Anticipated acquisition by Ambu A/S of the cardiology electrodes and diathermy business of Unomedical Limited

ME/5416/12

The OFT's decision on reference under section 33(1) given on 14 May 2012. Full text of decision published 24 May 2012.

Please note that the square brackets indicate figures or text which have been deleted or replaced in ranges at the request of the parties or third parties for reasons of commercial confidentiality.

PARTIES

1. **Ambu A/S** (Ambu) is a Danish company active in the supply of healthcare solutions within three business areas: anaesthesia, patient monitoring and diagnostics, and emergency care. Its products are sold worldwide, with exports accounting for 98 per cent of sales, handled via Ambu's foreign subsidiaries, or via distributors.

2. Ambu's business area relevant to the anticipated acquisition is patient monitoring and diagnostic products, which includes single-use electrodes for neurological and cardiological examinations. Ambu's total group turnover in its last financial year was around £110 million. Of this [30-40] per cent was in the cardiology electrodes sector, and of this around £[ ] million was derived in the UK.

3. **Unomedical Limited** (Unomedical) is a subsidiary of ConvaTec Healthcare, a company registered and incorporated in Luxembourg, which is itself owned by Nordic Capital and Avista Capital. Unomedical's primary focus is single-use products for operating room and intensive care use such as catheters and urine collection bags, as well as a variety of single use continence and critical care products. It has three UK business units; cardiology electrodes and diathermy, Unomedical's domestic UK sales unit and an office at Redditch. This transaction involves the acquisition of Unomedical's cardiology electrodes and diathermy division. For the financial year ended 31 December 2010, the cardiology electrodes and diathermy division had UK turnover of £[ ] million.

TRANSACTION

4. The transaction only involves the acquisition of Unomedical's cardiology electrodes and diathermy division (the Target). The purchase agreement was signed on 29 February 2012 and made public on 1 March 2012.

5. Ambu notified the merger to the OFT on 16 March 2012, and following receipt of a satisfactory submission the administrative deadline for a decision is 17 May 2012.

JURISDICTION

6. As a result of this transaction Ambu and the Target will cease to be distinct. The parties overlap in the supply of disposable cardiology electrodes in the UK with a combined share the UK of around [35-45] per cent, increment around [0-10] per cent. Thus, the share of supply test in section 23 of the Enterprise Act 2002 (the Act) is met. 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.

MARKET DEFINITION

7. The parties overlap in the supply of electrocardiogram (ECG) electrodes. These cardiology electrodes are the basic medical devices used to interpret the signal of the human heart. Generally stuck onto the patient's skin, they are used for two broad purposes: diagnosis of ailments and monitoring.

Product scope

8. Cardiology electrodes can be segmented into two distinct areas: diagnostic monitoring and general monitoring. Diagnostic monitoring involves the carrying out of tests in order to identify the nature of a condition through examining symptoms using Resting, 12 Lead ECG, Holter, 24 Hour Event and Stress Testing cardiology electrodes. General monitoring involves using electrodes to observe, regulate, record or control a patient's condition, for example intra-operative monitoring, ITU monitoring and on surgical wards. While diagnostic monitoring is generally done in the cardiology department of a hospital, general monitoring may be carried out in a number of different departments.

9. In addition, cardiology electrodes are generally broken down into the following sub-segments according to medical need: short term monitoring, Holter/Event

Recording and long term monitoring, neonatal, standard resting diagnostic (12 lead ECG), and stress diagnostic, see Table 1.

Table 1 – sub-segments of cardiology electrodes and their uses.

Sub-segment	Uses/Hospital departments
Short term monitoring	Operating Theatre, Ambulance, Emergency, and MRI scanning
Holter/Event Recording and long term monitoring	Cardiology, ICU – Intensive Care, and CCU – Coronary Care
Neonatal	Neonatal ICU
Standard resting diagnostic (12 lead ECG).	Ambulance, Emergency, Cardiology, ICU, CCU, and Operating Theatre
Stress diagnostic	Cardiology

10. The parties submitted that all disposable cardiology electrodes could be considered as being in one market, since each different sensor is designed to fulfil the same purpose (that is; to adhere to the surface of the skin to measure heart function) in different situations. The different uses of the sub-segments are outlined above, but the factors that vary between different types of electrodes are broadly: price, adhesion[1] and trace quality.[2]

11. The parties indicated that the standard 12 lead resting ECG electrodes tend to be used for multiple purposes, particularly in the developing world, as they are the 'standard common denominator'. However, in the UK there tends to be little switching between the different segments of cardiology electrodes, as customers will procure the most appropriate electrode for each individual task.

12. Third party customers who responded to the OFT's market investigation, indicated that should all producers of disposable cardiology electrodes increase their prices by five per cent, there was no practical alternative to switch to. They stated that whilst reusable cardiology electrodes fulfil the

[1] There are three main properties of adhesion; tack (how fast the adhesion sticks to a substrate,), adhesion (how strong it sticks to the substrate) and cohesion (how internally strong the adhesive is). Changing one of these properties will affect the others, for instance, if tack is increased, adhesion decreases.

[2] Trace is dependent on the electrical properties of the sensor part in the electrode, the gel properties towards the skin, the electrode configuration and the adhesion properties.

same function as disposable ones, they are no longer recommended due to hygiene reasons, and neither party manufactured reusable cardiology electrodes. Therefore, based on the evidence available to it, the OFT believes that the market should be no wider than disposable cardiology electrodes.

Segmentation by Category

13. The relevant product market is identified primarily by considering the response of customers to an increase in the price of one of the products of the merger firms.[3] In this instance the market is likely to be narrower than all disposable cardiology electrodes if customers would not switch between the different categories of disposable cardiology electrodes, in response to a five per cent price increase in one of the categories. In this case, the different characteristics of each type of disposable cardiology electrode (set out below) may mean that they are in different markets.

14. The individual NHS national panels in England, Scotland, Wales and Northern Ireland are the primary purchasers of disposable cardiology electrodes in the UK. Each national panel have similar systems to operate and procure framework agreements via EU Official Journal procedures. The Framework agreement sets out the prices and terms by which any NHS-based purchaser can source the products from the different suppliers.

15. The NHS Framework agreement offers a way for individual entities to purchase their cardiology electrodes should they so wish. Individual trusts and hospitals, and often individual units, are also free to negotiate their procurement independently. The parties stated that the recent NHS Framework tendering process for England segmented the cardiology electrodes on the basis of short-term monitoring, long-term monitoring, neonatal, 12 lead resting ECG and stress diagnostics, since cardiology electrodes for each of these segments have different properties of trace and adhesion, which makes them suitable for different monitoring tasks.

16. **Short-term monitoring** electrodes may be in use for up to eight hours. The adhesion has to ensure that the electrode does not fall off patients in shock,

[3] OFT CC Joint Merger Assessment Guidelines, paragraph 5.2.7

moving or during an operation. The trace quality has to ensure that the QRS[4] complex of the trace is easily distinguished by the ECG monitor.

17. **Long-term monitoring** electrodes are used for up to 48 hours, or in some cases longer. The adhesive has to keep the electrode in place for the whole of the application, and ensure that any background noise level is low so that there is no extraneous noise in the recording. The trace quality also has to be excellent so that all parts of the signal from the heart are analysed.

18. **Neonatal** electrodes have to ensure that the QRS complex of the trace is easily distinguished by the ECG monitor. These electrodes are typically used for 48-72 hours, as regular changes would risk damaging the skin of the baby. Therefore, the adhesive has to keep the electrode in place for the whole application, and ensure that the background noise level is low so that there is no extraneous noise in the recording.

19. **Standard resting diagnostics (12 lead ECG)** electrodes are normally only used for up to 10 minutes, and the adhesive has to stick very fast, allowing measurement immediately after application. The patients are resting, so there is not much movement, with the adhesive only required to reduce any potential movement due to trembling as a result of nerves or age. The trace quality of these electrodes has to be excellent, as all parts of the signal from the heart are analysed to allow diagnosis of heart conditions.

20. **Stress Diagnostics** electrodes are generally used for up to 30 minutes, during which time the patient will be engaged in strenuous exercise. The adhesive therefore has to adhere quickly, to allow for immediate measurement, and be strong enough to ensure the electrode is not displaced during the diagnosis, while the patient may be sweating and/or moving as a result of running on a treadmill or biking. The trace quality has to be excellent as all parts of the signal from the heart are analysed.

21. Third party customers who responded to the OFT's market investigation indicated that they would not switch to another category of cardiology electrode following a five per cent price increase for cardiology electrodes in any one of these segments. This behaviour would seem to be driven by the

[4] An electrocardiogram (ECG) has five deflections (peaks or troughs from a central line), arbitrarily named 'P' to 'T' waves. The central Q, R, and S waves occur in rapid succession and are called the QRS complex. It is usually the central and most visually obvious part of a tracing.

different product characteristics making each category of electrodes ideally suited to a specific task (even though potentially they may be able to be used more generally).

22. The boundaries of the relevant product market are generally determined by reference to demand-side substitution alone.[5] However, there are circumstances where it may be appropriate for the OFT to aggregate a number of markets together, based on suppliers' responses to a change in price. Therefore if two products are manufactured in a similar way, and a manufacturer would switch production to the second product in response to a five per cent price increase in that market, then the two products may be in the same market due to supply-side substitution.

23. The parties have stated that, in general, different processes and machinery are used to manufacture the different categories of disposable cardiology electrodes. Although for short, long-term monitoring and stress diagnostic electrodes, the manufacturing processes are similar. For example, both short and long-term monitoring electrodes are welded using high frequency welding, whereas neonatal electrodes are welded using ultrasonic welding. Thus, it may be the case that short and long-term monitoring, and stress diagnostic electrodes are in the same market due to supply-side substitution, due to their similar manufacturing processes.

24. Third party competitors views were mixed. One third party stated that new machinery would be required to produce cardiology electrodes for a category that they were not currently active in. While two other third parties considered that monitoring and diagnostic electrodes could be in the same product market. However, one competitor commented that, 'each product is manufactured to a critical specific design and there are a wide variety of component mixes which together produce the individual features and performance characteristics of the electrode concerned.'

25. From the evidence received from its market investigation, the OFT considers that since each category of cardiology electrode is designed for a particular task, substitution between the categories in response to a five per cent price rise would be unlikely. As a result the OFT considered this transaction on the basis of separate economic markets on the demand side for short-term

[5] OFT CC Joint Merger Assessment Guidelines, paragraph 5.2.17

monitoring, long-term monitoring, neonatal, 12 lead resting ECG and stress diagnostics cardiology electrodes.

Geographic scope

26. The parties submitted that the disposable cardiology electrodes market does not differ across the developed world. Products are easily transported and the same products are marketed in the UK, as are marketed elsewhere in other western countries. There are no products that are used only in the UK, or are designed to UK specifications.

27. Cardiology electrodes sold in the UK have to meet the requirements of the EU Medical Device Directive,[6] which ensures that all products in the EU meet common minimum standards. The Medical Device Directive is designed to harmonise national controls, therefore allowing free movement of medical devices throughout the EU. As a consequence a manufacturer selling cardiology electrodes in any member state can also sell them in the UK.

28. Third party customers indicated that they either currently purchase electrodes from non-UK based firms, or that geographic location of the manufacturer was not important, and that they procure according to EU procurement law. Commenting that they would switch to another manufacture outside of the UK if a UK firm[7] attempted to increase prices by five per cent. The majority of the parties' competitors manufacture outside of the EU, and are active throughout Europe.

29. Given the outcome of the competition assessment, the OFT has not found it necessary to conclude on the geographic market in this case. On the basis of the evidence above the OFT has assessed the merger on an EU-wide basis. However, even if the geographic scope was as narrow as the UK only, no competition concerns would arise.

HORIZONTAL ISSUES

30. The parties overlap in the supply of disposable cardiology electrodes.

[6] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
[7] There is only one UK based manufacturer – Unomedical, Ambu is not active in manufacturing in the UK.

Market shares

31. The parties' combined EU market shares by volume across all cardiology electrode segments is [10-20] per cent, increment [0-10] per cent. In the individual segments the parties' combined EU market shares are Long-term monitoring — [20-30] per cent, increment [0-10] per cent; Short-term — [five-15] per cent, increment [0-10] per cent; Stress diagnostics— [25-35] per cent, increment [0-10] per cent; Resting — [15-25] per cent, increment [five-15] per cent; and Neonatal — [20-30] per cent, increment [0-10] per cent. If the long-term, short-term and Stress diagnostic markets were to be aggregated due to supply-side substitution, the parties' combined EU market share would be around [10-20] per cent, increment [0-10] per cent.

32. By value in the individual segments the parties' combined EU market shares are Long-term monitoring — [35-45] per cent, increment [0-five] per cent; Short-term — [15-25] per cent, increment [0-five] per cent; Stress — [45-55] per cent, increment [0-five] per cent; Resting — [20-30] per cent, increment [0-10] per cent; and Neonatal — [25-35] per cent, increment [0-five] per cent. In all market segments the increment is below five per cent, save Resting, where the increment is [0-10] per cent. If the short and long term monitoring, and stress diagnostic markets were aggregated the parties would have a combined market share of [15-25] per cent, with a [0-five] per cent increment.

33. The parties submitted that differences between the volume and value market shares for the long-term monitoring, stress and neonatal segments could be explained by the differences in the parties' average selling price for products in these segments, since Ambu focus on more expensive 'high end' electrodes, whereas those produced by Unomedical are a cheaper product.

34. This, however, did not explain the difference between volume and value market shares for the short term monitoring and resting segments. To explain the differences here, the parties provided data on Unomedical's global sales in the short-term monitoring and 12 Lead resting ECG market, which allowed the OFT to calculated the weighted average selling price, as Unomedical have tended to sell more of the their cheaper electrodes and have multiple electrodes in each category. As a result, based on the information available, it would appear that the difference between volume and value market shares is explained by the difference in the parties prices, with Ambu, again, focusing on the more expensive high end electrodes.

Closeness of competition

35. As mentioned above Ambu primarily supplied high quality electrodes, which are inherently more expensive than the more basic electrodes supplied by Unomedical and as such are used in different circumstances. The parties therefore contend that they are not particularly close competitors and that their products are largely complementary. This view was supported by a survey carried out by Ambu,[8] which showed that customers who chose to purchase from Ambu, cited quality as the most important reason.[9] In addition, Unomedical were not cited as a major competitor.

36. The parties provided information on the recently tendered NHS framework agreement,[10] contracted by NHS Supply Chain. All NHS Trusts in England have access to the framework agreement and can purchase products from it at the tendered prices. While the prices tendered to the framework are binding, they are not reflective of any actual sales, with sales being 'called down' by individual trusts at the specified prices.

37. The OFT understands that a total of nine companies are on the framework agreement for cardiology electrodes, namely; AMBU, Unomedical, GE, Leonhard Lang, 3M, Cardiac Services, Covidien, Philips, and Conmed. The OFT has analysed what it understands to be the disposable cardiology electrodes section of the framework agreement,[11] finding that Leohard Lang has 46 products, AMBU — 25, Unomedical — 16, 3M — 15, Unilect — two and Supertab — one.

38. As noted, a company's presence on the Framework agreement does not equate to a sale, so it is not possible to estimate market shares from this information. However, the OFT has been told of ECG electrode contracts that have been tendered by individual NHS purchasers, outside of the central framework agreement, in which Ambu has competed. From this information, the OFT has been able to calculate that out of the nine contracts which had an outright winner, Unomedical only won one contract, while Ambu won five. This tender information is consistent with third party comments, which

[8] Ambu UK Customer Satisfaction Survey, February 2011. This survey was not specifically carried out for the purposes of the current investigation.
[9] The OFT does not have comparable information from Unomedical, so is unable to say that quality is less important for their customers.
[10] The framework agreement was last tendered in 2011 for two years, with the option to extend by a further two years.
[11] Lot 3, extracts from the relevant NHS catalogues, Informal Submission, Annex 8

suggest that the parties are no closer competitors to each other, than they are to the other main market participants.

Spare Capacity

39. Even if the parties are not particularly close competitors, the merger may lead to an anticompetitive outcome if they were to attempt to restrict supply, and third parties did not have sufficient spare capacity to expand their existing activities. However, this is not the case in this industry. The OFT is aware of high levels of spare capacity currently to be found across this market and the parties have stated that capacity utilisation for Unomedical is currently around 50 per cent.

Barriers to Entry

40. The parties submitted that de novo entry to the cardiology electrode market would require the design, development, and testing of a new electrode, which the parties estimate would cost approximately £1 million. Once the design had been finalised, the new electrode would need EU regulatory approval, which costs around £10,000. Third parties have informed the OFT that this process can take in excess of a year.

41. In addition to development costs, a de novo entrant would have to invest in manufacturing capacity either in the EU, or more likely in Asia. The parties have provided estimates of set up costs for a factory in the UK of £4.5 million for machinery and £2 million for buildings. Of this a minimum of £600,000 of the building costs would be sunk, as would a proportion of the machinery costs. The parties submitted that establishing a factory in Asia would be a lower cost option, using poorer quality machines and employing more unskilled labour. Therefore, de novo entry is likely to take in excess of a year and require over £2 million of sunk costs, with up to another £5.5 million of working capital.

42. However, as no competition concerns are raised by the proposed transaction it has not been necessary to conclude on barriers to entry.

THIRD PARTY VIEWS

43. Third parties' comments have been considered, where appropriate, above. None of the third party customers indicated that they were concerned by the

merger, with each citing a number of alternative sources of supply. No unsolicited responses were received following the OFT's invitation to comment.

ASSESSMENT

44. The parties overlap in the supply of disposable cardiology electrodes across five segments — Short-term monitoring, Long-term monitoring, Neonatal, Standard resting diagnosis, and Stress diagnostics. The OFT assessed the transaction on the basis of separate economic markets for short-term monitoring, long-term monitoring, neonatal, 12 lead resting ECG and stress diagnostics cardiology electrodes.

45. All cardiology electrodes sold in the UK have to meet the requirements of the EU Medical Device Directive, the result being that any cardiology electrodes sold in the UK are also capable of being sold across the rest of the EU. There is only one manufacturer in the UK and the majority of other suppliers manufacture outside the EU, on this evidence the OFT assessed the merger on an EU-wide basis.

46. While the parties will have a combined market share by value of over [25-35] per cent in three segments; long-term monitoring, resting, and neonatal, the increment in these segments is around [0-five] per cent, [0-five] per cent and [0-five] per cent respectively. By volume, the merger does not result in an increment of greater than five per cent for any segment where the parties' combined market share is greater than 25 per cent.

47. Third parties did not consider that the parties were particularly close competitors and differences in quality between the two parties' products may suggest that their product portfolios are, to a degree, complementary. High levels of spare capacity are also currently to be found across this market. Finally, no third parties raised concerns about the proposed merger.

48. 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

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