

2 Conclusions

Contents

	<i>Page</i>
The reference	8
The companies and the background to the merger.....	8
Coloplast	8
SSL	8
The background to the merger	9
The transaction.....	9
The Mentor agreement.....	10
Jurisdiction.....	11
The markets affected by the merger.....	12
The supply of continence care products.....	12
Supplies to the community.....	12
Supplies to hospitals	13
Comparison of prices to the community and to hospitals	14
Supplies to Primary Care Trusts	14
Competition in continence care products: the role of price, product development, innovation and marketing	15
The relevant product markets.....	15
Conclusion on product markets.....	16
The relevant geographic market.....	16
Conclusion on geographic market.....	18
The effect of the merger on competition within the market, including entry.....	19
Elimination of SSL as a competitor	19
Increase in Coloplast's market shares.....	19
Third party concerns	19
Coloplast's view	20
Assessment of third party concerns and of Coloplast's views.....	20
Individual product markets	20
Barriers to entry	21
Manufacturing and marketing barriers.....	22
Regulatory barriers.....	23
Summary on competition within the market and barriers to entry.....	23
Countervailing power of purchasers	24
Conclusion on countervailing powers of purchasers.....	24
Vertical integration: DACs and Thackray nurses	25
Increase in supplies through Coloplast-owned DACs.....	25
Third party concerns	25
Coloplast's response	26
Assessment of concerns over DACs and Thackray nurses	26
Conclusions on vertical integration.....	28
Effect on the public interest	28
Prices for supplies to hospitals.....	28
Prices for supplies to the community	30
Innovation, quality and service	31
Rationalization of the product range.....	32
Benefits of the merger.....	32
Conclusions on the public interest	32
Remedies.....	33
Recommendations.....	35

The reference

2.1. The completed acquisition by Coloplast A/S¹ of the continence care business of SSL International plc² was referred to us for investigation on 14 January 2002. Prior to the merger Coloplast A/S and SSL International plc were each engaged in the manufacture and supply of a range of appliances for the management of urinary incontinence (continence care products). Our terms of reference are in Appendix 1.1.

The companies and the background to the merger

Coloplast

2.2. Coloplast A/S is a Danish company, founded in 1957, that develops, manufactures and markets ostomy products, continence care products, dressings for chronic wounds, skin-care products, breast forms, special dressings, and special textiles for women. Listed on the Copenhagen stock exchange in 1983, it has subsidiaries in 22 countries with a market capitalization as at 1 October 2001 of approximately £1.1 billion and a global turnover in year ended 30 September 2001 of £336 million (DKK 4,069 million).

2.3. Coloplast Limited is the wholly-owned UK subsidiary of Coloplast A/S. It distributes ostomy care, continence care and wound care products in the UK. Coloplast Limited has, in turn, a wholly-owned subsidiary Coloplast Direct Limited (Coloplast Direct), which is a DAC³ and dispenses appliances directly to patients through a home delivery service. In addition, Coloplast Limited also has a 40 per cent interest in 4C Health Limited, a Scottish DAC and wholesaler supplying medical products to customers primarily based in Scotland. In the year ended 30 September 2001 the consolidated sales of Coloplast Limited of continence care products in the UK were £9.4 million, representing 13.3 per cent of the Coloplast group's global continence care sales.

SSL

2.4. SSL International plc was formed in July 1944, and took its current name in June 1999 following a merger with London International Group. In addition to its continence care business, which was sold in its entirety to Coloplast, SSL manufactures and markets medical and consumer healthcare products including family planning, footcare, over-the-counter drugs and surgical products. It has subsidiary operations in 35 countries. In the year ended 31 March 2001 group turnover was £649 million. The market capitalization of SSL International plc as at 30 September 2001 was £943 million.

2.5. The continence care business was introduced through the acquisition of Simpla Plastics Limited in September 1995. Its subsequent growth was primarily driven by acquisitions. At the time of the transaction SSL had six separate premises listed as DAC outlets, which collectively traded under the name ThackrayCare and included a team of 22 specialist nurses in the continence care field providing advice and assistance known as Thackray nurses, a sales team, and a home delivery prescription service with its patient database. In 2001 SSL's sale of continence care products in the UK amounted to some £25.1 million, approximately 4 per cent of the group's global turnover.

¹In this report we use 'Coloplast A/S' to refer to the Danish parent company of that name, 'Coloplast' to refer to Coloplast A/S and its subsidiaries, and 'Coloplast Limited' to refer to the UK subsidiary of Coloplast A/S and its UK subsidiaries.

²In this report we use 'SSL International plc' to refer to the parent company of that name and 'SSL' to refer to SSL International plc and its subsidiaries.

³For a description of DACs, see paragraphs 4.29 to 4.43.

The background to the merger

2.6. Initial discussions between the two parties, starting in May 2000, explored the possibility of Coloplast acquiring SSL's continence care business [*Details omitted. See note on page iv.*]. But for reasons explained in Chapter 3, the deal was finally structured as a straight purchase by Coloplast of SSL's continence care business. (See paragraphs 3.56 to 3.58.)

2.7. SSL told us that it was keen to expand operations internationally. But it believed that it would have had to invest heavily in its continence care business to do so in that sector. It did not regard the continence care business as core to the group's activities and preferred to divest it in order to strengthen its core operations. (See paragraph 3.59.)

2.8. Due diligence reports prepared by J P Morgan and board minutes prior to the acquisition (see paragraph 3.60) highlighted four benefits to Coloplast of this transaction:

- (a) the elimination of a competitor;
- (b) the opportunity to become the market leader in the UK in sheaths and leg bags and the ability to strengthen its position in intermittent catheters [*Details omitted. See note on page iv.*];
- (c) the acquisition of a [☒] community sales channel [*Details omitted. See note on page iv.*]; and
- (d) cost savings resulting from a [*Details omitted. See note on page iv.*] and from combining the home delivery services of ThackrayCare Limited (ThackrayCare) and Coloplast Direct.

2.9. In evidence to us Coloplast expanded on the points above by highlighting that the acquisition would offer opportunities to:

- (a) provide access to overseas markets for the SSL products through Coloplast's own existing infrastructure;
- (b) add value to the existing SSL product range through Coloplast's continued strong commitment to research and development (R&D); and
- (c) further improve Coloplast's understanding of the problems experienced by users of continence care products via Thackray nurses, which would facilitate more focused future R&D.

The transaction

2.10. The parties signed an agreement for the sale of the SSL continence care business to Coloplast A/S on 29 September 2001. It was completed on the same day with an Australian element completing on 30 September 2001. The completion of the transaction was not dependent upon clearance by the competition authorities. In return for accepting the risk inherent in the sale being unconditional Coloplast obtained a reduction in the consideration paid.

2.11. For a consideration of £80 million, Coloplast acquired the continence care business of SSL involving the design, packaging, marketing, supply and distribution of urine drainage bags, sheaths and catheters and ancillary activities including:

- (a) the intellectual property rights relating to the devices sold under the names Aquasleve, S4, Trident, Uriflex, Aquasafe, Sleptite for urine bags, AquaCath and Nelcath for intermittent catheters and the registered trademarks, Aquadry, Simpla and ThackrayCare;
- (b) the benefit of an agreement with Mentor of 1 September 2001, to which £[§] million was apportioned (see paragraphs 2.12 to 2.16);
- (c) the business carried on under the name ThackrayCare (see paragraph 2.5); and
- (d) the Australian continence care business owned by SSL.

The Mentor agreement

2.12. Mentor is a company incorporated in Minnesota with its headquarters in California. In 1997, as part of the acquisition of ThackrayCare, SSL acquired the exclusive UK distribution rights for Mentor sheaths under a five-year agreement. On 1 September 2001, Mentor and SSL International plc renewed this arrangement by entering into an agreement appointing SSL International plc as Mentor's exclusive distributor in the UK, the Channel Islands and Isle of Man (the territory) for sheaths sold under the names Clear Advantage, Freedom Cath and Freedom Plus.

2.13. The agreement of 1 September 2001 provided that:

- (a) it would commence on 1 September 2001 and remain in force until 31 March 2007;
- (b) SSL would purchase no less than [§] units in each quarter of the year (with the right to carry over any surpluses) and no less than [§] million units each year;
- (c) Mentor would package and label the products with references to the SSL trademarks Aquadry and Simpla;
- (d) neither party would have the right to assign its rights or obligations;
- (e) SSL would not during the term of the agreement directly or indirectly represent competing products in the territory and (with an exception for products required for its DAC business) would purchase all its requirements for the products in the territory from Mentor; and
- (f) Mentor would not sell the products to anyone other than SSL in the territory or for delivery into the territory.

2.14. On 29 September 2001 SSL International plc, Coloplast A/S and Mentor entered into a novation agreement (the Mentor agreement) immediately before Coloplast and SSL entered into the sale agreement. The agreement was conditional upon, and would become effective immediately following, the completion of the proposed sale agreement.

2.15. The Mentor agreement, in effect, amended the agreement of 1 September 2001 by, among other things, substituting Coloplast A/S for SSL as a party, increasing the minimum purchase obligation and increasing the price to Coloplast of Clear Advantage. Additionally, the non-compete provision in paragraph 2.13(d) relating to SSL was removed. Further details of these transactions are set out in paragraphs 3.56 to 3.76.

2.16. [

Details omitted. See note on page iv.

] As stated in paragraph 2.14, the Mentor agreement was conditional upon completion

of the sale agreement. Accordingly, we consider the Mentor agreement to be an integral part of the transactions that transferred the SSL continence care business to Coloplast.

Jurisdiction

2.17. Our terms of reference require us to investigate and report on the following questions:

- (a) whether a merger situation qualifying for investigation (within the meaning of the Fair Trading Act 1973 (FTA) has been created in that enterprises carried on by or under the control of Coloplast A/S (one at least of which is carried on in the UK) has, within four months preceding the date of this reference (or in the circumstances falling within section 64(4)(b) of the FTA), ceased to be distinct from enterprises carried on by or under the control of SSL International plc; and
- (b) if so, in either case, whether the creation of that situation operates or may be expected to operate against the public interest.

In relation to the questions in subparagraphs (a) and (b) above, we are required to consider, for jurisdictional purposes, whether the share of supply test or the assets test (embodied in subparagraphs (a) and (b) respectively of section 64(1) of the FTA) is satisfied. Broadly, the share of supply test is satisfied where as a consequence of the merger at least one-quarter of the goods or services of any description which are supplied in the UK, or in a substantial part of the UK, either: (a) are supplied by one and the same person or are supplied to one and the same person; or (b) are supplied by the persons by whom the relevant enterprises (so far as they continue to be carried on) are carried on, or are supplied to those persons. It is also satisfied if at least one-quarter of such goods or services were supplied before a merger and as a consequence of the merger the proportion so supplied has increased. The assets test is satisfied if the gross value of the worldwide assets taken over exceeds £70 million.

2.18. We begin by addressing the share of supply test. Before the merger Coloplast accounted for some 34 per cent by value of sheaths supplied in the UK, and as a result of the merger that share increased to 92 per cent. Before the merger Coloplast accounted for some 6 per cent by value of urobags¹ supplied in the UK, and as a result of the merger that share increased to 58 per cent. Before the merger Coloplast accounted for some 19 per cent by value of intermittent catheters supplied in the UK, and as a result of the merger that share increased to 26 per cent. (See Table 4.7.)

2.19. The parties signed agreements for the sale of the SSL continence care business to Coloplast A/S on 29 September 2001. Accordingly, the enterprises came under common control and therefore ceased to be distinct within four months preceding the date of the reference.

2.20. We therefore conclude that:

- (a) enterprises carried on by or under the control of Coloplast A/S, within four months preceding the reference, ceased to be distinct from enterprises carried on by or under the control of SSL International plc; and
- (b) the share of supply test is satisfied.

2.21. As we find that the share of supply test is satisfied, we have excluded the assets test from our consideration. We conclude that a merger situation qualifying for investigation has

¹The term 'urobags' is used here and throughout this report to denote urinary leg and night bags (see paragraphs 4.13 and 4.14) considered together.

been created. Thus we are required to consider whether its creation operates or may be expected to operate against the public interest.

The markets affected by the merger

The supply of continence care products

2.22. Urinary incontinence takes a number of forms. Whilst the condition is not uncommon, particularly among the elderly, only 10 to 15 per cent of sufferers seek medical assistance. For those who do seek assistance, there are two main channels through which to obtain continence care products under the NHS. The channels are primary healthcare (which is referred to in this report as the community channel or community sector) and secondary healthcare (which is referred to in this report as the hospital channel or hospital sector). The channel taken depends upon the severity and causes of the incontinence and its relationship to other medical conditions. In either case, where products for the management of incontinence are considered, the assessment is likely to be made either by a specialist continence care adviser or by a non-specialist nurse (including community nurses). These professionals therefore play a central role in determining the products used. The prescriptions are written either by General Practitioners (GPs) or by nurses with prescribing rights. Private retail purchases of sheaths, urobags and intermittent catheters, and supplies of these products to private hospitals, are not significant in terms of total sales and are not considered further. (See paragraph 4.25.)

2.23. Separate but similar arrangements exist for the supply of continence care products under the NHS in England, Scotland, Wales and Northern Ireland. Much of the description and analysis in this report refers to the arrangements in England, on which we were able to obtain more complete data and which accounts for approximately 85 per cent of all continence care products used in the UK. Given the similarities between NHS arrangements in all parts of the UK, most of our comments would be equally true of Scotland, Wales and Northern Ireland and should be read as applying to all four except where otherwise stated. Where there are significant differences, this is made clear. Where the data also covers Scotland, Wales or Northern Ireland, this is stated.

Supplies to the community

2.24. Products supplied under prescription via the community channel are obtained either from retail pharmacies (pharmacies), or through DACs. In England products supplied through the community channel account for approximately 90 per cent of costs to the NHS of these products. Both pharmacies and DACs dispense appliances and receive payment for these in accordance with the Drug Tariff published and maintained by the DoH and the National Assembly for Wales (and under equivalent arrangements in Scotland and Northern Ireland, to which separate reference will not be made hereafter). The basis on which pharmacies and DACs are remunerated for appliances is described in paragraph 2.28. Pharmacies in addition dispense drugs, but the basis of their remuneration for drugs differs from that for appliances.

2.25. Both a pharmacy and a DAC, when presented with a prescription ordering appliances, are obliged by their terms of service to supply with reasonable promptness 'such of the appliances so ordered as [they supply] in the normal course of business'. Coloplast told us that it understood this latter requirement 'to mean that, as a DAC supplying continence appliances, it must make all continence appliances available through its DACs on request'. It believed that this view was held across the industry. Pharmacies are obliged, in addition, to supply with reasonable promptness any drug that is specified in a prescription presented to them. We were told by the National Pharmaceutical Association (NPA) that in practice pharmacies played little or no role in determining the types or make of products used (see paragraph 6.138). We were told by AAH Pharmaceuticals (AAH) that the same is true of wholesalers (see paragraph 4.36).

2.26. The position in relation to DACs is more complex. We were told that the origin of DACs was as fitting houses for artificial limbs. However, it is clear from the evidence presented to us that they now serve mainly as specialist suppliers of ostomy and continence care appliances delivered to users' homes, and are not dependent for business upon visits by patients to their premises. This means that they must actively market themselves. They may employ sales teams, use databases and direct marketing for this purpose. Some DACs employ nurses to visit patients and assist in identification and use of appropriate products. Some DACs are also specialist wholesalers in appliances.

2.27. The requirement to supply appliances ordered on a valid prescription applies to DACs to the same extent as it applies to pharmacies. However, some DACs have marketed themselves in ways that influence the prescriptions they receive. Coloplast Direct, for example, has concentrated on the supply of Coloplast products. The role and significance of DACs in relation to the acquisition of SSL's continence care business by Coloplast is considered further in paragraphs 2.84 to 2.96.

2.28. Manufacturers who wish to supply appliances to the community must have them included on the Drug Tariff, which for each appliance details the supplier, the brand name, appliance order number, package quantity and list price. The operation of the Drug Tariff and the way in which this influences prices for products supplied via the community channel is discussed in paragraphs 4.47 to 4.66. In essence, determining the list price is a negotiated process between the DoH and the supplier, with subsequent increases in prices capped by an agreement between the Association of British Health-Care Industries (ABHI) and the DoH. The Drug Tariff price provides the basis for calculating the remuneration that the pharmacy or DAC receives when products are dispensed for patients, with different formulae applied to pharmacies and to DACs. One consequence of these arrangements is that it is in general financially advantageous to a manufacturer to supply its products direct to users through its own DAC outlet where possible, since supply by its own DAC business both attracts an additional payment (called an 'on-cost') of between 15.8 and 25 per cent of the Drug Tariff list price¹ payable to all DACs and avoids the discounts of up to 30 per cent that may need to be negotiated with wholesalers or with DAC businesses owned by others.

Supplies to hospitals

2.29. The hospital channel represents about 10 per cent of the total cost to the NHS of continence care products in England. However, it has an importance for manufacturers going beyond this. First, there is a widespread belief that hospital sales can serve as a gateway to community sales, because users of incontinence products in hospitals often continue to use those same products once in the community. Second, hospital trials and the use of products within hospitals provide a route by which companies can increase recognition and acceptance of their products by clinicians. (See paragraph 4.67.)

2.30. In the hospital sector supplies are obtained through a process of open competitive tendering. In England PASA, an executive agency of the DoH, runs the tendering process and decides which products are to be on a National Contract list. These products are then made available through the National Health Service Logistics Authority (Logistics). In England approximately 70 per cent of sales to hospitals are through Logistics. The remaining 30 per cent of continence care products supplied to hospitals are sourced directly by the hospitals. These arrangements, and the variations on them in Scotland, Wales and Northern Ireland, are outlined in paragraphs 4.67 to 4.74.

¹Fixed at 25 per cent in Scotland.

Comparison of prices to the community and to hospitals

2.31. The two routes to market produce different pricing structures to the community and to hospitals respectively. As indicated below, we shall be primarily concerned with three types of continence care product that were supplied by both Coloplast and SSL prior to the merger, namely, sheaths, urobags and intermittent catheters. We therefore undertook a comparison of prices between the two channels for these product types. To compare the value to a manufacturer of products supplied to the community relative to those supplied to hospitals it is not sufficient to compare the prices in the Drug Tariff with those in the National Contract for hospitals, since such a comparison would take no account of discounts given by manufacturers when supplying products through the community channel. We therefore compared the relative average unit revenues generated from products supplied through the two channels. The results are set out in Table 4.6. This shows that in 2001 Coloplast unit revenues from sales to the community were higher than for sales to hospitals by:

- 32 per cent for sheaths;
- 87 per cent for urobags; and
- 35 per cent for intermittent catheters.

2.32. We were told by both Coloplast and SSL that, although as a result of these differences profitability was lower on supplies to hospitals, these supplies were nonetheless profitable. Our analysis of the information provided by Coloplast confirmed that the gross margins for hospitals appear to be sufficient for this channel to be profitable. In another recent case considered before the CC Appeal Tribunals,¹ it was found that price differentials between hospital and community sales had been used in a strategy of anti-competitive behaviour. However, we received no evidence that Coloplast had followed such a strategy. The price differentials that produce the differences in unit revenues for continence care products are, in our view, a direct consequence of the different pricing regimes applied by the public authorities in the community and hospital channels respectively. It is on this basis that we have evaluated the effects of the merger.

Supplies to Primary Care Trusts

2.33. Primary Care Trusts (PCTs) usually fund the provision of continence care products under the arrangements for supplies to the community described above. However, we were told of the recent introduction of a new arrangement under which continence care products are supplied to patients within the PCT area by a single DAC appointed for this purpose following a tender. The products are then paid for by the body responsible for letting the contract on the basis of the rates specified in the contract rather than under the Drug Tariff formula. A number of those who gave evidence suggested that if such tendering became widespread this could have an impact both on prices and in strengthening the position of larger manufacturers with developed distribution arrangements and a portfolio of products. We therefore sought evidence from the PCT now responsible for these arrangements (South Sefton PCT). We were told that the arrangements had been in place for more than three years and were primarily introduced to provide easier access to specialist advice and management of patients, rather than on cost grounds. All continence products listed on the Drug Tariff were available under the arrangement. We heard of separate and slightly different arrangements operated by one Scottish PCT. (See paragraph 4.44.)

¹See *NAPP Pharmaceutical Holdings Limited and Subsidiaries v Director General of Fair Trading*. A case heard by the CC Appeal Tribunals under the Competition Act 1998 (Case No 1001/1/1/01).

Competition in continence care products: the role of price, product development, innovation and marketing

2.34. We took evidence from manufacturers, wholesalers and retailers of continence care products, government departments and NHS bodies involved in the regulation and purchasing of these products, individual Health Authorities and NHS Trusts, associations concerned with continence care and individual continence care specialists. There was widespread agreement that:

- (a) Neither patients nor those principally involved in advising them display much price sensitivity in choosing a continence care product.
- (b) Once products are listed on the Drug Tariff there is little scope for manufacturers to increase the volume of their products used in the community by increasing the discount offered to wholesalers or to retailers.
- (c) The price at which hospital supplies are made is primarily determined by the periodic tendering process and there is limited scope for increasing volumes sold by changing prices in the interim.
- (d) The most effective way for a supplier to increase sales is to convince the continence care professionals primarily responsible for determining the products used that its particular appliances are clinically superior because of innovative features or greater ease of use.
- (e) Product development, innovation and marketing other than through price play a particularly important role in competition.

The relevant product markets

2.35. There was less agreement on the product markets in which sheaths, urobags and intermittent catheters compete. Coloplast argued that the relevant product market included all disposable incontinence products, but might also be extended to include other solutions to incontinence problems including surgery, physiotherapy, electrotherapy and drugs. As regards surgery, it drew our attention in particular to the development of sling procedures and the use of stents (see glossary). However, other parties who gave evidence drew attention to the role of clinical judgement in determining the types of product used, which limits the scope for economic substitution. Whilst accepting the importance of clinical considerations, Coloplast put it to us that:

- (a) some incontinence conditions might require combined use of treatments and use of products to manage the condition;
- (b) there were examples of different clinicians recommending different products for patients with identical medical conditions;
- (c) the types of product used by an individual might change over time to reflect changes to their circumstances and condition;
- (d) some users might utilize a range of products over the course of a single day to accommodate their lifestyle; and
- (e) in some cases absorbent products such as pads could be, and were, used for patients who would benefit from the use of catheters or sheaths and bags.

These arguments are considered in paragraphs 4.85 to 4.105.

2.36. We recognize the points made by Coloplast. However, in defining the product markets for the purposes of our inquiry we must primarily have regard on the demand side to the extent to which the different incontinence products are economic substitutes in the sense that consumers would readily switch from one type of product to another in response to movements in price. The weight of evidence we received was that, at any given point in time, the clinical assessment would almost always lead to the choice of one product type in preference to others, and that the patient would rarely switch to an alternative product except in response to a change in his or her condition. This was supported by the evidence we received from IMS Health (IMS), a medical research consultancy, on rates of switching shown by analysis of GP prescriptions. We do not believe that it is undermined by Coloplast's suggestion that the products recommended for new patients by clinicians may change over time, which would not be captured in the data from IMS. Only if the rate of change were particularly rapid would we regard such behaviour as potentially significant for our assessment. In any case, low price sensitivity militates against switching. Neither inclusion on the Drug Tariff nor on the National Contract automatically leads to sales, and we have noted the limited role of price in determining demand in paragraph 2.34.

2.37. Whilst we accept some degree of overlap between the use of absorbent products such as pads and of sheaths, bags and catheters, it is clear that there is a significant difference in function between products designed to absorb urine releases and those designed to drain and store it away from the body. The evidence we received indicated that for many conditions absorbent products were not a suitable option. We therefore see these more as complementary to sheaths, bags and catheters than as substitutes for them. Since there is no impact of the merger on the supply of absorbent products that might give rise to competition concerns, we do not consider them further in this inquiry.

2.38. To assess the scope for supply-side substitution we considered evidence on the time taken to introduce products. Coloplast, which quoted the shortest times, took 18 months on average from conception to sales on its last five product launches. In our view this shows that it is not realistic to assume than an existing supplier could enter the market with a new product within a short time. A new supplier would take even longer to get its product listed.

Conclusion on product markets

2.39. This evidence leads us to conclude that, on both the demand side and the supply side, the relevant product markets are defined narrowly. Sheaths, urobags and intermittent catheters are considered to be in separate product markets from each other, from other continence care products and from other continence care treatments.

2.40. In our judgement the timescales for introduction of products not already included on the Drug Tariff or National Contract are too long for these to be substitutes for the purpose of the market definition. For this reason the products included in the product markets identified above are limited to those listed on the Drug Tariff or on the National Contract.

The relevant geographic market

2.41. We considered whether for each of these products the relevant geographic market is parts of the UK, the UK as a whole or some wider geographic area.

2.42. Coloplast argued that the relevant geographic market was at least the European Economic Area (EEA) plus Switzerland, citing both demand-side and supply-side factors. Coloplast argued that:

- (a) Wholesalers and distributors were able to source products on the Drug Tariff from around the world as the products were standardized internationally.
- (b) The CE marking for medical devices facilitated the use in the UK of products used in other states of the EEA and Switzerland and the approval process to get on to the Drug Tariff was relatively straightforward for products holding CE marks. (See paragraph 4.50 for more on CE marks.)
- (c) The majority of manufacturers of continence care products did not operate separate production facilities in each country, which demonstrated that transport costs were not significant.
- (d) Innovation was not related to any national market and competition for new products took place on a European or global basis.
- (e) There were a number of suppliers of continence care products in the EEA and Switzerland with products available and for whom entry into the UK would not be difficult.
- (f) Wholesalers either directly or indirectly procured products via parallel importing from other European countries.

2.43. Other parties who gave evidence were divided on the relevant geographic market. The reasons most commonly cited by those who argued for a separate UK market were differences in remuneration systems between national markets within the EEA, together with differences in the quality of products, in packaging and brand names. There were also historical/cultural features unique to the UK.

2.44. These points are considered in Chapter 4 (see paragraphs 4.106 to 4.118). We accept that most continence care products used in the UK are manufactured overseas, that the CE marking for medical devices eases entry into the UK of devices used in other parts of Europe, and that procurement by PASA involves a competitive tendering process in which overseas suppliers can offer products, including products not on the UK Drug Tariff.

2.45. On the other hand, we note the different regulatory, procurement and reimbursement arrangements in the various national markets, the substantial differences in price for the same products in different European countries, the fact that many continence care suppliers operate only in particular European countries, and that some companies that do supply across Europe choose to do so by treating it as a series of national markets.

2.46. Regulatory factors are central to any assessment of the geographic market, because of the dominant role of prescriptions in the provision of sheaths, urobags and intermittent catheters. Prescriptions written in the UK must be dispensed by UK dispensers unless the patient is prepared to pay the full cost. Patients are therefore unlikely to obtain or seek to obtain these products from outside the UK. The products dispensed must be as stated on the prescription. Since prescriptions typically specify the product by name (for example, Clear Advantage sheath size XX), the dispenser is not free to supply sheaths of a different name obtained from outside the UK. The dispenser may be able to obtain the named products from outside the UK. However, his ability to do so in practice may be constrained by a number of factors, discussed below.

2.47. Coloplast submitted evidence that showed that in 1998/99, prior to Coloplast increasing discounts on its sheaths to AAH and to Alliance UniChem plc (UniChem), a substantial proportion of the Coloplast sheaths sold by those wholesalers had been obtained from sources other than Coloplast Limited. This, it claimed, showed the extent of parallel importing and that AAH and UniChem considered the relevant geographic market to be wider than the UK.

2.48. In order to establish the extent and significance of parallel importing, we sought evidence from AAH, from UniChem, from The Boots Company PLC (Boots), and from a number of firms that specialize in parallel importing. None of the third parties we contacted knew of Coloplast continence care products being imported (other than by Coloplast), with the exception of Coloplast's two-piece sheath and two types of Coloplast leg bags. All were, however, aware of a grey market for these products. A grey market occurs when a manufacturer's products are bought by an intermediary from the manufacturer or others in the same jurisdiction and later on-sold to distributors or dispensers. More generally, our attention was drawn to a number of factors that constrain parallel imports. These include the existence of exclusive distribution arrangements for particular territories, as is the case for Mentor sheaths, and restrictions arising from differences in patent protection. For instance, the Coloplast one-piece synthetic self-adhesive sheaths as sold in Europe cannot be sold in the UK without infringing Mentor's UK patent (see paragraphs 4.138 and 4.139). Other factors are variations in packaging, instructions in different languages, trademarks and sometimes the use of different names for the same products in different European markets, though Coloplast told us that its continence care products were standardized internationally. It is difficult to disentangle parallel imports from grey market purchases. We were unable to establish the extent to which parallel imports of continence care products have occurred in the past, but the evidence submitted by all the parties appeared to confirm that the level of such imports is not now significant. Nor were we able to establish the importance of all the various factors identified above as constraining parallel imports, many of which are affected by EC law, though the importance of exclusive distribution agreements and patent restrictions was clear. We note, however, that a consequence of the arrangements for supplying continence care products under the Drug Tariff is that whilst access to parallel imports or grey markets may enable wholesalers to influence the level of discounts from manufacturers, this affects only the division of the price paid between the manufacturers and the wholesaler and has no direct impact on the total costs of supply to the NHS.

2.49. The constraints on use of parallel imports noted above are also relevant to the hospital sector. Where potential imports are not included on the Drug Tariff, their use in hospitals is also affected by the reluctance of hospital staff to use products that will not be available to patients once those same patients have returned to the community (see paragraph 4.112).

2.50. Coloplast referred to the findings of the European Commission in the case of the proposed acquisition of C R Bard Inc (Bard) by Tyco International Ltd (Tyco),¹ in which the European Commission held the relevant geographic market to be the EEA (see paragraph 5.13). We considered this case. One factor that appears to have influenced the European Commission was the extensive use of pan-European tendering procedures. In our case approximately 90 per cent by value of all supplies of sheaths, urobags and intermittent catheters are used in the community sector in the UK, where tendering is not normally used. We have also identified regulatory barriers that appear to us relevant in our case.

Conclusion on geographic market

2.51. We conclude that demand-side factors indicate that for sheaths, urobags and intermittent catheters Europe is more accurately characterized as a series of national markets, of which the UK is one, rather than as a single geographic market. The interpretation of supply-side considerations is less clear-cut. For some products it is difficult for firms to supply substitute products from the EEA and Switzerland into the UK market, due to regulatory restrictions, patent restrictions and barriers arising from distribution agreements. For other products these restrictions will not apply, or will be less significant, and therefore it will be possible to supply substitute products from these countries. Our judgement, based on the

¹Case No COMP/M.2505-TYCO/CRBARD.

evidence presented to us, suggested that most of the products relevant to this inquiry appear to fall into the former category, and for this reason we consider the most appropriate definition of the geographic market to be the UK.

The effect of the merger on competition within the market, including entry

Elimination of SSL as a competitor

2.52. One effect of the merger has been to remove SSL as a competitor. Coloplast put it to us that though SSL might have been an effective competitor, it would not have been able to sustain this because of its low levels of investment in R&D and lack of presence in international markets. In contrast, SSL argued that its continence care business had been an effective competitor to Coloplast with a good range of products that had been increasing their market shares. Whilst there had been some initial problems with its coated catheters, these had been resolved. It had been the first to identify the opportunities available through targeting nursing homes using the ThackrayCare DAC business. Whilst its expenditure on R&D was low, it had been able to develop its product range both by acting as a distributor of new products manufactured by others and by acquiring other firms. SSL saw no reason why its continence care business should not have continued to be successful in the future, but had made a strategic decision to focus on other areas of business (see paragraph 5.32).

2.53. For the purpose of our inquiry, it is sufficient to note that in our judgement SSL's continence care business was clearly not a failing business. Had the acquisition not occurred, SSL's continence care business would have continued to provide competition to Coloplast, though we would have expected it to be sold at some future date because of SSL's wider business rationalization plans.

Increase in Coloplast's market shares

2.54. The merger increases Coloplast's shares of the markets for sheaths, urobags and intermittent catheters, and therefore the degree of concentration in those markets. Following the merger:

- Coloplast's market share in sheaths in the UK rose from 34 to 92 per cent, and its largest remaining competitor, Bard, supplies around 2 per cent.
- Coloplast's market share in urobags in the UK rose from 6 to 58 per cent, and its largest remaining competitor, Bard, supplies 31 per cent, so two companies supply 89 per cent.
- Coloplast's market share in intermittent catheters in the UK rose from 19 to 26 per cent, and its largest remaining competitor, Astra Tech Ltd (Astra Tech), supplies 63 per cent, so two companies supply some 89 per cent. (See Table 4.7.)

Third party concerns

2.55. A number of Coloplast's competitors expressed concern that the merger would make it more difficult for them to compete successfully with Coloplast than it would otherwise have been for them to compete with Coloplast and SSL separately. In particular, concerns were raised over the impact of larger market shares increasing the scope for aggressive marketing and portfolio selling. Concern was also expressed over concentration of product supply through DACs under single ownership and over incorporation of the Thackray nursing service into Coloplast. We consider these latter concerns under issues of vertical integration in paragraphs 2.84 to 2.97.

2.56. It was put to us that Coloplast's ability to support increased marketing through its larger share of supply, its reputation for aggressive marketing and its ability to offer 'basket deals', either within the continence care area or across continence care and ostomy or wound care based on its portfolio of products, would damage competition. Our attention was drawn to Coloplast's use of databases for direct marketing, including obtaining patient lists from hospitals and the provision of free samples to individuals on request; to the range of Coloplast continence care products following the acquisition; and to Coloplast's position in fields related to continence care such as ostomy.

Coloplast's view

2.57. Coloplast contended that competition was strong in relation to each of sheaths, urobags and intermittent catheters, with numerous companies having products listed on the Drug Tariff. It further argued that far from weakening competition, the merger strengthened it by creating new opportunities for competitor companies. As regards the other particular concerns expressed, Coloplast believed that direct marketing increased user information and choice and that the provision of free samples was on too limited a scale to be significant. It saw few, if any, opportunities for 'basket deals', which it had never sought to offer.

Assessment of third party concerns and of Coloplast's views

2.58. The evidence on existing competition is set out in Chapter 4, including data on market shares by individual product in the community and hospitals sectors where available (see paragraphs 4.123 to 4.143 and Appendix 4.2).

2.59. It is clear that a profitable company with larger sales and a greater portfolio of products is likely to be able to support a larger marketing effort in the UK. However, we do not agree that this, in itself, is likely to have a detrimental effect on competition unless the nature of that marketing is such as to raise barriers to entry (considered in paragraphs 2.90 to 2.97). Nor do we believe that there is scope for competition to be damaged through Coloplast offering 'basket deals' involving preferential terms for purchase of a basket of products, either involving different types of continence care products or for a portfolio of products covering continence care, wound or stoma treatments. As regards continence care, we have previously noted the lack of price sensitivity shown by those responsible for choice of product for patients (see paragraph 2.34). Furthermore, the tendering exercises run by PASA for sales to hospitals do not accommodate basket deals, because they are approached on a product by product basis. As regards the possibility of combining the marketing of continence care with wound or stoma care, the evidence given to us suggested little overlap in terms of patients. Also the markets appear to us sufficiently different in terms of who determines the products to be used as to frustrate the likelihood of such deals.

Individual product markets

2.60. The market for intermittent catheters has grown by more than 17 per cent a year for the last three years. In that period, besides Coloplast, SSL and Astra Tech, the market leader, seven other companies supplied these products. Although the combined market shares of these companies remains small, they have been successful in increasing their combined share of the market for intermittent catheters from 11 per cent in 1998/99 to 17 per cent in 2000/01.

2.61. The market for urobags has been broadly static in recent years, and appears more mature with less radical innovation. SSL was the market leader prior to the merger, with Bard the second largest supplier. Coloplast had a 6 per cent share prior to the merger, so the increment over SSL's earlier share as a result of the merger is relatively modest though its post-

acquisition share is significant at 58 per cent. In that period, other than Coloplast, SSL and Bard, there have been 12 suppliers of urobags whose cumulative market share has been relatively static at around 7 per cent.

2.62. The market for sheaths has seen a 2 per cent a year decline over the last three years. There was general agreement that the single most important development in the last decade was the introduction of a silicon one-piece self-adhesive sheath, against a background of growing medical concern over the use of latex. The manufacture of these sheaths is protected by a patent held by The Rochester Medical Corporation (Rochester) in the USA which, we were told, expires in the USA in 2011 and in Europe in 2012. We were further advised that Mentor originally had an exclusive distribution agreement with Rochester to sell this sheath under the name Clear Advantage. However, when Mentor did not meet Rochester's sales expectations Rochester introduced a similar silicon product on to the market. Following a legal battle Rochester won the right to market an equivalent product and Mentor continued to have the right to manufacture and market Clear Advantage. Mentor in turn holds a patent primarily concerned with the way in which one-piece sheaths are made self-adhesive, which expires in Europe in October 2002. (See paragraphs 4.136 to 4.138.) This complex legal position appears to have inhibited the emergence of directly competing products from other companies. Coloplast has been the only company to have developed a non-latex one-piece self-adhesive alternative that has gained any significant market share. Coloplast sells this sheath under the name Conveen Security + Urisheath, as part of its Conveen range of products.

2.63. Prior to the merger SSL had sole distribution rights in the UK for Mentor sheaths, and Coloplast acquired these rights as part of the transaction (see paragraph 2.12). Clear Advantage sheaths are now the market leader in the UK, accounting for 40 per cent of costs to the NHS for sheaths used in the community and 37 per cent of costs to NHS hospitals (see Appendix 4.3 data for England). In the community sector the three next best-selling sheaths are latex (Aquadry Freedom with a 21 per cent share; Conveen Urisheath with a 13 per cent share; and Conveen Urisheath/Uriliner with a 11 per cent share) and the second best-selling non-latex sheath (Conveen Security + Urisheath) has a 4 per cent share. In hospitals, where there has been a more pronounced move towards use of non-latex sheaths, the Conveen Security + Urisheath (non-latex) and the Conveen Urisheath short (latex) together hold a 45 per cent share. As a result of the merger, all of these sheaths are exclusively distributed in the UK by Coloplast. Although silicon one-piece sheaths manufactured by Rochester are sold in the UK by Jade-Euro-Med Ltd (Jade) and by Sims Portex Ltd (Sims Portex), either under the Rochester name or under their own names, they have failed to gain any substantial share of the market.¹ The combined market share of latex and non-latex products from all 11 suppliers other than SSL and Coloplast has declined from 11 per cent in 1998/99 to 8 per cent in 2000/01.

2.64. We consider the significance of these changes in paragraph 2.78.

Barriers to entry

2.65. To assess further the potential significance for competition of the increase in Coloplast's market share as a result of the acquisition, we considered barriers to entry in each of the product markets.

2.66. Coloplast argued that entry barriers for all the product types were low. The products were relatively simple to make and, with the exception of silicon one-piece self-adhesive sheaths, not protected by patents to such an extent that new entrants would be unable to manufacture competing products. There were manufacturers of continence care products who did not currently compete in the UK but were active internationally and who could easily enter

¹The acquisition of the urology business of Sims Portex by Mentor was announced on 6 May 2002.

the UK, particularly where they already had products with CE markings. Manufacturing involved few sunk costs and existing manufacturers such as Maersk Medical A/S (Maersk) and Rochester produced products on others' behalf. It was easy to get products listed under the Drug Tariff. Nor were there major marketing barriers, because an in-house sales team could be recruited without great difficulty or expense, or a third party distributor could be used. A 'DAC licence', if required, could be purchased for around £40,000. The relatively small numbers of continence care professionals who were the key target audience were accessible and sufficiently well informed on all products to remove any significant marketing advantage based on product or company reputation. (See paragraphs 4.144 to 4.148.)

2.67. Most of the parties other than Coloplast who gave evidence agreed that manufacturing barriers to entry were not great in the case of intermittent catheters and urobags. Our attention was drawn, however, to the significance of the Rochester patent over one-piece self-adhesive silicon sheaths, discussed above (see paragraph 2.62). It was also put to us that there were significant marketing barriers. The time it took to get new products on to the Drug Tariff was a barrier, as was the need for clinical trials to generate data necessary to convince healthcare professionals of the performance and advantages of a product. Nurses would not readily recommend products with which they were unfamiliar, and once users had a product that worked for them and with which they were familiar they were generally reluctant to change. The reputation of a product and, to a lesser extent, that of its manufacturer or supplier played an important role in determining what was recommended, which tended to inhibit new entrants, of whom there had been few for these products in recent years. It was generally difficult to sell products into the community unless they were already established in hospitals. The widespread provision of free samples and training and literature to continence advisers also posed a barrier. Possession of a DAC business with its own nursing service conferred significant advantages, but the economics of DACs meant that for a manufacturer to own a DAC business was only realistic for larger companies with a range of products and significant volumes of sales.

2.68. An examination of changes to the Drug Tariff over the last ten years showed evidence of successful entry into the intermittent catheter market, but little evidence of successful entry into the sheath and bags markets (see paragraphs 4.147 to 4.152).

2.69. When examining barriers to entry we considered the different types of potential barrier identified to us above for each of the different product types.

Manufacturing and marketing barriers

2.70. There appear to us to be relatively few manufacturing barriers to entry for bags or, now that the process of coating single-use catheters is well established, for intermittent catheters. We find that the manufacturing barriers for sheaths are greater, given the very widespread preference for one-piece self-adhesive silicon sheaths and the patents previously noted (see paragraphs 2.62 and 2.67).

2.71. It appears to us that there are marketing barriers to entry arising from the importance of product and company reputation and the costs and difficulties of persuading advisers and users to change from existing products with which they are familiar. Whether or not names such as Clear Advantage are brand names within the commonly accepted meaning of that term, it is clear to us that possession of such a widely recognized name is helpful for marketing purposes and confers a significant advantage upon its holder. We were not convinced by Coloplast's argument that all continence care professionals are likely to be so well informed on the relative functional characteristics of all available products as to remove the value of reputational factors relating to particular products or suppliers. The barrier is likely to be lowest for urobags, which to some extent are interchangeable. However, we were told that even in this case relatively small differences, for example in backing or tap design, could have a considerable impact on comfort and ease of use. The barrier is likely to be higher in the case of

sheaths, where familiarity in fitting and confidence in the product's performance in use are of greater importance. The barrier is likely to be highest for intermittent catheters, which are required to be inserted into the body and have the greatest scope for medical complications.

2.72. On the other hand, we take the view that for none of these products does the distribution of free samples and services to continence advisers such as the provision of training and literature, whilst prevalent, constitute a major barrier to entry. We reach this conclusion because of the relatively limited volumes and costs involved.

2.73. It was put to us that the acquisition of SSL's continence care business by Coloplast has increased marketing barriers for sheaths, urobags and intermittent catheters, as a result of Coloplast's ownership of both the ThackrayCare DAC business, including Thackray nurses, and the Coloplast Direct DAC business. We examine this issue in paragraphs 2.84 to 2.97.

Regulatory barriers

2.74. The CE marking for medical devices facilitates the use in the UK of products supplied in other states of the EEA and Switzerland. Nevertheless, the need for products to be included on the UK Drug Tariff in order for pharmacies and DACs to supply them on NHS prescription represents a barrier to entry. The DoH controls over the price at which products enter the Drug Tariff and over subsequent price increases (concerning which an agreement has been reached with the ABHI (see paragraph 4.55) serve as a mechanism to control costs to the NHS. However, these controls have also led to barriers to entry both due to the time required to obtain a listing, which can be significant for new types of product, and because of the distorting effect it has on prices. The policy of allowing products that are similar to products already on the Drug Tariff to be listed only at prices at, or more usually below, the prices of the products already listed in effect sets a price ceiling on new products. This ceiling applies unless the manufacturer is able to convince the DoH that its product is a new and superior type of product justifying a higher price. In the latter case the company may be able to obtain a higher price, but will face delays in obtaining a listing while the application is considered by the DoH.

2.75. The inability of suppliers to use a low price to enter the market and gain market share is also a barrier to entry to the community market. This arises in part from the lack of price sensitivity of GPs and continence care professionals, which means that suppliers have little ability to increase sales through lower prices. It also arises because a supplier cannot follow a strategy of entering at a low promotional price with a view to raising prices once a product is established, as a result of his inability under the Drug Tariff arrangements to increase prices subsequently except within the terms of the agreement reached with the ABHI.

2.76. The fact that the process of tendering for inclusion on the National Contract for supply to NHS hospitals takes approximately seven months and occurs only every three to four years provides a further barrier to entry through the hospital channel.

2.77. It is, however, our view that regulatory barriers, which apply equally to sheaths, urobags and catheters, have not increased as a result of the acquisition which is the subject of our inquiry.

Summary on competition within the market and barriers to entry

2.78. Our consideration so far of the evidence suggests that the greatest effect on competition arising from the merger is in the market for sheaths, where the Coloplast's post-merger market share is very high, at 92 per cent, and where the acquisition has resulted in the elimination of Coloplast's main competitor and given it control of the market-leading latex and non-latex sheaths. All other suppliers of sheaths have small market shares, which they have

failed to grow over several years, and we saw no evidence that would lead us to expect that they will become large market players in the near future. New entrants face manufacturing, marketing and regulatory barriers. These include that arising from the Rochester patent (see paragraph 2.100). The evidence pointed to no similar combination of all the factors noted above in the markets for urobags and for intermittent catheters, where the market dynamics appear to us sufficiently different to suggest that the effects of the merger on competition will be less than for sheaths. Before reaching any conclusions on the significance of these effects for the public interest, we examine the extent of any countervailing power of purchasers, issues of vertical integration arising from Coloplast's increased ownership of DACs, and our expectations regarding the effects of the merger on prices, innovation, quality, service and consumer choice.

Countervailing power of purchasers

2.79. The ability of a firm with high market shares to exert market power depends upon any countervailing power of customers. We therefore considered the purchasing power of the NHS in relation to sheaths, urobags and intermittent catheters. We did not consider the purchasing power of wholesalers because, as discussed in paragraph 2.48, one consequence of the arrangements for supplying continence care products under the Drug Tariff is that any purchasing power of wholesalers affects only the division of the price paid between the manufacturers and the wholesaler and has no direct impact on the total costs of supply to the NHS.

2.80. The NHS might be expected to have considerable purchasing power. However, the role of clinical choice, the freedom of healthcare professionals to determine the products to be used in each case primarily on clinical grounds, and the way in which prices are set under the Drug Tariff, serve as a major inhibition on any attempt to exercise that power by making it more difficult for the NHS to negotiate lower prices by buying particular products in bulk.

2.81. It is nevertheless clear that in determining which products are to be included on the lists for supply to hospitals, PASA—and its equivalent bodies in Scotland, Wales and Northern Ireland—exercise some degree of purchaser power, as is demonstrated by the lower prices for supplies to hospitals than to the community for the same products. It was put to us by PASA that its ability to keep prices down was dependent upon the availability in sufficient quantities of products, whose clinical characteristics are sufficiently close to be regarded as acceptable substitutes within hospitals, from alternative suppliers capable of meeting its other requirements. We agree with this analysis and therefore consider that the degree of purchasing power is dependent upon the competitive position in each product market.

2.82. We consider that the Drug Tariff, while providing some control over NHS costs, does not represent an active use of buyer power. The prices of the majority of products are set relative to the price of the first product of that type listed rather than linked to the costs of producing the individual products and, as previously noted, prices are in general substantially higher than prices paid by hospitals.

Conclusion on countervailing powers of purchasers

2.83. We conclude that though PASA and the equivalent bodies in Scotland, Wales and Northern Ireland have some purchasing power in relation to supplies to hospitals, the exercise of this power is dependent upon the availability from alternative suppliers of products whose clinical characteristics are sufficiently close to be regarded as acceptable substitutes within hospitals. We do not consider that the Drug Tariff represents an active use of purchasing power in the community sector, although it is part of a regulatory regime that provides some control over NHS costs and over the ability of manufacturers to increase prices.

Vertical integration: DACs and Thackray nurses

Increase in supplies through Coloplast-owned DACs

2.84. A further effect of the merger has been an increase in the concentration of business handled by DAC outlets owned by a single company. We were informed by the Prescription Pricing Authority (PPA)¹ that there were 181 DACs (firms listed as DACs rather than individual outlets) in England as at 31 March 2001, of which 159 dispensed prescriptions in 2000/01. Over 80 per cent of appliances supplied through the DACs were ostomy products, 16 per cent were continence care products and 3 per cent were dressings and miscellaneous items. The value of products supplied by individual DACs varied considerably. Of the 159 DACs that dispensed prescriptions, 74 dispensed appliances with a total value of £25,000 or less, and just 17 dispensed appliances with a total value of more than £125,000. Collectively supplies through DACs in the calendar year 2000 amounted to some 28 per cent of total prescription costs for sheaths, 17 per cent of total prescription costs for urobags, and 35 per cent of total prescription costs for intermittent catheters in England (see Table 4.4).

2.85. ThackrayCare and Coloplast Direct have both been increasing the value of their continence care business substantially with an average annual growth rate of 21 per cent over the two years to 31 March 2001 in the case of ThackrayCare and of 15 per cent over the same period in the case of Coloplast Direct. In the calendar year 2000 ThackrayCare accounted for 75 per cent of all sheaths supplied through DACs in England (representing 21 per cent of total prescription costs for sheaths), 45 per cent of all urobags supplied through DACs in England (representing 8 per cent of total prescription costs for urobags), and 37 per cent of all intermittent catheters supplied through DACs in England (representing 13 per cent of total prescription costs for intermittent catheters). Coloplast Direct accounted for a further 3 per cent of all sheaths supplied through DACs in England (representing less than 1 per cent of total prescription costs for sheaths), 3 per cent of all urobags supplied through DACs in England (representing less than 1 per cent of total prescription costs for urobags), and 20 per cent of all intermittent catheters (representing 7 per cent of total prescription costs for intermittent catheters) (see Table 4.5). As a result of the acquisition, Coloplast-owned DAC businesses now account for:

- 78 per cent of all sheaths supplied through DACs in England (representing 22 per cent of total prescription costs for sheaths);
- 48 per cent of all urobags supplied through DACs in England (representing 8 per cent of total prescription costs for urobags); and
- 57 per cent of all intermittent catheters supplied through DACs in England (representing 20 per cent of total prescription costs for intermittent catheters).

Third party concerns

2.86. It was put to us that this level of concentration and the extent to which post-acquisition Coloplast supplies its products through its own DAC businesses would damage competition between manufacturers: first, by increasing barriers to entry; second, by giving advantage to Coloplast through its possession of sales and patient information not available to its competitors; and third, through Coloplast using its DAC businesses to favour its own products, both directly and through the Thackray nurses. This concentration raised barriers to entry by making it increasingly necessary for competing manufacturers to own their own DAC businesses. It conferred an information advantage since sales through DACs are not captured in

¹A Special Health Authority established under section 11 of the National Health Service Act 1977.

the general reporting systems used within the industry, such as that operated by IMS, which enabled Coloplast to ‘hide’ sales information from its competitors. It conferred a marketing advantage by assisting Coloplast to build up a database on patients, which could then be used for the purpose of direct marketing.

2.87. Particular concern was expressed both over the future of Thackray nurses and over sponsorship by Coloplast of NHS nurses, and Coloplast’s ability to use these to promote its own products. It was put to us that if the company-employed and -sponsored nurses recommended Coloplast products in preference to those of competitor companies, then they would provide a particularly effective sales force with which others would find it difficult to compete. The range of Coloplast products following the acquisition increased the scope for this. Because prescriptions arising from the recommendations of Thackray nurses would normally be dispensed through Coloplast-owned DAC outlets, it would be difficult for competitors to monitor the recommendations of Thackray nurses.

Coloplast’s response

2.88. Coloplast argued that there should be no concerns over vertical integration, because:

- (a) many of its competitors owned DAC businesses;
- (b) it was easy for a new entrant to acquire a DAC business;
- (c) there was a requirement on DACs to supply the product specified on each prescription;
- (d) the Thackray nurses were independent and free to recommend products from any manufacturer; and
- (e) company-sponsored NHS nurses were not a significant factor in relation to continence care (Coloplast sponsored just one nurse) and their relationship with the company that sponsored them was controlled by the NHS.

Coloplast argued that the lack of transparency due to the non-reporting of sales through DACs was as much a handicap to itself as to its competitors. It believed that the role and professionalism of the advisers, who were the key determiners of the products used, provided important safeguards. It had no intention of compromising either the independence of Thackray nurses or their freedom to recommend products of any manufacturer, because to do so would not be in Coloplast’s commercial interests. Also, Thackray nurses were required to be independent under the nurses’ Code of Professional Conduct. The main advantage Coloplast saw to itself from the Thackray nurses was the benefits this link provided in the pursuit of its strategy of moving closer to customers in order to assess user needs and how products might be improved. (See paragraph 5.21.)

Assessment of concerns over DACs and Thackray nurses

2.89. Whilst it is clear that the merger increases the proportion of sheaths, urobags and intermittent catheters supplied through Coloplast-owned DAC outlets, there will still be a wide range of outlets through which patients can obtain appliances. There will remain a substantial number of alternative DAC outlets. In addition, users of continence care products in the community will usually have a choice of local pharmacies and other pharmacies offering home delivery services. The practice of the DAC outlets supplying appliances of all manufacturers is unlikely to change. The increase in the proportions of continence care products supplied through Coloplast-owned DAC outlets is unlikely to give rise to competition concerns in relation to the wholesale of continence care products, given the presence of numerous wholesalers including major wholesalers such as AAH and UniChem.

2.90. Any competition concerns depend upon Coloplast's ability to use its increased vertical integration arising from the merger to foreclose the market to competitors. Coloplast may benefit from its knowledge of a larger volume of sales, that are not captured in the general reporting systems for medical sales data available to its competitors. It may also benefit from the increase in size and value of its database for direct marketing purposes. We do not believe that these are, in themselves, damaging to competition. Few markets are fully transparent, and how far transparency is necessary or desirable for competitive markets remains a matter for debate. The extent of the access of manufacturers other than Coloplast and SSL to information on patients has not been reduced as a result of the merger. The role of the Coloplast Direct and ThackrayCare DAC businesses was growing prior to the merger, and we do not expect the merger to substantially affect that trend. We found no reason to believe that Coloplast will attempt to use its DAC businesses in ways more disadvantageous to competitors than would have been the case in the absence of the merger.

2.91. We examined carefully the position of Thackray nurses. We note that under the terms of their contracts of employment and bonus scheme Thackray nurses have no significant direct financial incentive to recommend Coloplast products. We accept that it is in Coloplast's commercial interests not to jeopardize the reputation of Thackray nurses for clinical independence, which confers a number of benefits both in terms of the ability of those nurses to gain access to patients and to medical staff concerned with continence care and in recruiting business for the ThackrayCare DAC outlets. We would therefore expect Coloplast to retain the freedom of Thackray nurses to recommend the products of its competitors.

2.92. Nevertheless, it appears to us that the employment of company nurses can confer indirect advantages to a company's sales team. It appears to us highly likely that there will be a tendency for Thackray nurses to recommend their employer's products where there are no good clinical reasons not to do. This may to some extent arise from simple loyalty to their company, but also from a greater familiarity with, and experience of, those products. Furthermore, a sales team attempting to promote greater use of its products in a nursing home, to be supplied through the company DAC business, might be helped by the availability of company nurses to assist with initial assessments and fitting.

2.93. Whilst not conclusive, we take as evidence for this indirect effect the proportion of SSL products supplied by ThackrayCare compared with SSL's share of supply for those products in the market as a whole (90 per cent of SSL sheaths compared with 59 per cent, 80 per cent of SSL urobags compared with 52 per cent, and 25 per cent of SSL intermittent catheters compared with 7 per cent—see Table 4.10). Coloplast argued that little could be deduced from simple comparisons with market averages, since Thackray nurses were among the most knowledgeable of continence care advisers and therefore might most readily appreciate the particular advantages of a product such as the Clear Advantage sheath. Whilst we accept that such comparisons need to be treated with caution, we note that the proportions of SSL product supplied were greater than the market average for every product type, including for intermittent catheters where SSL's products were not among the market leaders.

2.94. To assess the potential ability of Thackray nurses to influence the products used, we sought information on the proportion of users who might be seen by Thackray nurses in a year. Coloplast assessed this as 1.5 per cent, based on the ability of the current 23 nurses to see 30,000 patients a year out of an estimated total population of 1.9 million people suffering from incontinence. It is not clear to us that this is the appropriate measure. We believe that it would lead to estimates at the lower end of the possible range. We were unable to identify a more authoritative figure but, even assuming a much smaller population of possible users of the products with which we are concerned, a reworking of that calculation would not lead to a figure above 10 per cent.

2.95. Coloplast told us that it had no plans to increase significantly the number of Thackray nurses, and we have no reason to conclude otherwise. We are aware that the DoH is conducting

a review of the level of the on-cost payment to DACs, and the outcome of this review could affect the financing of company continence care nurses. However, we have no knowledge of the timing or content of any decisions arising from that review, and so were unable to consider these in our assessment.

2.96. Company sponsorship of NHS nurses raises a number of issues, which, we were told by the Royal College of Nursing, were a matter of continuing debate and review. However, the numbers do not appear significant in relation to continence care, where we learnt of only two current examples. A number of third parties were concerned that these numbers might grow in future. Whilst we cannot rule out future increases in numbers, the value of continence care products used does not appear sufficiently high to support major growth in this type of sponsorship.

Conclusions on vertical integration

2.97. We conclude that whilst the acquisition of the ThackrayCare DACs business will increase the proportion of continence care products supplied through Coloplast-owned DAC outlets and provide certain advantages to Coloplast, it is not on such a scale as to give rise to competition concerns in relation to supplies at retail or wholesale level of continence care products. In the absence of concerns over horizontal competition we do not judge that there should be competition concerns over vertical integration. We found nothing to lead us to expect that Coloplast will seek to curtail the independence of Thackray nurses and their ability to recommend products of other manufacturers. We do not expect the number of Thackray nurses, or of Coloplast-sponsored NHS nurses, to increase substantially as a result of the merger. Overall we conclude that the increase in Coloplast ownership of DAC outlets and Coloplast's acquisition of Thackray nurses resulting from the merger is not damaging to competition in the supply of sheaths, urobags and intermittent catheters in the UK.

Effect on the public interest

2.98. We now turn to consider the likely effects of the acquisition on prices, innovation, quality, service and consumer choice in the light of the above analysis and conclusions. Although the acquisition took place in September 2001 we consider it too soon to be able to assess these on the basis of what has occurred to date. We have therefore needed to form judgements as to what can be expected to happen in future.

Prices for supplies to hospitals

2.99. We concluded from our discussion of purchasing power (see paragraph 2.83) that though PASA and the equivalent bodies in Scotland, Wales and Northern Ireland have some purchasing power in relation to supplies to hospitals, the exercise of this power is dependent upon the availability from alternative suppliers of products whose clinical characteristics are sufficiently close to be regarded as acceptable substitutes within hospitals. In view of the interchangeability of different brands and types of urobag, the range of manufacturers seeking to compete with Coloplast on both price and product innovation, and the relatively modest increase in Coloplast's share of the market for urobags over that previously held by SSL, we would not expect higher prices for the supply of urobags to hospitals to result from this acquisition. Similarly we would not expect higher prices to hospitals for the supply of intermittent catheters given Coloplast's need to compete with Astra Tech's market-leading LoFric products and the increasing availability and market share of similar coated products from other manufacturers.

2.100. We see a greater risk of higher prices for sheaths to hospitals. We have previously noted the higher proportion of non-latex sheaths used in hospitals due to concern over latex allergy (see paragraph 2.63). PASA told us that, provided, as it expected, a full range of sizes was available in non-latex sheaths, it would not expect any latex sheaths to be included on the National Contract following the next tender round for which PASA would be seeking bids in March/April 2003 (see paragraph 4.11). We therefore examined, in particular, the position in relation to non-latex sheaths. We have also previously noted Coloplast's control, as a result of the merger, of the two major non-latex one-piece self-adhesive products which are each other's main competitors, and that the Rochester patent has provided an effective barrier to entry to others seeking to introduce silicon one-piece self-adhesive sheaths (see paragraph 2.76). We would expect the patent to continue to provide an effective barrier for the foreseeable future. Whilst Jade and Sims Portex offer silicon one-piece self-adhesive sheaths made by Rochester, which are similar to Clear Advantage, neither has a significant market share and we judge that neither will be able to offer PASA a realistic alternative to including Coloplast products in the new National Contract for hospitals. Our judgement on this is not changed by the acquisition of the urology business of Sims Portex by Mentor, announced on 6 May 2002. Because of the Mentor agreement, Sims Portex will not be able to distribute Clear Advantage sheaths in the UK before 2007 at the earliest even though it is owned by Mentor.

2.101. Rochester non-latex sheaths are also supplied to B Braun Medical (Braun), which has the right to distribute these in the UK but does not currently do so. Whilst Braun may choose to do so in the future, we see no reason to expect any such decision to have such a major impact on the market for sheaths in the UK in the timescale required as to alter significantly the position PASA will face. We identified one other manufacturer that expects to be in a position to offer a new non-latex one-piece self-adhesive sheath in this tender, [

Details omitted. See note on page iv.

] (see paragraph 2.62). Whilst this may increase the range of alternatives available to PASA, we judge that the time between the earliest possible introduction of this new product and the new tendering round is too short for it to have established a sufficient reputation with continence care professionals to offer PASA an adequate alternative to including the Coloplast products on the National Contract.

2.102. We therefore believe that Coloplast could obtain from PASA and/or its equivalent bodies elsewhere in the UK a higher price for non-latex sheaths than it could have obtained in the absence of the merger.

2.103. As a result of the acquisition Coloplast also controls the best-selling brands of latex sheaths. We therefore considered whether Coloplast could obtain from PASA and/or its equivalent bodies elsewhere in the UK a higher price for latex sheaths than it could have obtained in the absence of the merger if, contrary to our expectation, PASA concludes that it is desirable to include latex sheaths in the new National Contract. We note that Hollister Limited currently supplies its Incare range of latex sheaths to hospitals, and that these account for a significant proportion of all latex sheaths supplied to the hospital sector in England (see Appendix 4.3). This is therefore a product with which hospital staff involved in continence care are already familiar and which should, in our view, be able to provide PASA with a realistic alternative to inclusion of Coloplast latex sheaths should the price of the latter rise. We would not expect Coloplast to be in a position to obtain from PASA a higher price for latex sheaths than it could have obtained in the absence of the merger, therefore, even if, contrary to our expectation, PASA does include latex sheaths in the new National Contract.

2.104. We recognize that in setting the prices at which it will bid for inclusion of its sheaths in the National Contract Coloplast will be influenced by a desire not to provide entry opportunities for competitors, both because of the potential for subsequent effects on its sales of these products into the community and its commitment under its agreement with Mentor to taking substantial minimum volumes. We would also expect it to wish to avoid being seen to

behave unreasonably in view of the long-term importance to it of the NHS as a purchaser. However, whilst accepting that these considerations might act as some constraint on pricing, we expect the price of non-latex sheaths to hospitals to be higher than they would otherwise be in the absence of the merger. We recognize that in the future this position may be affected as a result of:

- (a) new alternatives coming to market and establishing themselves with the health service personnel who determine the products used in hospitals; and/or
- (b) ending of the Mentor agreement, scheduled for 2007.

However, these possibilities will not prevent higher prices in the short term, and we do not believe that either can be regarded as certain.

Prices for supplies to the community

2.105. Coloplast's high market share in sheaths and the other factors discussed above lead us to believe that, in the absence of effective price control, prices for sheaths supplied to the community would be higher as a result of the merger than would otherwise be the case. As previously noted, however, the amounts paid to pharmacies and DACs for continence care products supplied under prescription are set by the Drug Tariff. The price at which manufacturers can introduce new products on to the Drug Tariff is controlled. Their ability to increase the prices of existing products is also in practice limited by the formula agreed between the DoH and the ABHI.

2.106. It was put to us that a manufacturer with a sufficiently large market share might be able to force an increase in the Drug Tariff price of its products by threat of withdrawal of supply.

2.107. Coloplast told us that it regarded such behaviour as impossible, noting that any company that tried to do so would risk having its products removed from the Drug Tariff, thereby losing all or nearly all of its market in the UK.

2.108. The DoH told us that, whilst in principle such action by a manufacturer in a sufficiently strong position could not be ruled out, it was aware of no case in which it had actually happened in the continence care area.

2.109. We undertook an examination of the Drug Tariff over the last ten years, but did not discover any evidence of such increases. We do not regard it as likely that Coloplast could successfully employ a price-increasing tactic in relation to the supply of Coloplast sheaths to the community.

2.110. However, the ability of the Drug Tariff to constrain prices for sheaths obtained under prescription through pharmacies and DAC outlets does not totally eliminate the possibility of prices in the community being higher than they would otherwise have been in the absence of the acquisition. First, as previously mentioned, in some areas continence care products used in the community are no longer supplied under the Drug Tariff arrangements but depend upon tendering by PCTs (see paragraph 2.33). Whilst the Drug Tariff still provides some cap on prices, in that the use of the Drug Tariff arrangement continues as an alternative to tendering, it does not guarantee that prices for sheaths obtained through tendering will not be higher than they would otherwise have been below that cap. Although PCT tendering arrangements are currently rare, the DoH told us that it retained an open mind on the desirability of such arrangements, the use of which might grow in the future. Second, the constraint depends upon the Drug Tariff arrangements for sheaths continuing in place for however long the conditions which would otherwise give Coloplast some degree of pricing power persist. We were told by the


DoH that the discontinuation of the part of the Drug Tariff covering appliances had been considered in the past, although there were no such proposals currently under consideration.

2.111. In order to make an adverse finding in relation to the supply of sheaths in the community channel we would need to form an expectation that the merger would have an effect adverse to the public interest in relation to such supply in that channel. It is not enough that there should be some possibility of higher prices. While the Drug Tariff does not allow normal competitive forces to operate, we take the view that it provides the context within which to evaluate the effects of the merger. In the community sector sheaths will remain subject to the provisions of the Drug Tariff on the same basis as before the merger. We do not, therefore, expect that prices for sheaths in the community will be higher as a consequence of the merger.

2.112. We noted in paragraph 2.78 that the effects of the merger on competition would be less for urobags and intermittent catheters than for sheaths. Having concluded that we do not expect that prices for sheaths in the community will be higher as a consequence of the merger for the reasons stated in paragraphs 2.105 to 2.111, we conclude that we do not expect that prices for urobags or intermittent catheters in the community will be higher as a consequence of the merger.

Innovation, quality and service

2.113. Diminution of competition can also manifest itself through non-price effects—for example, through less innovation. In the absence of the acquisition, we would have expected Coloplast to be one of the companies developing new products or improving its existing products better to compete with the market-leading Clear Advantage sheaths sold by SSL. However, Coloplast has entered into the Mentor agreement as part of the merger transaction, giving it the exclusive right to distribute the Mentor product in the UK until 2007 and committing it to the purchase of substantial minimum volumes. The incentive on Coloplast to develop new and competitive offerings therefore appears much reduced.

2.114. Coloplast argued, however, that its commitment to developing improved sheaths remained undiminished, and it was developing a new [] sheaths [*Details omitted. See note on page iv.*]. It pointed out that the Mentor agreement only ran to 2007, and it had clear indications that Mentor would not wish to renew it beyond that date, at which point Coloplast would need an effective alternative of its own. Furthermore the Mentor agreement only covered distribution in the UK. Coloplast was in head-to-head competition with Mentor in other parts of the world. Coloplast further stressed that it was strongly committed to innovation, which it saw as a key to competition, and had an explicit goal of achieving at least 20 per cent of turnover from sales of products introduced within the last four years.

2.115. We accept that Coloplast's arguments have some force. The loss of head-to-head competition with Mentor sheaths in the UK, where Clear Advantage has a greater market share than elsewhere in Europe, may have reduced somewhat the pressures on Coloplast to innovate in the short term. However, given the factors identified by Coloplast, and that the majority of R&D on these products takes place overseas with a view to supplying the products in many different countries, we would not expect any significant adverse impact of the merger on innovation.

2.116. Loss of competition may also lead to a reduction in the quality of products supplied. However, because of the key role of a relatively limited number of advisers in determining the sheaths used and the emphasis on clinical performance, a product's reputation for quality is central to its success. Furthermore, Coloplast will need to maintain or improve the quality of its sheaths in other markets if its products are to remain competitive, and we do not believe that it would make sense for Coloplast to manufacture different, lower-quality, sheaths for supply to the UK. Nobody who gave evidence cast doubt upon the quality of Coloplast's products. In the

light of these considerations and the commercial incentive on Coloplast to maintain and improve quality, we do not expect the merger to have any adverse effects on quality of products.

2.117. Loss of competition may also lead to lower standards of service. Whilst we do not believe that this can be ruled out entirely, it appears unlikely that any reduction in standards of service could be limited only to service in the provision of sheaths, and competitive pressures on Coloplast to maintain and improve standards in relation to supply of its other products will be unchanged.

Rationalization of the product range

2.118. A number of those who commented drew our attention to the risk of rationalization of product lines leading to loss of consumer choice. They noted overlaps between certain products in the Coloplast and SSL ranges, the experience of rationalization following previous takeovers by SSL, and Coloplast's announcement that it would be withdrawing the AquaCath product. Coloplast said that it had no plans to withdraw products other than AquaCath, whose withdrawal had been forced on it as a result of the fire in Scunthorpe (see paragraph 3.43). Withdrawal of products was bad for a company's reputation among both users and their continence advisers, and it reduced market share. Coloplast argued that product withdrawal therefore made little commercial sense except where unavoidable (see paragraph 4.157).

2.119. We accept that there are costs to withdrawing a product, including reputational costs. However, these must be offset against the normal advantages of greater efficiency in manufacturing and marketing arising from removal from the market of poorly-performing products. Whilst we do not believe that the possibility of some degree of product rationalization can be ruled out, we do not expect the rate of product withdrawal as a result of the merger to be detrimental to the public interest.

Benefits of the merger

2.120. Having reached conclusions on possible adverse effects of the merger, we now turn to consider whether there are benefits. Coloplast said that it would devote 4 per cent of its, increased, turnover to R&D, leading to greater innovation informed by improved understanding of patient needs, and identified this increase when compared with the situation under Coloplast and SSL separately as a benefit to the public interest. We considered the effects of the acquisition on innovation above. Whilst we would not deny that overall expenditure on R&D is likely to rise and some benefits can be expected to come from this, any incremental effect is likely to be modest, especially in relation to the scale of R&D that is undertaken internationally by Coloplast and other manufacturers.

Conclusions on the public interest

2.121. We expect that the acquisition will, through its impact on competition, result in the cost of non-latex sheaths to NHS hospitals in the UK being higher than would otherwise have been the case. We do not believe that the detriment that we have identified will be outweighed by any benefits to the public interest.

2.122. We conclude that the acquisition by Coloplast of the continence care business of SSL is expected to operate against the public interest with the adverse effects specified in paragraph 2.121.

Remedies

2.123. We discussed a range of hypothetical remedies with Coloplast on the basis of our Remedies Statement published on 4 April 2002 (see paragraph 5.27). However, we limit our consideration here to remedies that might be appropriate in the light of our finding that the acquisition is against the public interest through its impact on competition in non-latex sheaths in NHS hospitals.

2.124. Coloplast did not accept that its acquisition of the continence care business of SSL could be expected to operate against the public interest. However, it stressed that should the CC take a different view then any remedy should be proportionate, imposing no greater remedy than is necessary to address the detriment identified. Coloplast put it to us that if our main concern was over a possible impact on the price of sheaths to hospitals, then:

- (a) Coloplast would be prepared to commit to an agreed price cap with the NHS in relation to sheaths to all hospitals in England which Coloplast supplies; and
- (b) in order to ensure that such controls would not need to be in place indefinitely, Coloplast would commit not to renew the Mentor agreement at the end of the current contractual period in 2007, which could be expected to lead to a significant reduction in Coloplast's share of the supply of sheaths in five years' time.

2.125. Coloplast further argued that if a structural remedy was felt to be necessary, then any requirement for Coloplast to divest the business acquired from SSL as a whole, or the sheaths business acquired from SSL, or to terminate the Mentor agreement, or to grant to a third party an exclusive right to distribute Conveen sheaths in the UK in perpetuity, would be disproportionate. It would, however, be willing to contemplate a renegotiation of the Mentor agreement. It envisaged two ways in which this might be achieved. Either:

- (a) Coloplast might undertake to enter into negotiations with Mentor to make the agreement non-exclusive, ensuring that the right to use the Clear Advantage trademark in the UK reverts to Mentor and that Coloplast ceases further use of that trademark. As an alternative, Coloplast would grant to a person approved by the DGFT an exclusive licence of the Conveen trademark for use in the UK in relation to those sheaths to which it is applied in the UK at the date of the undertaking, until expiry of the Mentor agreement, and enter into an agreement with the licensee for the supply of Conveen sheaths; or
- (b) Coloplast might undertake to enter into negotiations with Mentor to cease supply by Mentor to Coloplast of the sheaths to which the Clear Advantage trademark is applied in the UK and cease any further use by Coloplast of the Clear Advantage trademark in the UK. As an alternative, Coloplast would license and supply its Conveen sheaths as in (a) above.

2.126. In our consideration of remedies, we start by noting that the detriment we have identified arises from the Mentor agreement which, in combination with the merger, has the effect of concentrating in Coloplast's hands control, at least until 2007, of the two market-leading brands of non-latex sheaths in the UK. These had previously been in head-to-head competition. A remedy that directly addresses this cause and restores competition in the sheath market would therefore appear to us to offer the best outcome if one is available that is not disproportionate, bearing in mind the nature of the detriment we have identified and the possibility that the Mentor agreement will not continue beyond 2007.

2.127. We do not believe that a limited licence arrangement covering supply of Conveen sheaths in the UK, as suggested by Coloplast (see paragraph 2.125), would be effective in restoring competition. Creating barriers within Europe between Conveen sheaths supplied under licence in the UK and products of the same name supplied elsewhere, appears to us


undesirable and liable to lead to confusion in the minds of prescribers. In discussion Coloplast acknowledged this risk and the detrimental effect such confusion might have on the public interest. We put it to Coloplast that a licence for such a limited period may be unattractive to prospective licensees. Coloplast argued that it might be attractive to an existing supplier seeking to reinforce its sales volume and revenues for broader strategic reasons, although it acknowledged that such a licence would not be of interest to any who, like Coloplast itself, saw the market as European. It appears to us that any such licensee would provide less effective competition to Clear Advantage than would have been provided by Conveen sheaths in the hands of Coloplast itself had the merger not occurred. Our concerns are compounded by the risk that Conveen sheaths being sold in Europe by Coloplast may find their way into the UK through secondary markets.

2.128. Remedies dependent upon modifying the Mentor agreement raise difficulties of a different kind. The agreement is subject to the laws of New York and Mentor is not within the UK jurisdiction. Moreover, the power of the Secretary of State to transfer the benefits of the agreement enjoyed by Coloplast to a new party is legally constrained. If the Secretary of State were, by order, to limit Coloplast's ability to exercise its rights under, or to carry out, the agreement, it seems to us that the effects could be damaging to Coloplast, without necessarily ensuring the continued availability of Clear Advantage sheaths in the UK.

2.129. We therefore take the view that any changes to the agreement between Coloplast and Mentor would be best achieved through negotiation. The aim of such a negotiation should be to secure either divestment of the Clear Advantage brand, leaving Coloplast with the right to source the silicon sheaths but market them under a different name, or divestment of the Clear Advantage brand and product, which would involve terminating the Mentor agreement with respect to the silicon sheaths. Either of these outcomes would appear to us to represent an acceptable way to address the detriment that we have identified.

2.130. Coloplast told us that it believed that Mentor would be keen to renegotiate the Mentor agreement either to secure its early termination or to make it non-exclusive. Contact with Mentor leads us to believe that this is the case.

2.131. We considered the alternative of a remedy based on controlling the price at which Coloplast would supply non-latex sheaths to NHS hospitals until the expiry the Mentor agreement in 2007, together with an undertaking by Coloplast not to renew or otherwise enter into any agreement having similar effect to the Mentor agreement beyond that date. It would certainly be possible to impose a price cap so as to ensure that the prices of Coloplast non-latex sheaths supplied to NHS hospitals throughout the UK do not rise between now and 2007. There are, however, disadvantages:

- (a) Competitive tendering for inclusion in the contracts for hospital supplies is the one area in which price competition has played a significant role in the supply of continence care products to the NHS. The introduction of price controls for Coloplast sheaths will reduce the role of price competition and may further inhibit new competitive entry.
- (b) The continuation of the current agreement between Coloplast and Mentor, with its minimum volume obligations, will reduce the incentive on Coloplast to market aggressively before the ending of the agreement in 2007 the new [] product which Coloplast told us it was developing, even if that product is available before that date.

2.132. By contrast, amending the Mentor agreement in relation to Clear Advantage avoids these difficulties by facilitating competition in non-latex sheaths and, in our view, provides the better approach providing it can be achieved without unreasonable economic damage to Coloplast.

Recommendations

2.133. We accordingly recommend that Coloplast be required to give an undertaking to the DGFT that it will use its best endeavours to negotiate an agreement with Mentor to achieve either of the outcomes specified in paragraph 2.129. It is important that such negotiations take place expeditiously, bearing in mind that PASA expects to seek new tenders for the supply of sheaths to hospitals in England starting in March/April 2003.

2.134. The issues involved are complex and we cannot anticipate the precise outcome of those negotiations. We do not feel it appropriate to specify at this stage what should occur in the event of unforeseen and insuperable difficulties arising. We further recommend, therefore, that, in the event that no such agreement has been put in place in a form acceptable to the DGFT within six months of the date of publication of this recommendation, then the DGFT takes such other action as he deems appropriate. In deciding on such action the DGFT will wish to have regard to the specific nature of the detriment we have identified, the need for speedy resolution in view of the impending tender round, the effect of the acquisition by Mentor of the urology business of Sims Portex announced on 6 May 2002, and the need for any action to be proportionate. The option of a price control remedy together with an undertaking from Coloplast not to renew the Mentor agreement beyond 2007 will continue, despite its drawbacks, to be among those available for consideration.

2.135. We add one final comment. It became clear to us in the course of our inquiry how far the behaviour of companies supplying continence care products in the UK is influenced by the impact of regulatory arrangements which have the effect of either distorting competition or limiting the scope for normal price competition. In particular, two-tier pricing as between supplies to hospitals and supplies to the community (and the role of sales to the former as a gateway to sales in the latter) may produce a pricing structure which is not related to costs in the two sectors and thus distort normal patterns of competitive entry. Furthermore arrangements under the Drug Tariff and its equivalents appear to offer little incentive to suppliers of products to negotiate prices significantly below those of similar products already listed or, once they have obtained a listing, to reduce prices to reflect economies achieved in production costs. In addition, the use within the Drug Tariff of different formulae for remunerating pharmacies and DACs for appliances supplied under prescription gives DAC businesses an advantage over pharmacies that may be unrelated to the costs incurred by the respective operations (see paragraph 2.28).

2.136. We understand that the DoH has had the level of on-cost payable to DACs under review for some time and we would encourage those responsible to bring this review to a conclusion as soon as possible. As regards the other points noted above, we invite the DGFT to consider whether a review of potential anti-competitive effects of the current rules in relation to the supply of appliances might at some stage be appropriate, having regard also to the broader context of NHS reforms.