OFFICE OF FAIR TRADING

Anticipated acquisition by Mayne Pharma plc of Intra-Tech Healthcare Ltd

The OFT's decision on reference under section 33 given on 26 April 2005. Full text of decision published 4 May 2005.

Square brackets indicate information removed or replaced for confidentiality reasons at the parties' or third parties' request.

PARTIES

1. **Mayne Pharma Plc (Mayne)** is a worldwide provider of healthcare products and services. In the UK Mayne supplies a wide range of sterile injectable products, aseptic manufacturing services and generic medicines to UK hospitals. Mayne's 2004 UK turnover was approximately £[ ] million of which around £[ ] million was achieved through aseptic manufacturing.

2. **Intra-Tech Health Care Ltd (Intra-Tech)** is a pharmaceutical company providing aseptic manufacturing services. It was incorporated in 1997 having been founded by two hospital pharmacists and built its licensed aseptic unit located in London in 1998. Intra-Tech's turnover for the year ending 31 March 2004 was £[..] million all of which was accounted for in the UK.

TRANSACTION

3. Mayne has announced its intention to acquire the whole of the issued share capital of Intra-Tech for a consideration of £[ ] million. The merger was notified to the OFT on 25 February 2005 and the OFT's administrative deadline for consideration of the case expires on 26 April 2005.

JURISDICTION

4. As a result of this transaction Mayne and Intra-Tech will cease to be distinct. The parties overlap in the supply of aseptically manufactured drugs in Great Britain

(GB)[1]. The share of supply test in section 23 of the Enterprise Act 2002 (the Act) is met if hospital and home-patient supply of such products is excluded (the parties estimate their combined share of supply in such circumstances to be [35-45] per cent). The OFT therefore believes that it is or may be the case that arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation.

RELEVANT MARKET

Product market

5. The parties overlap in the manufacture and supply of toxic and non-toxic aseptic special pharmaceuticals. 'Specials' are unlicensed medicinal products prescribed by doctors where a patient is intolerant or allergic to an ingredient contained in the licensed product or where a patient requires a dosage form different to the licensed product (e.g. as a liquid rather than a tablet). The main area of overlap between the parties is the manufacture and supply of toxic aseptic specials which account for [90-100] per cent of Mayne's aseptic production[2].

6. Aseptic manufacturing[3] of specials entails the transfer of a sterile pharmaceutical product from the container in which the product is delivered (e.g. a vial or ampoule) into a device with which it can be administered (e.g. a syringe or infusion bag). To avoid the risk of contamination the process is carried out using cabinets in a clean room.[4] Aseptic manufacturing can be carried out for both toxic[5] and non-toxic[6] medicinal products. Aseptic manufacturing of toxic medicinal products carries the additional risk of exposing the pharmacists or technician transferring the toxic product into the administering device to harm from the toxic drug. For this reason toxic aseptic manufacturing is undertaken in special purpose built cabinets in the clean room. A further distinction between cytotoxic and non-toxic aseptic specials is that cytotoxic specials tend to have a shorter shelf life (48-72 hours) and usually require near-patient preparation. At present aseptic

[1] Neither party supplies aseptic manufactured products to Northern Ireland.
[2] Mayne does a small amount of aseptic manufacturing of non-toxic products; [ ].
[3] Aseptic manufacturing is also referred to as 'compounding'
[4] This is an area with a defined environmental control of particulate and microbial contamination constructed and used in such a way as to reduce the introduction, generation and retention of contaminants within the area.
[5] Examples of toxic aseptically manufactured medicinal products include cytotoxic drugs used for oncology such as epirubicin and bleomycin. Cytotoxic drugs appear to be the predominant form of toxic drugs for the purpose of aseptic manufacturing and in this decision the two terms are used interchangeably.
[6] Examples of non-toxic aseptically manufactured medicinal products include Total Parenteral Nutrition (TPN) – an intravenous feed for patients - and Central Intravenous Additional Services (CIVAS) – an intravenous source of pain control and antibiotics.

manufacturing is carried out by hospitals, commercial suppliers and homecare providers.

7. There are two other forms of special pharmaceutical – sterile and non-sterile specials. Sterile specials such as eye drops and injections are subject to sterilisation after the production process. Non-sterile specials such as creams, lotions, gels and powders are not designed to be free of micro-organisms. The parties do not overlap in the supply of either of these forms of special.

8. Patients being administered with aseptically manufactured products will generally be treated in hospital rather than by GP's or community pharmacies[7]. Hospitals tend to purchase aseptically manufactured products on an ad hoc basis, placing orders either weekly or monthly for individual products on the basis of price lists and service level agreements sent by manufacturers. Hospitals are not usually bound by formal contractual agreements.[8] Pricing of aseptically manufactured products is also differentiated on the basis of the level of service required, so batch products with longer turnaround times will be less expensive than patient specific products with short turnaround times; as such, service can be an important purchasing consideration as well as price. Third party responses have indicated that hospitals do not face significant switching costs and that they are price sensitive. The parties have also provided evidence of hospitals switching commercial supplier.

Demand and supply side substitution

9. On the demand side there is virtually no substitution between individual special products as each product is a bespoke medicinal product. On the supply side, the OFT does not consider that manufacturers of non-sterile or sterile specials can easily switch production to aseptic special manufacturing. As noted in the OFT's decision in Intercare/Eldon[9], switching supply from sterile and non-sterile production to the production of aseptic specials is considered costly due to the vastly differing production processes and no evidence has come to the OFT's attention in this case that contradicts this finding.

[7] The parties overlap to a minimal extent in the supply of these products to community pharmacies (just over [0-10] per cent of Mayne's production of aseptics is supplied to community pharmacies) and as no third party concerns were raised this sector is not considered further in this assessment.

[8] Although this is not always the case and where the outsourcing contract for the aseptic manufactured products has a value of over £99,695, the hospital is required to tender the contract. These contracts are on the NHS's standard terms and conditions and will usually have a duration of up to two years but may be between 1-5 years. Mayne estimates that less than 10 per cent of its contracts are tendered.

[9] Anticipated acquisition by Intercare Group plc of Eldon Laboratories Ltd (10 September 2004).

10. The parties submit that the market for aseptic manufacturing includes manufacturing of toxic and non-toxic products as hospitals and all commercial manufacturers currently produce, or have some capability to produce, both and are able to switch between the aseptic manufacture of the two. The parties submit further that the special chambers required for toxic aseptic manufacturing are not costly at approximately £20,000. Moreover, the manufacturing can take place in the same clean room provided there is some segregation between the two areas to avoid cross contamination. Other third party manufacturers in the sector have confirmed that they would be able to reallocate productive resources between cytotoxic and non-toxic within a short time frame and at no significant additional cost.

11. Notwithstanding the above, some third party responses indicate that there may be additional costs in switching production to cytotoxic drugs. These include additional specialised cytotoxic product handling training for staff and licence variation to include the handling and manufacture of cytotoxic drugs. Since the issue of whether toxic and non-toxic aseptic specials belong to the same product frame is not crucial to the competitive assessment, the issue can be left open and the effect of the merger will be analysed separately on the supply of aseptic (non-toxic and cytotoxic) and cytotoxic aseptic specials products.

Routes to Market

12. The parties submit that over 80 per cent of aseptic manufacturing is done by hospitals either for their own use (for which no licence is required), or as a licensed activity, which permits supply to other hospital customers. Depending on the nature of the product, the aseptic manufacturing will be carried out either in the hospital pharmacy, in a clean room by hospital pharmacists, or at ward level by nurses. Hospitals also outsource their aseptic manufacturing requirements, either to other hospitals with licensed facilities, homecare providers or to commercial manufacturers.

13. The parties argue that hospital supply (either in-house or cross supply from other hospitals) represents a competitive constraint and so submit that the relevant market includes both hospital and commercial supply of aseptically manufactured products. As shown below in Table 1, hospital supply of aseptic products represents approximately 85 per cent of the total GB production. The key question here is whether hospitals would be able and willing to replace current purchases of aseptic specials from commercial suppliers with internal/external hospital supplies in the event of a 5-10 per cent price rise by commercial manufacturers. If this were possible, hospital supply would be a significant competitive constraint on commercial suppliers.

14. The decision making process determining whether hospitals outsource aseptic manufacturing to commercial suppliers is at present largely dependent on the assessment of each hospital.[10] From responses received, hospitals will tend to outsource as and when required, for instance if they lack the necessary facilities themselves or if faced with increased demand. The majority of hospitals contacted by the OFT that outsource indicated that they are currently producing at full capacity internally and would have great difficulty in expanding production further. Alternatively, some hospitals do appear to have a genuine choice between outsourcing – whether to another hospital or to commercial providers -and in-house production.

15. There is evidence of increased investment becoming available in this sector (for instance, £42 million of additional NHS funding has been made available for sterile, non-sterile and aseptic manufacturing over three years from 2004). It is also the case that hospitals and trusts will themselves conduct cost benefit analysis to consider whether additional funds should be directed at their own aseptic manufacturing. Third party responses suggest increases to a number of hospitals' capacity being planned in the next few years. As responses indicate that replacing outsourced products with in-house supply would require additional facilities and staff, in-house supply is likely to be more of a constraint in the medium and long run.

16. The parties submit that licensed hospitals also supply other hospitals outside their Trust area and so compete directly with commercial suppliers. Evidence supplied by the parties indicates that certain hospitals do bid for, and win contracts to supply other NHS hospitals in competition with Intra-Tech, Mayne and others. The parties have also provided evidence of hospitals switching supplier of aseptics away from commercial suppliers to NHS suppliers. Other third party responses indicate that the effectiveness of cross supply will vary in each region. However, in a region where NHS cross supply is available it is likely to be a strong constraint on commercial providers. By way of example, from the limited third party responses the OFT has collected, hospital cross supply amounted to some [ ] units of aseptic products. This is equivalent to the total quantity supplied by the merging parties in 2003.

17. Certain homecare providers[11] also provide limited aseptic manufacturing of toxic and non-toxic products to hospitals, although their primary commercial focus is to serve home patients. There is evidence however that homecare companies have competed for contracts with all the main commercial aseptic suppliers including Intra-Tech and Mayne, and one homecare company has informed the OFT that

[10] Although policy on this issue is currently being considered at a national level by the National Production Committee for Aseptic Manufacturing (NPCAM) which advises the Department of Health.
[11] Commercial companies providing care and support for patients in their own homes.

apart from capacity issues, it would have no difficulties in increasing supply to hospitals (and that company is considering investing in the additional capacity required). Nonetheless, overall it is not clear that homecare providers would necessarily switch existing resources to supplying hospitals since such a decision would constitute a strategic decision and a switch of commercial focus.

Conclusion on product frame of reference.

18. For the purposes of this decision, it is unneccessary for the OFT to conclude on the product frame because competition concerns do not arise under any definition. This merger will be assessed on the narrowest frame of reference, namely the supply of aseptic specials (both overall and for cytotoxic specials alone) by commercial suppliers to hospitals. However, it is recognized that hospitals' cross supply and supply from care home providers will pose some form of competitive constraint while hospital in-house supply could pose a competitive constraint in the medium and long term.

Geographic market

19. The parties submit and third parties confirm that in the area of overlap commercial suppliers supply the whole of GB from facilities in different parts of GB. Delivery of aseptic specials is usually carried out through a dedicated courier service. This suggests a GB dimension to the relevant geographic scope of reference.

20. One exception may be products which require a fast turnaround time (24-72 hours). Although the parties stated that they can and do supply such products throughout GB from a single clean room, the parties also noted that competition for such products could have a more local dimension. Some third party responses also commented that they only consider alternatives in close proximity to their facilities, although other third parties stated the opposite. Therefore for the purposes of this assessment the OFT adopts a GB wide geographic frame of reference but on the basis that any potential regional issues which arose would be considered.

HORIZONTAL ISSUES

21. Although share of supply data is limited in this sector, the parties have provided estimates of their shares in the supply of aseptic and cytotoxic products as shown in the table below. Given their method of calculation these figures should perhaps be viewed with some caution.[12]

[12] The total 'Units' figure has been arrived at by taking the number of aseptic products made in the North West and Midlands in 2001 (2 English regions for which accurate figures are known) and multiplied by 7 to account for all 12 regions in England as well as Scotland and Wales.

Table 1: Supply of Aseptically manufactured products in GB 2003

		Shares%			
Company	**Units (,000)**	including hospitals and homecare Co's	excluding all hospital supply	excluding home-patient supply and hospital in-house[13]	excluding hospitals and home-patient supply
Mayne	[…]	[0-10]%	[5-15]%	[5-15]%	[10-20]%
Intra-tech	[…]	[0-10]%	[5-15]%	[10-20]%	[20-30]%
combined	[…]	**[0-10]%**	**[15-25]%**	**[20-30]%**	**[35-45]%**
Baxter	[…]	[0-10]%	[25-35]%	[30-40]%	[45-55]%
Dabur	[…]	[0-10]%	[0-10]%	[0-10]%	[0-10]%
Calea	[…]	[0-10]%	[5-15]%	[0-10]%	[0-10]%
Other Homecare providers	[…]	[0-10]%	[35-45]%	-	-
Hospitals	[…]	[80-90]%	-	[30-40]%	-
Total	[…]	100%	100%	100.0%	100%

Source: Parties, OFT calculations (totals not always equal to 100% due to effect of rounding)

22. Shares of supply of cytotoxic products alone are shown in Table 2.

Table 2: Supply of Aseptically manufactured cytotoxic products in GB 2003

		shares (%)	
Company	**Units (,000)**	including hospitals	excluding hospitals and homepatient supply
Mayne	[…]	[0-10]%	[15-25]%
Intra-tech	[…]	[0-10]%	20-30]%
Combined	[…]	**[5-15]%**	**[40-50]%**
Baxter	[…]	[5-15]%	[40-50]%
Dabur	[…]	[0-10]%	[0-10]%
Calea	[…]	[0-10]%	[0-10]%
Hospitals	[…]	[70-80]	-
Total	[…]	100.0%	100

Source: The parties, OFT calculations

Potential competition effects

23. Even noting issues over the accuracy of the 'total' figure, the above tables show that if the overall supply of aseptic products is analysed, the combined share of Mayne and Intra-tech is small and the merger will not raise competition concerns. However, if commercial supply of aseptic and cytotoxic products is analysed separately from hospitals' and home care production, the merger could be seen to lead to a significant increase in concentration in the sector.

[13] Including commercial supply and [ ] units of hospital cross supply identified by the OFT (see paragraph 16 above).

24. On this narrowest frame of reference, the merger effectively reduces the number of competitors in the commercial sector from four to three. However, the parties claim that a number of factors ranging from increased demand for these products (due to increased life expectancy for patients and new treatments) to an increasing NHS focus on outsourcing to licensed facilities should be fed into any competition assessment.

25. Dabur have constructed a new aseptic manufacturing facility which will be fully operational in May 2005. This will give it a very large amount of spare capacity and will be amongst the largest commercial aseptic units in the UK with capacity exceeding 200,000 units per year. Dabur has informed the OFT that 80 per cent of output will be cytotoxic products, though it stated that it could easily redistribute resources to increase non-toxic manufacturing. Therefore looking forward Dabur is likely to be a significant player. [ ]

26. As noted at paragraph 18 above, cross supply from hospitals is considered to pose some competitive constraint and including cross supply would give the merged entity a combined share of supply in the region of [20 - 30] per cent on present figures. A further development in this sector is the large number of hospitals contacted that are planning expansion of their aseptic manufacturing facilities, and anticipate increased in-house capacity within the next two years.

27. Though it is not possible to predict with accuracy future shares of supply, the facts above clearly indicate that commercial suppliers are anticipating increased demand from the NHS and this has triggered expansion and new entry. It is also clear that the new entry and expansion will provide the hospitals with more options for outsourcing and increase competition in the commercial sector, and that hospitals themselves are looking to expand their own production facilities.

Barriers to entry and expansion

28. Barriers to entry and expansion are considered to be low and this is evidenced by several examples of recent entry and expansion. Intra-Tech was setup in 1997 by two pharmacists who left NHS hospitals, while Mayne and Dabur are pharmaceutical companies which entered in 2000 and 2002 respectively. Similarly Clinovia and Nova have only started aseptic manufacturing in the recent past and the examples of Dabur's and [ ] future plans are given above. Mayne itself has invested in additional capacity which should provide it with an additional [ ] units of capacity by August 2005 and Intra Tech is also building additional facilities to increase its capacity by a further [ ] units. The parties and a number of third party responses suggest that the anticipated demand arising from increased outsourcing will attract new entrants.

29. Start up costs are estimated to be in the range of £1 million though it does not seem that a large element of that would be sunk and entry is possible within approximately a 1 year timeframe. Some third party responses suggest that a barrier to entry appears to be the availability of adequately trained staff. Responses indicate that staff who supervise the process appear to be in short supply with staff retention particularly a problem for NHS expansion since it is widely accepted that commercial suppliers offer higher remuneration than the NHS (contrary to what the merging parties consider to be the case). However, one manufacturer informed the OFT that it runs an internal training programme for technicians performing the aseptic manufacturing and so for them staffing is not an issue.

30. Other costs include constructing the clean room and purchasing the necessary apparatus. It should be noted that Mayne currently has agreements with universities to lease clean rooms which provides an alternative to building a new clean room.

31. Thus, while there do appear to be difficulties in entering, barriers are not insurmountable as evidenced by recent and planned expansion and entry.

Buyer power

32. The parties submit that the fact that hospitals themselves carry out (or have some capability to carry out) production of these specials implies that buyers are very sophisticated. In particular they will know whether a price increase is determined by a corresponding cost increase in the drugs or not.

33. In general, however, if a hospital does not have or cannot easily obtain spare capacity in-house, then its bargaining power vis-à-vis its suppliers will depend on the options that the hospital has in terms of third party suppliers (be that other hospitals or commercial providers). Given the nature of demand, however, it seems unlikely that capacity constrained hospitals would possess significant buyer power in themselves.

VERTICAL ISSUES

34. Mayne manufactures a range of cytotoxic drugs that are subsequently aseptically manufactured by commercial providers and hospitals. A suggested potential concern was that post merger Mayne could foreclose the supply of these drugs to other aseptic manufacturers. However these drugs are generic (i.e. non patent protected) and can be obtained from other generic drug manufacturers in competition to Mayne (as Intra-Tech currently does).

35. Another potential concern is that the merger will foreclose the downstream aseptic market to Mayne's competitors at the drug manufacturing level. However, the OFT does not consider this feasible. Intra-Tech currently purchases a small amount of the total purchases of these drugs (between [0-10] per cent depending on the individual drug and [0-10] per cent for Fluorouracil) and combined, their purchases are at most [5-15] per cent (for Epirubicin) so a large proportion of the demand for the drug can still be competed for.

36. Consequently, the OFT does not consider that the merger raises vertical competition concerns.

THIRD PARTY VIEWS

37. Third party views have been reflected throughout the text above. In terms of the hospital customers, the majority were unconcerned by the merger, although this view was not necessarily shared by all hospitals, particularly those with limited or constrained in-house supplies. Although some vertical concerns were expressed by competitors, the majority did not think that the merger would raise competition concerns given the overall level of expansion in the sector.

ASSESSMENT

38. The parties overlap in the supply of aseptic products in GB. This inquiry has focused on the supply of such products to the hospital sector and considered the constraints against the parties existing in that sector. The evidence collected shows both hospitals and homecare providers currently competing against the parties for business and looking ahead shows considerable expansion in both the hospital and commercial sectors. It is noted that barriers to entry are considered low and there is much recent evidence of both entry and expansion.

39. Consequently, the OFT does not believe that it is or may be the case that the merger may be expected to result in a substantial lessening of competition within a market or markets in the United Kingdom.

DECISION

40. This merger will therefore **not be referred** to the Competition Commission under section 33(1) of the Act.