

6 Views of third parties

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Introduction

6.1. We invited views 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 other interested parties. This chapter summarizes the evidence we received. Oral hearings were held with AAH, the Association for Continence Advice (ACA), Astra Tech, Bard, the DoH, Flexicare, Hollister Limited, Jade, PASA, PromoCon and a senior continence adviser within the NHS.

Manufacturers

Astra Tech Ltd

6.2. Astra Tech told us that it was a division of the Swedish company Astra Tech AB, a company in the AstraZeneca Group of companies. In the UK it operated in the urological, surgical and dental markets, urology being its main area of operation with 80 per cent of the company's turnover. The only urology products it supplied in the UK were intermittent catheters which were made in Sweden. Astra Tech said it was concerned that the acquisition, which had left Coloplast in a dominant position in at least three markets, might result in product rationalization, a reduction in competition in the UK, and possibly lead to price rises ultimately paid for by the taxpayer. It was opposed to the merger and did not believe it was in the public interest.

6.3. Astra Tech said that the product market could be divided into products that (a) contained urine and were applied externally to the body and (b) products that drained urine retained in the bladder. It believed the continence market was worth about £75 million. The three main suppliers were Coloplast, SSL Continence Care and Bard.

6.4. Although Astra Tech UK was only responsible for sales in the UK and Ireland, the Astra Tech intermittent 'LoFric' catheter was sold in most European countries by sister companies that worked in much the same way. There were, however, national differences in the reuse of catheters, possibly on cost grounds. They tend to be reused in the UK but not in Europe.

6.5. Astra Tech said that there was considerable inertia in the market for continence care products, in that once healthcare professionals were familiar and happy with a product, it took quite an effort to persuade them to recommend the products of another company.

6.6. Astra Tech said that price was largely irrelevant in relation to the hospital market because of the volume of free samples companies provided in an attempt to secure patients as long-term users in the more profitable community market. It was concerned that in the latter market the Drug Tariff would not, following Coloplast's acquisition of SSL's continence care business, protect the NHS against the possibility of price rises.

6.7. Astra Tech said that there was little parallel importing of continence products.

6.8. It said that not having a DAC was a barrier to entry into the continence care market in the UK, but they could be purchased. It believed the provision of free samples, holding conferences for healthcare professionals and providing training for nurses were essential for effective marketing purposes. It did not regard patents or obtaining a listing on the Drug Tariff as being insurmountable barriers to entry. New entrants did not require a sales force because they could operate through DACs that had their own nursing services.

6.9. Astra Tech estimated that after acquiring SSL's continence care business Coloplast had significant market shares in sheaths (90 per cent), leg and night urobags (55 per cent), single-use intermittent catheters (35 per cent) and reusable intermittent catheters (20 per cent). Coloplast's share of the intermittent catheter market had increased significantly since 2001 and had continued to do so after the acquisition. Astra Tech believed that Coloplast's undoubted dominance in both the continence and stoma markets would enable it to provide a wide range of products and offer portfolio deals with which smaller companies could not compete.

6.10. Astra Tech also pointed out that as part of the acquisition Coloplast had acquired the ThackrayCare nursing service and additional DACs. The Thackray nurses were in a strong position to recommend and influence which products were used and could pass prescriptions to Coloplast's own DACs. Use of its own DACs could make it easier for Coloplast to bypass the traditional wholesale route and supply direct to patients, thereby avoiding discounts to wholesalers or pharmacists. In this way Coloplast could, depending on the number of Coloplast and ThackrayCare DACs it used, maximize its handling fee from 15.8 to 25 per cent on the prescriptions it dispensed. The additional profit Coloplast could gain by avoiding discounts to wholesalers allied to the handling fee obtained could cover the costs of its own Thackray nurses and possibly allow it to sponsor more NHS nurses.

6.11. Astra Tech was concerned that patients on the ThackrayCare database, using other reusable or single-use catheters, could be encouraged to switch to Coloplast catheters via Coloplast Direct, for commercial rather than clinical reasons. It was also concerned that Coloplast might exercise control over its Thackray nurses who could favour Coloplast products when advising GPs.

Bard Limited

6.12. Bard told us that it was a subsidiary of C R Bard Incorporated, a US company, and that it was a UK supplier of continence products. C R Bard had a worldwide turnover of \$1.1 billion. It started as a urology company but now focused on four areas: urology, surgical products, peripheral technologies and radiology. Bard was the UK market leader in long-term indwelling catheters, also known as Foley catheters, and also competed in the sheath, bag and intermittent catheter markets.

6.13. Bard said that the UK was part of a European market characterized by different reimbursement and healthcare delivery systems. It said that the UK market was favourable because more patients were being treated in the community than in hospital. The main suppliers were Coloplast (25 per cent) and Astra Tech (70 per cent) in the intermittent catheter market, Coloplast and Rüsck UK in the permanent catheter market, Coloplast (55 per cent) in the urinary bag market and Coloplast (94 per cent) in the sheath market. The intermittent catheter market was the fastest-growing sector of the entire urinary catheter market, with a growth rate of about 10 per cent a year.

6.14. Bard said that parallel imports were a feature of the UK market and that the products imported were often inappropriately packaged. [*Details omitted. See note on page iv.*]

6.15. Bard said that manufacturers marketed their products in a number of ways, including the provision of free samples (including ancillary products), by holding exhibitions and conferences, employing a sales force and by offering sponsored nurses to PCTs and hospitals. Bard believed that sales representatives were paid a fixed amount for each patient recruited. Manufacturers directed their main marketing effort towards urology nurses, continence advisers, patient user groups and those within PCTs and hospitals directly responsible for purchasing. Bard believed that members of the Association for Continence Advice had been asked to provide patient data in exchange for educational remuneration.

6.16. Bard said that the combination of a leading market share, numerous DACs, the use of sponsored nurses and/or Thackray nurses formed an impenetrable barrier to entry for companies such as itself. Bard believed the current pricing structure deterred manufacturers from introducing innovative products. However, it said that within five to ten years drug therapy could transform the way incontinence was treated; the only limitation would be cost. It was not aware of any patents preventing entry into any of the product markets.

6.17. Bard said that product prices within the hospital sector tended to be lower than in the community sector because manufacturers hoped to establish patients on their product before they were discharged into the community. Some competitors chose to sell their products to hospitals at a loss. [*Details omitted. See note on page iv.*]

6.18. Bard said that Coloplast had acquired an additional four to five DACs as a result of the acquisition. Companies chose to acquire DACs because they offered a number of strategic and financial business advantages, including the opportunity to:

- (a) build patient databases, which enabled a company to protect its business from competitors and market directly to patients;
- (b) 'hide' the sales of incontinence/stoma products from manufacturers who subscribed to and purchased sales data from IMS; and
- (c) increase profitability through reduced discounts to distributors.

6.19. Bard said that patients referred to DACs had a limited product choice because the company responsible for their care would simply issue repeat prescriptions rather than have them reassessed by a healthcare professional. Coloplast operated its DACs in conjunction with its Thackray nurses, which it used as an extension of its sales force. Coloplast employed a team of over 20 Thackray nurses who were given the objective of registering as many patients as possible on to the ThackrayCare prescription service. Thackray nurses obtained patient registration through discharge planning nurses in hospitals or continence nurses in the community. Once a patient was registered, a prescription was almost always written for Coloplast or SSL products. Bard said that the practice of giving hospitals free products to ensure patient registration and subsequent product sales within the community was common. Patients were rarely asked for their input about the service or product choice.

6.20. Bard believed that Thackray nurses did not necessarily choose objectively. It had been told by patients using Thackray nurses that they could no longer get Bard's product because there was a problem with supply. Bard found that in markets where it was competing with Coloplast, the volume of its product bought by ThackrayCare was declining. It believed that this would continue given Coloplast's range of products and its dominant market share.

6.21. Bard said that the Thackray nurses also provided continence care for patients discharged from hospital in lieu of community-based continence advisers and district nurses. This practice was likely to lead to the clinical deskilling of community-based continence carers and the loss of funding for continence posts in the PCTs.

6.22. Bard said that Coloplast's direct prescription service did not provide transparency of sales activity or market share: sales made through DACs were not reported through IMS's statistical service. Bard believed that Coloplast had larger market shares in sheaths and intermittent catheters than had been reported through IMS. This situation created a very uncompetitive marketplace for other manufacturers. Bard estimated that the value of the UK continence business not reported through DACs to be worth £6 million.

6.23. Bard said that in an effort to increase product sales and improve market share Coloplast had offered to sponsor continence nurse positions in hospitals and [redacted]. These nurses provided patient care and strongly encouraged the use of Coloplast's products. During the term of the contract other manufacturers were locked out. Patients did not participate in the decision-making process, thus being denied product choice. Bard believed nurse sponsorship was an unethical practice because it compromised the nurses' prescribing objectivity and deprived the patient of the most clinically appropriate continence care product. Bard said that it had been told by the [redacted. See note on page iv.], with which it had an existing business relationship, that Coloplast had offered two sponsored nurse posts in return for [redacted] sheaths, bags and intermittent catheter business. It believed that if [redacted] accepted this offer there would be a strong possibility that all community-based patients discharged through [redacted] would move on to Coloplast/SSL products. Bard also said it had been told that Coloplast/SSL had offered three [redacted] free bladder scanning equipment in exchange for direct access to the [redacted] patient and nurse databases and a defined level of product purchases. Bard viewed this as an unfair inducement, highly aggressive and a strategy aimed at eliminating competition in the marketplace.

6.24. Bard said that the acquisition gave cause for concern in respect of Coloplast's increased market share, additional DACs and questionable marketing practices. The principal area of concern was the sheath market, which was dominated by Coloplast. The acquisition would enable Coloplast to offer portfolio deals and would result in decreased competition, higher prices, limited patient choice, less product innovation and fewer new entrants into the market. The acquisition had consolidated Coloplast's dominant market position [redacted. See note on page iv.]. This was not in the public interest and would impact on the standard of nursing care, denying patients the freedom of choice with regard to their care.

6.25. Bard believed that Coloplast should be required to divest the continence care business acquired as a result of the acquisition. Failing that it suggested a combination of several structural remedies including the divestment of the sheath business acquired as a result of the acquisition, or of several DACs or of the Thackray nursing service. It did not believe it would be possible to satisfactorily regulate or enforce behavioural remedies.

Clinimed Ltd

6.26. Clinimed Ltd said that it had minimal interests in the continence care market and was not opposed to the acquisition.

Flexicare Medical Limited

6.27. Flexicare told us that it was involved in the manufacture and marketing of a wide range of medical appliances. These activities involved the production of urology products, including urine bags. Flexicare said that it supplied other companies under contract and offered its own branded products in the UK and in some European markets. Flexicare's turnover was estimated at £5 million a year, of which 10 per cent related to its continence care business. It believed that Coloplast would, through its increased product range and market shares, have total control of the market. This would be of concern to smaller companies and ultimately the consumer.

6.28. Flexicare said that the continence market consisted of two separate sectors, ostomy and urology. Most suppliers operated in both sectors because the ability to offer a wider range of products strengthened their marketing power. The main suppliers were Bard, Rüsck UK, Tyco and Coloplast for Foley catheters; Astra Tech, Bard and Coloplast for intermittent catheters; Coloplast for sheaths; Bard, Coloplast, Flexicare and Maersk Medical for leg bags; and Bard, SSL, Maersk Medical and Flexicare for night drainage bags. As a result of the acquisition, and based on the prescription audit report 1998, Coloplast would have a very high market share. It had combined market shares in the sheath, leg bag and night drainage markets of 93, 56 and 57 per cent respectively. Coloplast had an overall market share of 47 per cent. Flexicare said that the community market was worth about £49 million and the hospital market about £10 to £12 million. It believed the market was growing at about 6 to 8 per cent a year.

6.29. Flexicare said that the UK market differed from the European market in terms of the system for reimbursement and the frequency with which products were used. The community market in the UK was larger than the community market in Europe.

6.30. Flexicare said that the number of new entrants into the continence care market had been very limited. Companies found it hard to enter what was a very competitive market unless they had manufacturing capabilities or had access to a low-cost manufacturer. The main barriers to entry were the cost of marketing a product, the length of time taken to obtain a listing on the Drug Tariff, the existence of patents on the components of certain products and the practice of discounting to hospitals. It believed that entry by companies involved in the manufacture of plastic or plastic-based products was possible, provided they met the requirements of the Medical Devices Agency and went through the process of evaluating and validating new products. European manufacturers could theoretically supply the UK market but would have difficulty marketing products that had brand names which were unfamiliar to continence care professionals. Flexicare said that it had been eliminated from two hospitals because of the support services provided by a competitor.

6.31. Flexicare said that the principal decision-makers as regards choice of product were the Continence Adviser and District Nurse. GPs generally did not get involved in selecting products. Switching did occur, though generally a patient would remain on a product unless it became unavailable.

6.32. Flexicare said that the prices of products sold in the hospital market were subsidized in order to generate business in the community market (where prices were much higher) and prevent new entry. The community market was not price-sensitive because products were provided on prescription at the recommendation of the continence adviser or district nurse, who were not particularly concerned about price. Flexicare was concerned that the acquisition would enable Coloplast to increase its already high share of the community market.

6.33. Flexicare said that the sponsorship of nurses and continence advisers resulted in the recommendation and prescription of the sponsors' products. The acquisition would enable Coloplast to sponsor nurses and continence advisers to a greater extent. Smaller companies could not afford this kind of marketing cost, which put them at a competitive disadvantage.

6.34. Flexicare believed Coloplast had acquired SSL's DACs as a result of the acquisition. It did not believe that the process of referral and prescription by company-supported nurses was always neutral and expected this unfair practice to continue.

6.35. Flexicare believed that Coloplast had, following the fire at SSL's manufacturing facility in Scunthorpe, decided to subcontract the manufacture of urine bags to Maersk Medical, which manufactured the majority of bags for the European market. Any alliance between these two companies would not be in the interest of customers.

Hollister Limited

6.36. We were told that Hollister Limited (Hollister) was a wholly-owned subsidiary of Hollister Incorporated, a medium-sized healthcare company based in the USA with manufacturing facilities in the USA and the Republic of Ireland. Although Hollister's core business was said to be ostomy/stoma care products, it also had a portfolio of continence care products. Hollister's total turnover in 2001 was £15 million, of which less than £1 million was generated by its continence care business in sheaths, intermittent catheters and bags.

6.37. Hollister told us that it targeted the UK only and did not believe it could cover the whole of the EC from one base. It saw its main competitors in the UK continence care market as Coloplast (sheaths, intermittent catheters, leg bags and night drainage bags), Astra Tech (intermittent self-catheters) and Bard (night drainage bags). [

Details omitted. see note on page iv.

] Its market share was therefore only 2.4 per cent. Hollister's share of the intermittent catheter market was about 3 per cent and of the bag market 0.4 per cent. Hollister considered the intermittent catheter market to be growing, the permanent catheter market to be static and the sheath market to be growing very slightly. The bag market was thought to be in decline. Competition in all markets was said to be tough.

6.38. Hollister regarded specialist nurses as the most important element in deciding which continence care products were used and therefore targeted its marketing campaign at them mainly through advertising. Hollister believed that specialist nurses tended to become attached to certain products and thought it difficult to tempt them to try others unless these were innovative products offering patient benefits. R&D was therefore very important.

6.39. Hollister thought that the bulk of intermittent catheter clinical assessment was carried out in hospitals and acknowledged the importance of 'pull-through' where products used in hospitals were then supplied through prescription when patients were discharged into the community. Hollister considered clinical judgement to be the most important factor in product choice but thought that price was also important. It said that although some products were to a certain extent interchangeable, switching between brands and products was rare as also was changing treatment types except in the event of a change in the patient's condition. It considered the principal element of competition to be within rather than between appliance ranges and that innovation had been crucial in developing the continence care market.

6.40. Hollister had not sought to increase sales volumes by reducing its Drug Tariff prices. It thought that the Drug Tariff acted as a ceiling on prices. It further thought that products supplied to the NHS were, or could be, significantly cheaper than those supplied to the community market. On-costs charged by Logistics were, however, thought in some cases to push up hospital prices beyond those on the Drug Tariff.

6.41. With regard to NHS tendering through PASA, Hollister thought there might be a move to tendering by individual PCTs and that with more than 500 of the latter, this would present problems for the smaller suppliers. Hollister also noted that some PCTs were drawing up product formularies, but felt that this had not yet affected its own operations.

6.42. Hollister believed that manufacturers' margins in the UK were squeezed because they could not raise their prices. They were, however, obliged to offer discounts to wholesalers, which varied according to the volume of product handled. Raising discounts to wholesalers increased the volume of products sold only for a short period and had no impact on the clinical judgement of the continence specialists.

6.43. Hollister thought it was the only new entrant into the continence care market in recent times with its intermittent catheters and could think of no companies that had left the market.

6.44. Hollister believed that there was a considerable amount of parallel importing of continence care products generally but not of Hollister brands and had not therefore needed to take any action in that regard. Parallel importing was not regarded as a significant barrier to new entrants. It could, however, deprive individual companies of sales in particular countries.

6.45. Hollister saw the main barrier to entry for new companies as being sheer weight of competition. It regarded patents as being important and considered regulatory procedures to be difficult and costly where new, innovative products were concerned. Sales forces were considered important marketing tools. Hollister had its own DAC (TVM) but believed that obtaining one was not easy. It acknowledged that there was a lack of clarity in the sales data of DACs. Hollister received data from other DACs but was unable to validate it. Research findings and literature were essential for new products.

6.46. With regard to marketing practices, like other manufacturers Hollister felt obliged to give free samples of its products to decision-makers. It had not itself sponsored conferences nor invited decision-makers to any of its factories but was aware that other manufacturers had. Hollister also believed that nurses were put under pressure, for example to supply patient databases, but did not know if these practices had increased following the Coloplast/SSL merger. Hollister believed that NHS Trusts' hospital management should do more to manage the sponsorship of nurses since companies were clearly involved in sponsorship for some sort of return. It was also concerned about direct marketing to patients.

6.47. Hollister believed that ThackrayCare operated six DACs and employed 22 nurses. It saw some conflict where manufacturers owned both a DAC and a nursing service but thought that this depended largely on how aggressively a company marketed its own products. It did not know how Thackray nurses were incentivized but believed that some felt they were being pressed to be too sales-orientated and that the objectivity of clinical judgement might be infringed. Hollister had two nurses operating through TVM, who were not incentivized to sell Hollister products. There were no other nursing services on the scale of Thackray.

6.48. Hollister said that the merger had reduced competition dramatically in the sheath, leg bag and night drainage bag markets and because the market share of other suppliers was relatively small, Coloplast had achieved a monopoly position in those markets. It did not, however, believe that Coloplast could use this position to impose price increases on the hospitals or the Drug Tariff for fear of letting in its competitors.

6.49. Coloplast might resort to 'portfolio selling' in the community market. This might include its stoma and wound care products. Hollister thought that because bags were arguably less sophisticated products, this sector of the market might be more readily accessible to new entrants including generalist manufacturers of plastic-based products. Hollister did not believe that the merger would lead to a significant rationalization of product lines within Coloplast and saw no danger of a reduction in patient choice. Hollister was, however, concerned that if a significant move towards PCT tendering were to occur, Coloplast would be in a strong position to benefit.

6.50. [

Details omitted. See note on page iv.

]

Jade-Euro-Med Ltd

6.51. Jade told us that it was a small family-run concern, which manufactured surgical appliances in the incontinence field. These included sheaths, bags and other body-worn appliances in similar

proportions. It also distributed sheaths produced by Rochester Inc in the USA. It was opposed to the acquisition because it would enable Coloplast to dictate pricing and product availability, which in turn would result in limited product choice for both the NHS and the end-user.

6.52. Jade considered the UK market to be unique from other European countries in many areas. It thought the UK market was more advanced in terms of product development and choice. It also saw a major difference in the way prices were set in Europe, where most incontinence sufferers had to buy their own equipment.

6.53. Jade believed Coloplast now controlled 30 per cent of the intermittent catheter market, 56 per cent of the bag market and 92 per cent of the sheath market. Coloplast's total share of the UK continence market was thought to be 51 per cent. Jade had a 1 per cent share of the sheath and leg bag markets. It had hoped to increase its market share by supplying wholesaler groups and hospital networks but found it virtually impossible because of the way SSL had marketed itself. Whenever Jade started hospital trials, SSL would offer a substantial supply of free samples to discourage the hospital concerned from purchasing from Jade. Jade also claimed that hospitals would not allow small companies like Jade to tender for contracts.

6.54. Jade said that new entry was unlikely because a new entrant would need to acquire a DAC, establish its own nursing service, invest heavily in advertising, have the ability to manufacture its own products, and provide free samples to the hospital network. A new entrant would require millions of pounds for marketing. It did not believe that the Drug Tariff was a barrier to entry.

6.55. Jade said that the Thackray nursing service was no longer independent. It believed that prior to the acquisition Thackray nurses had been paid a form of commission dependent on the sale of SSL's products and received larger bonuses for products SSL wished to market in the community. Brand switching and directional selling were therefore common.

6.56. It believed the acquisition would, in the long term, result in price rises, which the Drug Tariff would be unable to prevent because Coloplast would eventually be the dominant supplier and able to dictate to the marketplace. Jade thought that in the next four years Coloplast would be in a position to threaten not to supply a particular product.

Mentor Corporation

6.57. Mentor described itself as a publicly traded company based in California with manufacturing facilities and subsidiaries throughout the world including Mentor Medical Systems UK, Mentor Medical Limited and Porges UK Ltd. It told us that it developed, manufactured and marketed specialized medical products, including surgical urology and disposables, that were sold to hospitals, physicians and various healthcare dealers, wholesalers and retail outlets. It viewed Europe as one market.

6.58. Mentor said that it had had an exclusive distribution agreement with SSL for many years and had supplied it with certain products, primarily male sheaths, which were protected by patent. Following Coloplast's acquisition of SSL's continence care business, Mentor had agreed to transfer this agreement to Coloplast. Mentor noted that the CC's possible structural remedies included the termination of this agreement. Mentor said that it would be willing to accept this proposal or to make the distribution agreement non-exclusive.

6.59. Mentor did not oppose the acquisition and believed it would not adversely affect its own business or the public interest. It competed with Coloplast in various geographic and product markets and would continue to do so in the future, either by introducing new products, enhancing existing products or by acquisition.

The Rochester Medical Corporation

6.60. Rochester, which had its headquarters in the USA, told us that it had invented and patented an all-silicon self-adhering male catheter in 1991, which it sold to Mentor under an exclusive supply agreement. Rochester believed that Mentor, which had previously supplied ThackrayCare and SSL, had now signed a new five-year agreement with Coloplast to continue supply. Rochester added that SSL's

main competitors had been Coloplast, Sims Portex and Bard and pointed out that Sims Portex sold silicone catheters purchased from Rochester.

6.61. Rochester said that the acquisition would be beneficial in that it would guarantee that the UK had access to all available sheath types. It believed that the UK sheath market remained competitive: the silicon sheath would be available in the UK from four competing suppliers, in addition to non-latex and latex products sold by competitors.

Tyco Healthcare UK Ltd

6.62. Tyco stated that from its own product portfolio perspective the merger did not have any impact on its business.

A manufacturer of continence appliances

6.63. A manufacturer of continence appliances said that the linkage between the hospital and community markets was strong. If patients were assessed and fitted with an appliance in hospital (even as an outpatient) they would expect to be prescribed the same product in the community. The manufacturer said that it was in a company's interests to secure hospital contracts even if that meant selling products at cost price because the margins in the community were so high. Small companies did not have the resources to compete in this way.

6.64. The company said that a product had to be listed on the Drug Tariff or available through the NHS supplies catalogue in order for it to be considered by the healthcare professional. It found that even though its products offered significant cost savings, equal functionality and, in the majority of cases, additional features making them more comfortable and secure for patients, healthcare professionals still used the products with which they were familiar. Although the company had received awards from the Association of Continence Advice and the British Association for Urology Nurses for having the best product and being the most innovative company, it had difficulty trying to arrange appointments within the hospital network. Product choice within hospitals was generally limited to what an NHS Trust had decided to buy on contract. Many NHS Trusts prepared formularies of medical appliances recommended for use by its staff. Formularies varied from Trust to Trust. Small companies did not have the resources to make representations to Trusts even if they knew formularies were being drafted. As a result of the acquisition, Coloplast had by far the largest number of hospital contracts, enabling it to introduce new products into the marketplace. In the community, healthcare professionals could theoretically obtain a prescription for any product on the Drug Tariff. However, product choice was often determined by whatever free samples were available.

6.65. The company said that the supply of self-adhesive sheaths to the UK was governed by a worldwide patent held by Mentor. Following the acquisition Coloplast had by far the largest market share, comprising its own two-piece systems and Mentor's one-piece product. Various one-piece sheaths designed to circumvent the patent had had limited success. The patent was a major barrier to entry. The company said that even if it had the opportunity to market non-latex one-piece self-adhesive sheaths when the Mentor patent expired in 2002, it would have difficulty in doing so in such a mature market. If Coloplast managed to extend the patent it would have cornered the market.

6.66. The company said that individual public authorities and NHS Trusts might be able to use their buyer power to negotiate lower prices, but in doing so, would more than likely reduce the product choice of the individual healthcare professional. It believed a company offering a wide portfolio of products might be in a position to offer larger discounts if all its products were used within a Trust. If companies specializing in one specific area did not have the opportunity to get products into NHS Trusts they would be unlikely to succeed in the community market.

6.67. The company said that larger companies marketed their products by providing unlimited free samples, through mail shots, by employing sales representatives, DAC ownership, by offering site visits to manufacturing plants in Continental Europe and incentives to set up named patient trials. These were costly activities and were major barriers to entry.

6.68. The company said that owning a nursing service or acting as a DAC had the following advantages:

- (a) Companies that owned a DAC did not have to give the pharmacist or wholesaler a discount (ranging between 10 and 25 per cent).
- (b) Companies could claim an additional sum of up to 25 per cent of the value of the product for dispensing it. By owning multiple DACs and moving prescriptions between them a company could maintain higher percentages.
- (c) By obtaining the names and addresses of patients, a company would have the potential to switch a patient to its own products, particularly if it owned a nursing service such as Thackray nurses.
- (d) Owning a nursing service gave a company access to patients that might be willing to participate in the trials of new products.
- (e) A nursing service generated income through dispensing prescriptions.

6.69. The company said that not owning a nursing service or DAC and not being able to afford one were major barriers to entry and to gaining market share for smaller companies. It said that it was possible to purchase existing DACs, although the cheapest one it had been quoted was £114,000. It was difficult to see how nurses could maintain their clinical impartiality if they reported to the sales manager of a nursing service owned by a manufacturer. The majority of DACs owned by manufacturers were only really interested in dispensing their own products.

6.70. The company said that nurse sponsorship could save a Trust £40,000 per post; in return the Trust bought the sponsors' products. It believed sponsored nurses could possibly recommend that a patient use the sponsors' DAC or nursing service. Unless there was some sort of regulation the system would be open to abuse and healthcare professionals were likely to be put in a position of recommending the sponsors' products in order to keep their jobs, thereby compromising their professional integrity.

6.71. The company said it had heard that in the past staff had under SSL left the ThackrayCare nursing service after being told by their sales managers to prioritize the type of patient they saw according to prescription value, and see at least six patients a day.

6.72. The company said that manufacturers should either be prevented from running nursing services or a regulatory body should be set up with powers to act should there be any abuse of the system. It believed incentives and commission bonus payroll structures should be open to scrutiny, as should detailed statistics of items dispensed by the nursing service to ensure no bias towards particular manufacturers.

6.73. The company said that new entrants could not obtain the same prices as Coloplast's more expensive products due to the policy of not listing similar products at higher prices to those already on the Drug Tariff. This did not give new entrants the chance to achieve the profit margins Coloplast made. The company said that because Coloplast now had overlapping product lines, switching patients to the most profitable products would be a great temptation.

6.74. The company believed the acquisition had made it more difficult for existing companies to compete and for new companies to gain entry.

Wholesalers and retailers

AAH Pharmaceuticals Ltd

6.75. AAH told us that its parent company was Gehe UK, which was also the parent company of Lloyds Pharmacy Limited. AAH was part of a larger European wholesale business, Gehe AG, based in Stuttgart. AAH said that it was a major supplier to the hospital sector and to pharmacies and DACs within the community market. It told us that it owned one DAC, but that this was not its core business.

6.76. AAH believed the continence care market was worth about £100 million. Its total business on prescription medicines was worth between £1.8 billion and £2.1 billion.

6.77. AAH did not know whether there was one market in continence care products or whether there was actually a series of markets for specific products. However, it believed there was genuine competition between three major wholesalers (AAH, UniChem and Phoenix) and said that switching between wholesalers was commonplace. AAH did not regard the continence care market as a growth area. The main suppliers of continence products that AAH dealt with were Tyco, Bard and Coloplast. AAH said that there had been no significant newcomers to the market.

6.78. AAH's concerns about the acquisition centred on the impact on competition of Coloplast's ability to reduce discounts to wholesalers because of its large DAC ownership. AAH thought that a manufacturer who was successfully expanding its DAC business, and capturing the additional margin associated with this, might seek to reduce discounts to wholesalers. It believed that any discount reductions would not be passed on to retailers, but would be borne entirely by the wholesaler since retailers would otherwise switch suppliers. The wholesaler competitors of the DAC-holding manufacturer would therefore face either diminished profits or loss of business to the DAC. AAH believed that owning a DAC gave a manufacturer direct access to patients and secured profit optimization. AAH could not compete on an even footing with a DAC-owning manufacturer because it did not have the level of profit required to invest in a sales force or sponsored nurses.

6.79. AAH did not believe that any rationalization caused by the merger would be cause for concern, except that it might allow Coloplast to approach the PCTs with a complete package of continence care products, thus cutting wholesalers out of the supply chain.

6.80. AAH observed some product switching in the market, but did not know what caused this.

6.81. AAH said that it had no influence over the shape of the market through its discount structure: it merely supplied what was prescribed. It added that its size did not affect the level of discount it received from manufacturers.

6.82. Because prescribers were the market-shapers, AAH reported that the main marketing effort by manufacturers was focused on prescribers. It thought that while manufacturers could use pricing policies to promote a particular brand, historically this strategy had not widely been used. It said that almost all the prescriptions received by the retail dispensing outlets from the prescriber were brand specific.

6.83. AAH did not feel that there was a European market for continence care products because it was not aware of true parallel import products being made available in the UK. Although there were parallel importers of pharmaceutical items, who were specialist merchants arbitraging between European markets, such importers had not entered the continence care market, presumably because of its small size. AAH sourced all its product in this market from suppliers located in the UK. It thought that manufacturers would not undertake arbitrage between different European markets, although generally prices were higher in northern than southern Europe, due to regulatory issues and differences in pricing structures. AAH thought that the major suppliers might tolerate a certain amount of parallel importing at the margin, but that they would probably be averse to a substantial erosion of their conventional channels of distribution.

6.84. AAH thought that the weakness of parallel imports in the continence care market stemmed from pricing, regulatory and trademark issues. Even if a parallel import had a CE mark, which was accepted throughout the EC, there were packaging issues to be resolved before it could be sold in the UK. AAH was also concerned not to become involved in litigation cases with its supply base over misuse of trademark or damage to trademark. The product's brand name had to be the same as the brand name in the UK for it to be sold against that UK prescription. AAH also said that sometimes manufacturers made slight differences in their products to cater to a local need, which made like-for-like imports difficult.

6.85. AAH thought that nurse sponsorship within the hospital sector in the continence care market created a different dynamic regarding hospital tenders, with less emphasis on price than with tenders related to standard drugs. AAH believed that specialist nurses were the most important decision-makers where product choice was concerned. It also reported that loss leading took place in hospitals, since that was where the relationship with the patient began, and that patients were likely to continue to use products they had used in hospital once they moved into the community. However, there was no

evidence to suggest that this occurred in the continence care market. AAH thought that company investment in nurse sponsorship was linked to sales, otherwise there would be no point in such sponsoring. It had been AAH's experience that those manufacturers with the most resources to invest in sales forces and sponsor nurses within hospitals could achieve a market share within this market. However, AAH had no evidence that sponsored nurses promoted only their own company's products. AAH employed five nurses, four directly in the community and one as a sponsored position within the NHS. It also offered a home delivery service through its retail pharmacies. It could not afford to give free samples to consumers at home because its margin came only from its purchase price, as opposed to that of manufacturers whose margin came from their cost base. AAH thought that the acquisition meant that the continence care part of SSL's business would become core business to Coloplast, giving it more focus and drive, and therefore greater impact on the marketplace.

6.86. AAH's experience was that a new supplier in the market could take up to two years to obtain a listing on the Drug Tariff, which it saw as a significant barrier to entry. AAH believed that it would be difficult for the merged company to extract more value from the Drug Tariff.

Government departments

Department of Health

6.87. The DoH told us that it was responsible for Part IX of the Drug Tariff, which listed the appliances that GPs could prescribe. It said that the Medical Devices Agency was responsible in the UK for the controls over the marketing of medical devices, which were set out in the Medical Devices Regulation 1994 and the Council Directive 93/42/EEC. Medical devices marketed in accordance with the Regulations were required to carry a CE mark, of which there were various levels. The CE mark could be awarded in any European country, allowing a product to be marketed in all. The DoH regarded the CE mark as an indication that a product was safe and of good quality. When considering whether or not to admit a product on the Drug Tariff, the DoH also considered whether it was appropriate to prescribe the product in the community and whether it was cost effective. It would not admit a product to the Drug Tariff if it were more expensive than an equivalent that was already listed. It said that the period taken to obtain a listing varied: on average it took six to nine months, though it could take as little as two to three months or as long as two to three years depending on the complexity of the product. The DoH said that products had been withdrawn from the Drug Tariff by manufacturers but not by the DoH. In principle, a manufacturer with a sufficiently large market share, including control of all major brands, might be able to force an increase in the Drug Tariff price of its products by threat of withdrawal of supply. The DoH was, however, aware of no cases in which this had actually happened in the continence care area.

6.88. The DoH said that appliances could be purchased without the need for a prescription but many were supplied on prescription by a pharmacist or DAC. Incontinence pads were prescribable in Scotland but not in England or Wales. Most hospitals could supply appliances but preferred the GP to prescribe them because this eased the pressure on the hospitals' budget. The DoH believed GPs did not pay a great deal of attention to price. It said that some Primary Care Groups produced product formularies, a list of the most cost-effective appliances, which could be prescribed.

6.89. The DoH said that pharmacists received reimbursement for the prescriptions they dispensed. The level of reimbursement took account of an assumed discount that the pharmacist was able to obtain from its wholesaler. DACs, on the other hand, received the price listed on the Drug Tariff plus an on-cost allowance ranging from 25 to 15.8 per cent, depending on the overall number of prescriptions dispensed by the DAC.

6.90. There were a number of difficult issues concerning the way DACs operated, which the DoH had been considering for some time. However, it believed DACs provided a good service, dispensing and delivering appliances to patients in the community.

6.91. The DoH believed hospitals were paying significantly less for appliances than the community sector because hospitals could buy in bulk, and PASA was often able to negotiate favourable contracts with suppliers. It had been suggested that suppliers recouped their losses by charging higher prices in the community. The DoH had taken a neutral stance on the issue of PCTs setting up their own tendering arrangements. It said that it had an agreement with the ABHI which limited manufacturers' annual price rises to the forecast GDP deflator for the coming year minus 0.75 per cent.

6.92. The DoH believed companies marketed their products in a number of ways.

6.93. It sent pharmacists and GPs copies of the Drug Tariff every month, Part IX of which was a list of appliances which could be prescribed by GPs, together with the 'basic price' which was the basis for the calculation of the reimbursement to pharmacists. The DoH was not currently proposing to abandon Part IX of the Drug Tariff, not least because of the difficulty of finding an alternative mechanism for controlling the prices of appliances, which were prescribed.

Department of Health, Social Services and Public Safety

6.94. The Department of Health, Social Services & Public Safety said that it did not believe the acquisition would have a detrimental effect on patient care or have any obvious financial consequences in Northern Ireland. The acquisition had broadened Coloplast's product range but did not give cause for concern as regards supply because there were a large number of potential competitors in the market. Both Coloplast and SSL had offered consistently high-quality products within a lower price range.

Purchasing and Supply Agency

6.95. We were told that PASA was an executive agency of the DoH and that its aim was to achieve the best possible value for money for the NHS for both goods and services. It acted as a strategic adviser and as a centre of excellence, expertise and knowledge. In practical terms it awarded contracts on a national basis for the supply of products and services to some 400 NHS Trusts and Health Authorities. It managed 3,000 national purchasing contracts and influenced half of the £7 billion spent on purchasing goods and services within the NHS. PASA was not involved in the supply of products to the community market.

6.96. With specific reference to continence care products, PASA said that its procurement procedures followed EC guidelines and that contracts normally ran for four years. There were no limitations on which companies might respond to a tendering request; those that did were assessed to see if they were capable of meeting PASA's requirements. Fixed volumes of supply were not normally quoted so that smaller suppliers were not discouraged and there were normally no price differentials between large- and small-volume suppliers. Product quality and a company's ability to supply the required volume of product to PASA's deadlines were important considerations in awarding contracts.

6.97. PASA sought to keep its tendering process very competitive and would itself take the initiative in identifying possible suppliers. However, it was not possible for new suppliers to be appointed outside the normal tendering process unless significant technological changes were offered. Contractors were occasionally delisted during the term of a contract because of quality of supply problems.

6.98. PASA added that although ideally it preferred to award several contracts for the supply of each product, there were occasions when only one contract was awarded. Success in PASA's tendering process meant that the company concerned was added to PASA's list of contractors. This did not automatically result in hospital orders being placed. It was, however, difficult and very rare for companies not on PASA's list to secure orders direct from individual hospitals and Trusts.

6.99. Describing the main range of products available within the continence care market, PASA considered catheters and sheaths to be fairly brand dominated. Bags were considered to be much more generic and were said to represent a significant proportion of the overall market, which was described as very competitive. The only differentiating factor where bags were concerned was their taps. The sheath market had changed considerably in recent times due to a significant move toward all silicon or other non-latex products.

6.100. Almost all PASA-supplied products were listed on the Drug Tariff and all were CE marked. PASA thought that parallel imports played no part in its procurement activities. It said that there was little overall advantage in a company being able to offer a range of products or a home delivery or nursing service. PASA added that the outcome of its tendering processes was made public.

6.101. PASA described hospital prices as completely transparent. Volumes were less obvious since market share data was more confidential. PASA agreed that there was a striking differential between hospital and Drug Tariff prices due largely to the much larger size of the community market.

6.102. Companies were permitted to seek price increases during the term of a contract but these were rarely approved; in fact, over recent years prices had been very stable.

6.103. PASA said that although hospitals and NHS Trusts were at liberty to run their own tenders and occasionally did so in an attempt to secure cost savings, 70 per cent of continence care products used in hospitals were obtained through Logistics.

6.104. PASA was unaware of any difference between the UK's continence care market and the rest of the EC although it had been told by suppliers that because of different reimbursement schemes the Continental EC market was much more profitable. It did not liaise with similar organizations within the EC, nor did it monitor prices.

6.105. Asked about new entrants into the UK market, PASA said that the only one that was starting to have any significant impact was Sims Portex, with an all-silicon sheath, but its share of sales was small, though growing.

6.106. PASA thought that continence care advisers played the most important role in determining which products were used but added that hospitals and PCTs were increasingly drawing up formularies from which products might be prescribed. Continence advisers were thought to be generally price sensitive; this was increased as they came under budgetary pressures.

6.107. PASA thought there was a good deal of product switching in hospitals but not in the community, where patients were routinely prescribed whatever products they had used in hospital. Product innovation was thought to be a major cause of product switching in hospitals.

6.108. PASA thought that price played virtually no part in community prescribing. It did, however, believe that brand loyalty played a significant role in both the hospital and community markets.

6.109. With regard to product promotion, PASA mentioned company-sponsored conferences plus nurse education and training. However, it did not believe that these were successful unless the product being promoted was clearly superior. Nurses and continence advisers were generally the target of such promotional efforts. PASA was also aware of hospitals having been offered free equipment by companies, for example bladder scanners.

6.110. Commenting on the capital investment required for market entry, PASA thought that smaller companies often had the advantage of lower overheads. Where generic products were concerned it was important to keep cost structures and overheads low and enter the market with competitive prices.

6.111. PASA thought that the main advantage of owning a DAC was the access this gave to patient data.

6.112. On the issue of nursing ethics, PASA thought that DoH Guidelines helped to a certain extent to protect nurses from being pressurized by suppliers, but PASA had nevertheless heard of nurses being asked to sell product information and provide access to patient data. PASA considered nurses generally to be very committed and protective of their independence.

6.113. In commenting specifically on Coloplast's acquisition of SSL's continence care business, PASA thought this a very positive development. Under SSL, continence care had been non-core and had not benefited from R&D. PASA believed that Coloplast would be much more committed to and capable of developing SSL's product range. Its only fear related to the supply of sheaths, 85 per cent of which would now come from one supplier and where there were no other major alternative suppliers. It had no such reservations about bags or catheters because there were sufficient suppliers to ensure an acceptable degree of competition.

6.114. 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 will be seeking bids in March/April 2003.

Health Authorities

Ayrshire & Arran NHS Board

6.115. Ayrshire & Arran NHS Board said that it was not opposed to the merger.

Fife NHS Board

6.116. Fife NHS Board believed the acquisition would give Coloplast a larger portfolio of continence care products, but this did not lead to a monopoly supply situation because companies such as Sims Portex, Maersk, Tyco and Astra Tech offered competing products.

Lanarkshire NHS Board

6.117. Lanarkshire NHS Board said that it did not oppose the acquisition provided it resulted in an enhanced service to patients with continence problems. This included the continuation of a range of products and services provided by SSL's continence care business, which were considered by patients and clinicians to be of the highest quality. The Board hoped that the acquisition would result in the development of a service that retained the best products and features of the SSL service and combined them with the service advantages currently enjoyed by Coloplast.

6.118. The Board believed that an appropriate level of competition would be maintained provided other suppliers retained the confidence of clinicians and procurement managers. In this respect the Association for Continence Advice and the Scottish Strategic Alliance Partnership provided strong links to suppliers, by ensuring that the views of practitioners were considered in respect of product design and quality.

South Cheshire Health Authority

6.119. South Cheshire Health Authority said that both Coloplast and SSL provided a good standard of product and service. It was not opposed to the acquisition provided that quality and cost were not unduly affected.

NHS Trusts

Ayrshire & Arran Primary Care NHS Trust

6.120. Ayrshire & Arran Primary Care NHS Trust said that Coloplast was a good supplier. It was not opposed to the merger.

Chelsea and Westminster Healthcare NHS Trust

6.121. Chelsea and Westminster Healthcare NHS Trust considered that the impact of the acquisition was unlikely to be significant taking into account its own spending on continence products.

Craigavon and Banbridge Community HSS Trust

6.122. Craigavon and Banbridge Community HSS Trust said that the majority of patients in its area used the Simpla (SSL) product through personal preference. Many individuals had expressed dissatisfaction with the quality of the Coloplast alternative. Coloplast and SSL had both provided an excellent standard of patient and professional support.

6.123. The Trust believed, however, that the acquisition would reduce patient choice and would ultimately reduce both quality of service and the levels of satisfaction experienced by the patient. It was concerned that the acquisition might result in product rationalization and price rises.

Frimley Park Hospital NHS Trust

6.124. A urology nurse specialist at the Frimley Park Hospital NHS Trust said that she used a wide range of products from as many different companies as possible, thus offering her patients a real choice.

6.125. She believed the acquisition would not substantially affect other manufacturers and distributors provided that their products and patient/client support service were of an equally high standard. She did not have a strong view about the acquisition as experience showed that previous acquisitions had not adversely affected the choice or supply of products.

Royal Devon and Exeter Healthcare NHS Trust

6.126. A clinical nurse specialist/continence adviser at the Royal Devon and Exeter Healthcare NHS Trust said that the acquisition meant Coloplast would have a significant share of the market. She added that the Trust used both Coloplast and SSL products. She believed it was unlikely that Coloplast would discontinue the manufacture of the products used by the Trust because these were large contracts. Other merged companies had not resorted to product range rationalization. Significant choice would remain provided the Simpla and Coloplast products were continued.

6.127. The specialist said that she had concerns about Coloplast's practice of promoting successful products to patients without the input of a clinician. Coloplast had its own delivery service which gave it access to patient details.

University College London Hospitals NHS Trust

6.128. University College London Hospitals NHS Trust remarked that previous mergers in the continence care field had resulted in a reduction in product availability and that minimizing choice was not helpful. It hoped therefore that sufficient consideration would be given to this issue.

Worcestershire Community and Mental Health NHS Trust

6.129. Worcestershire Community and Mental Health NHS Trust said its principal concern was that Coloplast should ensure that a wide range of continence care products continued to be available to patients and those advising them on their continence problems.

Associations

Association for Continence Advice

6.130. The Association for Continence Advice (ACA) told us that it was founded in 1981 by a group of healthcare professionals with an interest in continence. It said that it was a membership association and had about 800 members comprising manufacturers, pharmaceutical companies, statutory groups and authorities, and healthcare professionals. Its main objective was the education, training and support of healthcare professionals, which it achieved in a number of ways. It held an annual conference, produced a quarterly journal and organized a variety of educational initiatives for members. It had also published a document entitled *Notes on Good Practice* and had developed a pack for nursing homes to enable continence nurse specialists to move into the private sector.

6.131. The ACA said that the UK market for continence care was separate from Europe and was, in value terms, large. The main suppliers were Bard, Simpla and SSL for leg bags and catheters; Bard, Coloplast and SSL were the main suppliers of sheaths. Entry into the continence care market was

possible, as Careline, Hunter Urology and Manfred Sauer had shown. The ACA believed a new entrant needed to ensure that its name and products were well known, but did not require a sales force. Manufacturers marketed their products in a number of ways including the provision of supporting advertising in nursing journals and by contacting the members of relevant associations. It said that concerns about some of the marketing techniques being employed, including inducements to use a particular product, sponsorship, education bursaries and the use of patient evaluation forms, had been brought to its attention. These could put nurses and specialists in a difficult position with regard to their professional accountability and conduct. The practice of supplying free samples direct to healthcare professionals raised concerns regarding the issue of indemnity. PASA had arranged a master indemnity scheme, which provided NHS Trusts with cover should there be a problem with one of its listed products. However, if a free sample supplied to a patient via a healthcare practitioner was not listed and developed a problem, practitioners could find that they were not indemnified.

6.132. The ACA said that most continence care took place in the community. Hospitals provided little continence care and often used products to treat post-operative problems. The specialist nurse and district nurse had the greatest influence in determining which product was used. The ACA believed products were prescribed on the basis of clinical judgement and, with the exception of GPs who had budgetary considerations, not because of cost. It said that hospitals received discounted products because suppliers believed patients would continue using their products in the community. Switching between types of product did occur but was dependent on a patient's condition. Generally, a patient would not change products unless it was necessary.

6.133. The ACA said that most manufacturers had a DAC. DACs provided a useful service to those living in rural areas and enabled a manufacturer to market its products directly to a patient. The ACA believed there were financial advantages to be gained from using a DAC, which were not available through the pharmacy route.

6.134. The ACA believed Thackray nurses were unbiased but was concerned that NHS Trusts were employing an increasing number of sponsored nurses rather than appointing their own staff. It considered this to be inappropriate.

6.135. It said that Coloplast had removed the SSL Aquacath from its product range but believed it had done so because the catheter had had a lot of problems. It said that some products were not listed on the Drug Tariff but could be obtained by mail order or bought at a pharmacy. Hospitals could use these products but needed to consider whether a patient would be able to afford to continue using them at home. The ACA believed that the Drug Tariff protected the NHS from excessive price rises.

Association for Spina Bifida and Hydrocephalus

6.136. The Association for Spina Bifida and Hydrocephalus said that Coloplast and SSL produced a range of good products and that these continued to be available through Coloplast. It believed the presence of other manufacturers in the market would preserve an element of competition. The Association did not oppose the acquisition.

The National Pharmaceutical Association

6.137. The NPA told us that it represented the interests of 4,800 owners of some 11,000 community pharmacies throughout the UK.

6.138. The NPA said that community pharmacy was the principal route by which continence care products provided by the NHS were supplied to patients. The retail sale of products for male incontinence was insignificant. The role of pharmacies was to supply the products specified on the prescription, and they had little choice of products.

6.139. The NPA's main concern was that the merger should not disrupt supply routes nor fetter prescriber choice.

6.140. It said that the supply to pharmacies was achieved through three routes: direct from the manufacturer, through specialist surgical supply wholesalers, and from traditional pharmaceutical

wholesalers. It was possible that the acquisition of SSL's continence care business might give Coloplast a means to control distribution by reducing the number of primary supply points, although it had seen no evidence of this. The NPA said that it would be concerned if the acquisition enabled Coloplast to insist on trading terms that would damage its members' ability to discharge their duty under the NHS to supply 'with reasonable promptness'.

6.141. The NPA was also mindful that a lack of competition might impact on prices and lead to an additional drain on scarce NHS resources.

Others

A clinical nurse specialist (continence)

6.142. A clinical nurse specialist, based in the north Midlands, expressed concern about the acquisition because of Coloplast's more dominant position in the market. She was particularly concerned about the abuse of commercial power and had very real fears that the acquisition might lead to the removal of many reputable manufacturers from the field, thus reducing competition and the opportunity for ethical partnerships to be developed between healthcare professionals and the industry.

6.143. The specialist identified nurse specialists as being primarily responsible for product choice, and pointed to a recent increase in sponsored nursing posts which had led to the patient's choice being restricted to products manufactured or supplied by the company funding the posts. The specialist added that sponsored posts represented a saving only to the NHS Trust and not to the NHS itself. The ongoing cost of prescribable items was also borne by the NHS and not the individual Trusts. The specialist listed a number of safeguards that should be sought to maintain the independence of sponsored nurses, to secure the confidentiality of patient databases and to prevent unjustified product switching. The specialist also stressed the need for complete transparency with regard to the terms and conditions of service under which company and sponsored nurses were employed.

PromoCon

6.144. PromoCon told us that it was established in 1996 with a grant from the DoH; its main objectives were to establish a national display of continence care products and a help line. It offered impartial information and advice to consumers, healthcare professionals and the industry concerning the availability of continence products in the UK.

6.145. PromoCon was not opposed to the merger provided that Coloplast did not rationalize its product range, for example by replacing Simpla products with its own. PromoCon believed that the merger might have beneficial effects, in that it might enable more product development and education. However, it was concerned that smaller companies might suffer as a result of the dominance of the merged company.

6.146. PromoCon said that there were 21 companies in the UK that provided a representative range of continence products. It believed the principal suppliers were: Astra Tech and Coloplast for coated intermittent catheters; Bard and SSL for permanent catheters; SSL and Coloplast for sheaths; and SSL and Bard for leg bags. It thought that the product range available to end-users was good but that patients themselves were frequently not aware of this.

6.147. PromoCon considered that new entry would be very difficult. A company needed to ensure that its products were listed on the Drug Tariff and required a sales force in order to promote them. The larger companies marketed their products in various ways, including the use of specialist nurses, the provision of free samples to hospitals, advertising, holding conferences or study days for healthcare professionals, the provision of patient literature and ownership of a DAC.

6.148. PromoCon said that it was generally the case that patients prescribed a particular product in hospital would continue to use that product in the community unless clinical considerations or lack of product availability dictated otherwise. Price did not usually affect product choice, though it might become an issue should a product be discontinued. In this event the patient's GP, who might not know the difference between products, might prescribe a cheaper, less cost-effective and less appropriate

product. It believed manufacturers and suppliers of continence products had a duty adequately to inform healthcare professionals of the exact differences between product ranges, so that they could select products to cater for different needs and preferences. PromoCon said that there was little switching between products, outside those necessitated by a patient's deteriorating condition, because products were specific to particular conditions. It believed that on occasions manufacturers had charged higher prices to the community care sector than those charged to hospitals.

6.149. PromoCon considered the Thackray nursing service to be very good as long as it maintained its independence. It regarded the individual Thackray nurses as being highly skilled and very knowledgeable, but argued that they should remain impartial. It believed that nurse sponsorship could impair the ability of nurses to assess patients' conditions and decide what product was best for them.

A senior continence adviser within the NHS

6.150. A senior continence adviser within the NHS said that Coloplast was a leading manufacturer in the continence market and had a reputation for producing good-quality products. The adviser believed the acquisition would result in product rationalization in the intermittent catheter market and that competition in the intermittent catheter and sheath markets would be reduced. Coloplast owned the two leading products in the sheath market, which could enable it to control price. The adviser would be concerned if Coloplast decided to discontinue one of the sheaths but considered this unlikely.

6.151. The adviser said that manufacturers used a number of incentives to market their products including the provision of free samples to hospitals, the use of sponsored nurses and holding conferences and product launches. Manufacturers supplied hospitals with free samples because they wanted to establish patients on their products before they were discharged and entered the more profitable community market. The manufacturers that provided sponsored nurses to hospitals usually owned a DAC, through which they could dispense prescriptions into the community and claim an on-cost allowance. Manufacturers were able, through their DACs, to develop patient databases so that they could market their products directly to the patient. Coloplast owned a DAC, a patient database and, as a result of the acquisition, the Thackray nursing service. There was some concern that the Thackray nurses might favour Coloplast's products in their recommendations to patients.

6.152. The adviser did not offer patients a choice as to which product was used but selected the one that was most appropriate for the patient's condition. Cost was not particularly important but the product had to have a CE mark. However, some health trusts had established local product formularies, a restrictive list of items that could be prescribed. This was an attempt to guide employees to best practice and identify cost savings.

6.153. In some situations certain patients might require a combination of products to manage their bladder dysfunction.

A J PRYOR (*Chairman*)

J BAILLIE

D PARKER

S WALZER

A M YOUNG

R FOSTER (*Secretary*)

13 May 2002