tribunal is required to exercise its own judgment.
256. In exercising our judgment we have had regard, in particular, to the interests of Gaucher patients and to the interests of the customer, the NHS. Those are the interests which the legislation is primarily designed to protect although, of course, the interests of Genzyme and of healthcare providers are also important. In our view, the NHS and Gaucher patients will be best served by a remedy that ensures effective competition in the supply of Homecare Services. It is, in our view, unrealistic to assume that the market for Homecare Services is already characterised by undistorted competition. In our view, that market has been disrupted, and competition has been distorted, by the abusive actions of Genzyme which have yet to be remedied.
257. In our view, there is little point in devising the remedy on the basis of a margin which no homecare services provider would consider commercially acceptable, or which bears no relation whatsoever to the levels of margin that, for whatever reason, have traditionally come to exist. We bear particularly in mind the small number of sufferers from Gaucher disease and their wide distribution geographically, combined with the specialised nature of the services required. Providers are unlikely to remain in that market unless they have an appropriate incentive to do so. Contrary to Genzyme's submissions, we do not see this case as setting down any wider benchmark, because of the special nature of the facts we are dealing with.
258. We agree with the OFT that, in this case, the risks associated with a remedy that may under-compensate third party Homecare Services providers are greater than those associated with over-compensation. However, even if, contrary to our view, the

remedy now imposed might lead to an element of over-compensation, that can be expected to encourage competing providers to tender for contracts to provide Homecare Services in future and to compete away, over time, any such over-compensation. On the other hand, if from the start our remedy were to under-compensate third party providers, it is likely that competition would be muted immediately and possibly irretrievably, since existing providers would withdraw and new providers would not come forward. Alternatively, the level of service currently offered to sufferers of Gaucher disease would, in the future, be diminished. We have taken account of these risks.

*The historical information*

259. In our earlier judgment we noted the considerable historical information that had already been presented to us concerning the margins typically observed in this area in the past (see paragraphs [673] to [678]). Although some of that information is now of a certain age, it has the particular benefit of having been prepared during a period when none of the parties concerned were involved in proceedings. In particular we noted that: (i) Genzyme's correspondence with the DoH in 1999 suggested that the costs of homecare would be 34p per unit or just over 11 per cent of the list price of £2.975 per unit; (ii) the margin agreed between Genzyme and Caremark in 1993 was in the order of 10 per cent of the then list price; (iii) when the contract with Healthcare at Home was terminated in 2001, having been re-negotiated in 2000, the average remuneration was approximately 28.4p per unit, or 9.5 per cent of the then list price; (iv) the figures in the Dixon Wilson Report produced for Genzyme and dated 18 October 2002 suggested that 10 per cent of the then list price would cover costs and overheads of Homecare Services; and (v) Genzyme's hospital price of £2.73 per unit represented a discount of 24p per unit or about 8 per cent of the then list price.

260. We were invited by Genzyme and its experts to disregard that historic information entirely. It was suggested that it is all either too old to be of assistance or that it reflects an imbalance of negotiating position between Genzyme and suppliers of Homecare Services. It was also suggested that that information, if relied on, would result in the Tribunal endorsing excessive and/or discriminatory prices for Homecare Services. The OFT, on the other hand, submits that the historic information before the

Tribunal is of assistance in devising the remedy in this case, in particular it is a useful “cross-check” against the OFT’s own cost calculations as to the realism of the margin suggested.

261. We agree with the OFT that the historic evidence to which we made reference in our earlier judgment is important evidence before the Tribunal. Although we accept that the earlier historical evidence is of less weight, we attach particular importance to:

- (a) The figure negotiated between Genzyme and Healthcare at Home in 2000 which gave Healthcare at Home a remuneration of some 28.2p per unit, or about 9.5 per cent of the then list price. That negotiation was at arm’s-length, with bargaining power on both sides.
- (b) The figures relied on by Genzyme itself before the OFT and the Tribunal in the Dixon Wilson Report showing that a margin of some 10 per cent, or 29.7p per unit, would cover the costs and overheads of Homecare Services.
- (c) The hospital price of £2.73 per unit, which covers delivery to the hospital but no other aspect of Homecare Services, which represented a discount of some 24p per unit or 8 per cent off the then list price.

262. These figures continue to suggest to us that margins of 24p to 29p per unit (which would correspond to between 8.6 and 10.5 per cent of the new list price of £2.767 per unit) are within the range that an efficient Homecare Services provider might historically have sought to achieve in this small and highly specialised market.

*Clinovia and Central Homecare*

263. Contrary to Genzyme’s submissions, we do not consider it appropriate to dismiss information submitted by Clinovia and Central Homecare in relation to hypothetical tenders for Homecare Services. Clearly, that information was prepared in a short timescale and it has not been possible for the OFT to ensure perfect consistency in the information submitted. In addition, those companies prepared their information on the basis of using agency nurses, whereas neither Healthcare at Home nor Genzyme

Homecare use agency nurses for this service. According to the OFT, Mr Farrell, who is the Chief Pharmacist at the Royal Free, and whose evidence we entirely accepted in our judgment on the merits, is of the view that the use of agency nurses is inappropriate.

264. Central Homecare considered that a market entry price of around [...] per cent was required. Adjusting that figure according to various different assumptions as to the number of nurses required, the OFT considered that Central Homecare's figures suggested margins of between [...] per cent and [...] per cent of the then list price of £2.975 per unit. Clinovia's figures, as similarly adjusted by the OFT, suggested margins of between [...] per cent and [...] per cent of that price. We have taken account of the fact that Clinovia does not itself currently provide Homecare Services to any Gaucher patient and of the fact that the OFT had more confidence in the information of Central Homecare, not least because that company currently services at least one Gaucher patient. We note, however, that neither of these companies has extensive recent experience of the relative complexity of supplying services to Gaucher patients. Given that both companies rely on agency nurses, which is not the regular practice of either Genzyme Homecare or Healthcare at Home, we think it possible that both companies may have underestimated the cost of providing trained nursing of the quality currently enjoyed by Gaucher patients.

265. Taking these factors into account, the indicative figures for Central Homecare do not seem to us to be significantly below the bottom of the range suggested by the historical evidence, although the Clinovia figure – which seems to us to be prepared on a less detailed and slightly different basis – is admittedly lower.

#### *The costs figures*

266. As outlined above, Professors Appleyard and Yarrow criticised the OFT Costs Report and the Supplementary Report. They submitted that the correct remedy in this case should be based on a margin of no more than 6p (or about 2 per cent). We note that the conclusions reached by Professors Appleyard and Yarrow are at variance with the historical evidence, with the evidence of Central Homecare and Clinovia, and with Genzyme's latest proposals. We note that Genzyme has now stated that Genzyme

Homecare needs a margin of at least 5 to 6 per cent to viably maintain its level of service to patients. The margin currently offered by Genzyme to Homecare Services providers including Careology is 6.5 per cent. As a result, on a practical level, we consider that the evidence of Professors Appleyard and Yarrow, which is directed to supporting a margin of 1 to 2 per cent, has been cast into serious doubt. We do not, therefore, address that evidence in detail. Nonetheless we comment briefly on the principal issues.

267. The costs evidence is canvassed in detail in the OFT's Costs Report, Supplementary Report, and the February 2005 Progress Report, the various corresponding submissions of Genzyme and Healthcare at Home, and the reports of Professors Appleyard and Yarrow. There are four main areas to consider, namely the treatment of common costs and overheads, delivery, nursing and profit margins.

268. As regards the treatment of common costs and overheads, we agree with the OFT that the price arrived at should recover an appropriate share of the Homecare Services provider's fixed costs and central overheads – including directors' costs – for the reasons given in paragraph 3.3 of the Costs Report and 2.4 of the Supplementary Report. We understand that this is not now disputed. As to how such costs should be allocated to the Cerezyme activity, we also agree with the OFT's rejection of Healthcare at Home's submission that certain costs should be allocated solely according to turnover: such an approach would allocate an unduly high proportion of overheads to Cerezyme, because of the high cost of the drug (Costs Report at 3.98). As to the various methods of allocation, the differences between the parties are summarised at paragraph 3.2 of the Supplementary Report. While the OFT agrees with Professor Yarrow that certain items such as finance, IT, retail costs and general overheads can be allocated on the basis of delivery numbers, there is a difference of view as to whether for certain items e.g. direct delivery costs and directors' time, an allocation should be made on the basis of delivery numbers alone. On that issue we agree with the OFT that in considering delivery costs account needs to be taken of the more complex nature of the delivery process for Cerezyme (Supplementary Report, 3.2 to 3.7). On the other hand, we share the OFT's reservations about accepting without qualification Healthcare at Home's "complexity quotient analysis". The OFT's conclusion that the figure for delivery costs is in a range between a figure

based on delivery numbers alone and the figure produced by Healthcare at Home's complexity quotient seems to us to be a reasonable approach. As regards the costs of directors, the OFT did not accept Healthcare at Home's original figures. While we understand Genzyme's point that this item too should be allocated on the basis of deliveries, as a proxy for the amount of activity concerned, the allocation, on a time basis, carried out by the OFT seems to us to be within the bounds of reasonableness.

269. As to Genzyme's submission that the OFT's resulting figure for delivery costs is above market rates – by reference particularly to some evidence about a contract Healthcare at Home has with the Royal Free for haemophilia – the comparability of the haemophilia contract is strongly disputed. The figures produced by the OFT at page 9 of the Supplementary Report show a wide variation in rates, some below and some above the OFT's estimate for Cerezyme, and some varying with the value of the drug. The delivery figures for Clinovia and Central Homecare are either similar to or above the OFT's estimate (page 5 of the Supplementary Report). In these circumstances we do not accept that there are significant valid criticisms to be made to the OFT's approach to delivery costs.

270. With regard to nursing costs, the OFT estimated an upper and lower bound based on the information provided by Healthcare at Home, and the Royal Free Hospital as to the actual numbers of nursing visits provided. The OFT's upper limit in the Costs Report is 6.4 full time equivalent nurses, while the lower limit is 4.5. We note that the Dixon Wilson Report estimated that Genzyme Homecare would itself need to employ 9 nurses (including a Head Nurse) and that 8.4 full-time equivalent nurses would be involved in providing a service to Gaucher patients. Healthcare at Home's evidence is that, because of the geographic spread of patients, it would be impossible to operate at national level on less than [...] [C] full-time equivalent nurses.

271. A number of detailed points have been contested between the OFT and Genzyme, on such issues as nursing efficiency, the number of visits required and hourly charges. Given that the margin now under consideration is much higher than Genzyme was suggesting at the time the expert reports were prepared, we do not think it is necessary to consider these points in detail. For the reasons given in paragraphs 4.1 *et seq* of the Supplementary Report, we think the OFT's approach is reasonable. We also have in

mind: (i) that Healthcare at Home employs [...] Gaucher trained nurses; (ii) Genzyme's own estimate at the time of setting up Genzyme Homecare that some 8.4 full time nurse equivalents would be required; and (iii) Mr Farrell's evidence to the Tribunal (Day 2, p.51) that the Royal Free would require about 10 nurses if it were to look after its Gaucher patients itself. In these circumstances, in our view, the correct figure to take is the OFT's upper figure of 6.4 full-time nurse equivalents. Indeed, that figure may be well be on the conservative side. We also note that Genzyme Homecare did not and Healthcare at Home does not generally employ agency nurses to provide Homecare Services. We consider, in those circumstances, a calculation based on employed nurses to be reasonable.

272. The final issue between the parties was how to calculate the profit margin. This item accounted for the major difference between the parties' figures. Genzyme argued that return on capital (in this case, effectively, fixed assets) was the appropriate yardstick, but the OFT contended that in a service business, where fixed assets were low, that was inappropriate, and that return on sales was the correct approach. The approach of Genzyme's expert evidence would have given a profit margin of some 0.1 per cent of the drug price whereas the OFT's figure is in the range of [...] per cent to [...] per cent (Supplementary Report, pages 18 to 25).

273. The discount of 6.5 per cent now offered by Genzyme, and Genzyme's earlier statement that Genzyme needed an overall margin of at least 5 to 6 per cent, imply to our mind that the profit margin assumed by Genzyme as necessary is well above the 0.1 per cent of the drug price suggested by Genzyme's expert evidence. Particularly in the light of that evidence, the figure of 0.1 per cent seems to us to be wholly unrealistic in practical terms. Despite the disadvantages of a return on sales yardstick – which links profit to the drug price, although costs are not necessarily linked to the drug price – a return on sales approach for the purposes of the present exercise does not seem to us unreasonable for the reasons given by the OFT in the Costs Report (paragraphs 3.1 to 3.27) and the Supplementary Report (paragraphs 4.23 to 4.47). The OFT's approach is supported by the study prepared for the OFT by Oxera in July 2003 entitled "*Assessing profitability in competition policy analysis*" (see OFT 657, paragraphs 1.24-1.25 and 4.49). That approach also appears to reflect how the industry actually works. As to the actual figure, the OFT's range of [...] per cent

to [...] per cent, based on the evidence of Clinovia and Central Homecare, appears to us to be a reasonable range. Given that Healthcare at Home submits that it works on an overall margin of [...] per cent, in our view the figure is likely to be at the upper end of the OFT's range. The figure of [...] per cent used by the OFT is approximately the mid-point between Clinovia and Healthcare at Home, and seems to us to be reasonable.

274. Our overall conclusion is that the OFT's approach to cost analysis has been a reasonable one.

275. We accept also the OFT's submission that the 2005 reduction in the NHS list price of Cerezyme to £2.767 per unit as a result of the operation of the PPRS gives rise to a need for the OFT to adjust its original estimates in the Costs Report and Supplementary Report. The range now suggested by the OFT's analysis is 5.3 to 7.7 per cent of the new list price, or between 15p and 21.3p per unit.

276. The OFT notes that Genzyme's latest offer of 6.5 per cent of the new list price of Cerezyme is exactly in the middle of the OFT's range of between 5.3 per cent and 7.7 per cent. A margin of 6.5 per cent at the new list price of £2.767 is equivalent to 18p per unit.

#### *Overall assessment*

277. Although we consider that the OFT's detailed costs studies should play a substantial part in our assessment, we do not consider that those studies should be the sole determining factor. Estimates and allocations of costs will always have a degree of arbitrariness. In addition, a particular problem in the present case is what assumption to make about the scale of operation of the notional reasonably efficient homecare provider upon which the exercise is predicated. Healthcare at Home is well established and experienced in the market. Other homecare providers have substantial homecare businesses in other sectors, but little direct experience of Gaucher disease. Careology, as it now is, has hitherto been largely confined to Cerezyme and Fabryzyme.

278. Summarising:

- (a) the more recent historical information would suggest a range of 24p to 28p per unit, i.e. between about 8.5 and 10 per cent of the new list price;
- (b) the evidence from Clinovia and Central Homecare suggests a range of between [...]p and [...]p per unit, i.e. between [...] and [...] per cent of the new list price;
- (c) the OFT's Supplementary Report suggests a range of between 14.6p and 21.3p per unit, i.e. between 5.3 and 7.7 per cent of the new list price; and
- (d) Genzyme's recently offered margin of 6.5 per cent of the new list price represents 18p per unit.

279. The actual margin to be set is not a matter of precise mathematics. In our view we should set the initial margin at or near the top of the OFT's range for several reasons: (i) erring on the low side may affect the quality of service to Gaucher patients; (ii) we need to ensure that there is a sufficient margin to enable the envisaged new tendering system to work effectively; (iii) in our view the lower end of the OFT's range does not take sufficiently into account the special features of the delivery services for Cerezyme; (iv) the OFT's estimation of full-time equivalent nurses required is likely, on the evidence, to be too low at the lower end and possibly conservative at the upper end; (v) the OFT's lower range assumes a lower profit margin than we consider to be reasonable whereas in that regard, Central Homecare's figure, approximately at the mid-point between Clinovia and Healthcare at Home, seems to us the more appropriate to adopt; and (vi) a figure towards the top of the OFT's range is more consistent with the historical evidence.

280. Taking all these considerations into account we consider that the discount off the existing NHS list price at which a bulk pharmacy price should be offered by Genzyme to bona fide healthcare providers should be not less than 20 pence per unit. That is equivalent to 7.2 per cent of the current NHS list price and gives an ex-manufacturer bulk pharmacy price of £2.567 per unit. We propose to set that margin.

281. We note that the above level of margin is considerably less than the level of margin enjoyed by Healthcare at Home in 2001 (28.4 pence per unit). Nonetheless, the evidence is that the margin we propose to set should enable a reasonably efficient provider of Homecare Services to remain in the market. If Genzyme's submission, to the effect that such a margin would significantly over-compensate providers of Homecare Services, were correct, which we do not consider it to be, it can be expected that the tender process now envisaged will quickly result in the elimination of any such over-compensation. On the other hand, the margin we envisage leaves considerably more of the "value chain" associated with Cerezyme in the hands of Genzyme than was historically the case up to 2001.
282. The existing hospital price appears to us to be a separate matter outside the scope of the direction. However, if the hospital price and the new bulk pharmacy price were to differ, we cannot at present see any basis for imposing a restriction on the hospitals to the effect that the hospital price is limited to circumstances where the patient is infused in the hospital, as is currently the case: see paragraph [256] of the judgment on the merits.
283. We do not accept Healthcare at Home's submission that it is appropriate that there be a transitional restriction setting minimum prices for Homecare Services. On the contrary, we consider it appropriate that competition now take place in the market as quickly as can be achieved. That is a matter for the relevant NHS authorities and hospitals to take forward.

*Genzyme's disclosure application*

284. For the reasons already given, we think that it is neither necessary nor proportionate to grant Genzyme's disclosure application, which mainly sought disclosure of information relating to tenders for the provision of homecare relating to other drugs or treatments. As already stated, in our view this application has largely been overtaken by events, since it was made in support of the margin of 1 to 2 per cent for which Genzyme was then contending. Moreover, in order to satisfy ourselves that the disclosure sought is relevant, it would have been necessary for us to consider to what

extent, if any, the services provided in respect of those other treatments are comparable to Homecare Services for Gaucher patients. Even if we were so satisfied, we would nevertheless have then had to consider to what extent market-specific factors applicable to those services rendered such comparisons of limited relevance. The consideration of particular tenders would have had to have been gone into in detail. We note that, according to the evidence in the Supplementary Report, the delivery costs associated with different drug treatments appears to vary significantly. As already explained, we consider the disadvantages of embarking upon the costly and time consuming disclosure exercise which Genzyme suggests far outweigh any supposed advantages given, in particular, the narrowness of the issue we now have to resolve.

285. We do not consider it necessary to order disclosure of any of the other underlying documents which Genzyme also sought. Various documents underlying the OFT Costs Report and Supplementary Report were, in any event, disclosed to Genzyme by the OFT. There is no reason to doubt the various other figures in the OFT report. We note that Genzyme itself presumably has considerable documentary information about its delivery and nursing costs, and the margin it requires, which it could have produced, but Genzyme chose not to do so.

286. Genzyme's further submissions of 14 September 2005 repeated, in effect, its submissions of October 2004 and thus did not, in our view, take account of the developments in this case since the disclosure application was first made. As already stated, we do not accept the suggestion that it would be impossible for the Tribunal fairly and properly to resolve the remaining issues without these documents, particularly since in our view the Tribunal already has ample evidence before it. In our view the matters relied on by the OFT have already been fully disclosed to Genzyme, who has had the fullest opportunity to comment on these matters in the course of proceedings.

*The Tribunal's order*

287. We attach a draft direction.

Christopher Bellamy

Peter Grinyer

Graham Mather

Charles Dhanowa

29 September 2005

## **DRAFT DIRECTION**

1. Genzyme shall:
  - 1.1. forthwith bring to an end the infringement referred to at paragraph 640 of the Tribunal's judgment of 11 March 2004, namely setting a price for the supply of Cerezyme to providers of Homecare Services which results in a margin squeeze, with the effect of foreclosing the downstream supply of Homecare Services;
  - 1.2. hereafter, refrain from repeating that infringement; and
  - 1.3. refrain from adopting any measures having an equivalent effect.
2. In particular, within fifteen working days from the date of this direction Genzyme shall supply Cerezyme [and Ceredase] to any bona fide provider of Homecare Services at a drug-only price exclusive of any charge in respect of any element of Homecare Services, at a discount from the prevailing NHS List Price for such drugs from time to time of not less than 20 pence per unit.
3. The OFT may if it thinks fit, after consulting interested parties,
  - 3.1 modify any provision of this direction, with a view to ensuring that this direction remains appropriate and effective for its purpose; and
  - 3.2 revoke this direction or any provision of it, provided that this direction shall not be revoked until three years from the date hereof without the prior consent of the Tribunal.
4. Genzyme shall ensure that any trading as regards Cerezyme [or Ceredase] taking place between Genzyme and any company carrying on Genzyme's former homecare business is carried out strictly at arm's-length in all material respects, and on the same terms and conditions as trading with any other supplier of Homecare Services.
5. Genzyme shall supply to the OFT such information as the OFT may require in order to:
  - 5.1 monitor Genzyme's compliance with, and to assess the effectiveness of, this direction; and
  - 5.2 satisfy itself that any trading between Genzyme and any provider of Homecare Services is at arm's-length and on the same terms and conditions as aforesaid.

6. The term 'Homecare Services' in this direction means, in respect of each of Cerezyme [and Ceredase], the delivery of the drug to a patient's home and the provision of homecare services (including, but not limited to, basic stock check, supply of and monitoring of the need for accessories such as fridges and syringes, waste removal, dispensing the drug, training on how to infuse the drug, infusing the drug, providing an emergency helpline, respite care and full nursing support).