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***Case No COMP/M.6851 - BAXTER INTERNATIONAL/
GAMBRO***

Only the English text is available and authentic.

**REGULATION (EC) No 139/2004
MERGER PROCEDURE**

Article 6(1)(b) in conjunction with Art 6(2)
Date: 22/07/2013

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EUROPEAN COMMISSION

Brussels, 22.7.2013
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PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the notifying party

Dear Sir/Madam,

**Subject: Case No COMP/M.6851 – Baxter International/ Gambro
Commission decision pursuant to Article 6(1)(b) in conjunction with Article 6(2) of Council Regulation No 139/2004¹**

1. On 3 June 2013, the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which Baxter International Inc. ("Baxter" or "the Notifying Party", United States) acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of the whole of Gambro AB ("Gambro", Sweden) ultimately controlled by Indap Sweden AB, by way of purchase of shares (hereinafter referred to as "the Transaction").² Baxter and Gambro are collectively referred to as "the Parties".

I. THE PARTIES AND THE OPERATION

2. Baxter is a healthcare company, which develops, manufactures and markets products used in the treatment of patients suffering from haemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions.

¹ OJ L 24, 29.1.2004, p. 1 ("the Merger Regulation"). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ("TFEU") has introduced certain changes, such as the replacement of "Community" by "Union" and "common market" by "internal market". The terminology of the TFEU will be used throughout this decision.

² OJ C 165, 11.6.2013, p. 13.

3. Gambro is a medical technology company, which develops, manufactures and supplies products and therapies for acute and chronic kidney dialysis, liver dialysis, myeloma kidney therapy, water treatment systems and other extracorporeal therapies for chronic and acute patients.
4. On 4 December 2012, Baxter and Indap Sweden AB entered into an agreement by which Baxter intends to acquire all of the share capital of Indap Holding AB, a wholly-owned subsidiary of Indap Sweden AB, whose only assets are the shares in Gambro. Since Baxter will acquire sole control of Gambro, the Transaction constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

II. EU DIMENSION

5. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million³ (Baxter: EUR 11 044 million, Gambro: EUR 1 245 million). Each of them has an EU-wide turnover in excess of EUR 250 million (Baxter: EUR [...] million, Gambro: EUR [...] million), but they do not achieve more than two-thirds of their aggregate EU-wide turnover within one and the same Member State. The notified operation therefore has an EU dimension pursuant to Article 1(2) of the Merger Regulation.

III. MARKET DEFINITION

A. Introduction

6. The Parties' activities overlap in markets for the supply of renal replacement therapy ("RRT") products. In addition, the Parties' activities overlap to a limited extent in the areas of water treatment equipment, therapeutic plasma exchange and saline solutions, which are adjacent to the renal replacement therapies markets.⁴ An overview of renal replacement therapies is provided in the remainder of this Section.
7. When renal function deteriorates or fails, renal replacement therapy ("kidney dialysis") is required, unless the patient receives a kidney transplant. Kidney dialysis is an artificial process that performs the key functions of healthy kidneys: filtering the blood, controlling the blood's electrolyte composition, and balancing fluid levels. Two types of patients require such therapies: (i) chronic patients with an end-stage renal disease and (ii) acute patients facing a sudden kidney failure.

³ Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C 95, 16.4.2008, p. 1).

⁴ Saline solutions are sterile solutions of sodium chloride which can be used for a variety of purposes including intra-venous therapies and as a cleaning agent. Baxter's EEA revenues in saline solutions in 2012 amounted to some EUR [...] million ([10-20]% market share). In contrast, Gambro, which does not manufacture saline solutions itself or actively market them in the EEA, recorded sales of less than EUR [...] million ([0-5]% market share). At a national level, the Parties' sales overlap in four Member States: Austria, France, Germany and Spain. In Austria and Germany, the market would not be affected as the merged entity's market share was only [0-5]% and [5-10]% respectively. Although the market in France and Spain would be affected with market shares of [20-30]% and [30-40]% respectively, in each case the increment is negligible at [0-5]% or less. As such, the Transaction will not significantly change the competitive structure of the market either at national or EEA-wide level.

8. Three categories of dialysis treatments exist: (i) peritoneal dialysis ("PD"), (ii) haemodialysis ("HD") and (iii) continuous renal replacement therapy ("CRRT"). In the remainder of this Section, each of these therapies will be introduced in turn.
9. In PD, a dialysis fluid ("dialysate") is run into the abdomen's peritoneal cavity through a soft plastic tube, called a PD catheter. PD is used almost exclusively to treat chronic patients. The equipment required to perform PD consists of a small pumping machine, a so-called cycler (only necessary for so-called automated PD treatments) and several disposables, including a transfer set that connects the catheter to a bag system.



PD cycler, catheter and transfer set

10. In HD, blood is pumped into a machine and purified through an exchange with another fluid (dialysate or replacement fluid) through a membrane (dialyser). The blood is then returned to the patient's body. HD is mainly used for chronic patients but can also be used for acute patients in certain circumstances. Unlike CRRT, which is continuous (see below), HD is an intermittent therapy, which means that patients receive HD through various sessions each of which lasts several hours.
11. An HD treatment system consists of a monitor, disposables (including a dialyser and bloodlines) and fluids that are prepared from concentrates (fluids and disposables being also referred to as "consumables").⁵ The monitor allows the physician or nurse to choose the treatment modalities (such as blood pump speed) and to check how the patient responds to the treatment. The monitor has a control display and serves as the apparatus to which the disposables are attached. Bloodlines are tubes that connect the patient's blood stream with the dialyser and the fluids. Dialysers perform the blood filtering.

⁵ Two different concentrate types are required to prepare fluids, namely acid concentrate ("A-concentrate") which is supplied in liquid form in bags and base concentrate ("B-concentrate") which is generally bicarbonate-based and supplied in powdered form in a cartridge. The two are mixed and diluted with pre-treated water with the help of the monitor.



HD monitor, fluids (concentrates), bloodlines, dialysers

12. CRRT is based on the same principles as HD but is a continuous treatment, that is to say, it is applied 24 hours a day for several days in a row to treat acute patients. CRRT is generally performed in intensive care units ("ICU") using special equipment, consisting of a dedicated CRRT monitor and disposables.

Gambro CRRT monitor

Baxter CRRT monitor



13. Disposables include dialysers and bloodlines, which can be provided together as a "set". Moreover, CRRT requires fluids that are delivered in ready-to-use bags.



Source Form CO: CRRT fluids, pre-connected set

14. The Parties' activities overlap in the supply of HD and CRRT monitors and consumables. Gambro, unlike Baxter, does not supply PD products⁶.

⁶ In addition, Baxter operates [...] dialysis clinics on the Canary Islands, which represent [0-5]% of the market for dialysis services in Spain and less than [20-30]% of the market for such services in the event that the geographic market is no broader in scope than the Canary Islands. In view of these limited

B. Product market definition

1. Distinction between HD, CRRT and PD

a. Baxter's view

15. Baxter considers that PD, HD and CRRT products belong to separate product markets for the following reasons.
16. First, Baxter stresses that each product is specifically designed for a given type of therapy and cannot be used for other therapies⁷. Second, Baxter submits that for a given patient, the three therapies are not fully substitutable. When it comes to acute patients, Baxter claims that medical studies suggest that CRRT should be preferred to HD for certain types of patients, whereas other patients could be treated with either CRRT or HD but this depends on the equipment available at the hospital and/or the ward where the patient is being treated. As regards chronic patients, Baxter indicates that PD is not suitable for a significant proportion of them and HD is not suitable for another significant sub-group, for medical reasons or on other grounds such as mobility and assistance needed to perform the treatments at home in the case of PD.
17. Third, Baxter argues that the selection of a particular type of therapy depends to a significant extent on physicians' preferences linked to therapeutic considerations and on the location of the patient when the kidney condition is diagnosed (general renal ward, where the patient will most likely be treated with HD or ICU where CRRT is typically administered).
18. Fourth, cost differences exist between the various types of therapies. As regards acute patients, Baxter claims that there are a number of factors suggesting that CRRT is more expensive than HD and that the cost differences translate into different reimbursement rates for the two types of therapies in most national health reimbursement systems⁸. As regards chronic patients, HD is typically seen as more expensive than PD and the reimbursement schemes for HD and PD differ across countries.
19. Fifth, Baxter submits that HD, CRRT and PD products are usually purchased through different tenders, or are at least part of separate lots within a given tender.

b. Commission's assessment

20. In past cases, the Commission did not conduct an extensive market definition analysis in the area of RRT equipment and consumables. In a previous case, the Commission has left open the question whether the product market definition for dialysis services

market shares and in the absence of concerns during the market investigation, this vertical link is not further analysed in this Decision.

⁷ For example, HD monitors and fluids cannot be used to deliver CRRT. Indeed, a HD monitor uses as inputs fluid solutions and concentrates which, when they are fed into a HD circuit, are mixed with purified water. As a result, HD monitors require constant access to purified water. By contrast, the fluids used in CRRT are already diluted and supplied in bags. CRRT monitors thus do not require access to purified water but must be designed so they can be run with bags.

⁸ These systems, instead of the patients, pay healthcare centres for dialysis treatments provided to patients.

should cover both HD and PD⁹. Another Commission decision briefly considered fluids for dialysis treatments without reaching a conclusion on the product market definition.¹⁰ Lastly, the Commission has also considered a separate product market for catheters and kits used in haemodialysis.¹¹

21. As regards the possible distinction between HD and CRRT products, replies to the Commission's market investigation have indicated that CRRT equipment can normally not be used for HD treatments and vice versa.¹² Acute patients are relatively rarely treated with HD.¹³ Moreover, respondents have confirmed that the treatment location (ICU, or nephrology units) of acute patients influences the choice of the treatment: CRRT is mainly used in ICU, while HD is used in nephrology units.¹⁴ Although hospitals purchase both HD and CRRT equipment, specialised clinics and dialysis centres generally do not purchase CRRT equipment because they do not treat acute patients.¹⁵ Importantly also, price differences between HD and CRRT products do not appear to be a significant criterion for the physicians to prescribe one treatment rather than the other.¹⁶
22. Therefore, a small but significant increase in the price of CRRT products would be unlikely to induce a significant number of customers to switch to a significant degree to HD to treat acute patients, and vice-versa. In light of the above, the Commission considers that CRRT products and HD products belong to separate product markets.
23. As regards the possible distinction between HD and PD, replies to the Commission's market investigation have indicated that HD equipment cannot be used for PD treatments and vice versa. The choice between HD and PD to treat a given chronic patient mainly depends on the clinical status of the patient, but also on the patient's preferences and the suitability of the treatment with his or her lifestyle (in particular because PD, which is performed at home, requires a certain level of assistance and autonomy on the part of the patients, unlike HD¹⁷)¹⁸. Importantly, price differences

⁹ Case No COMP/M.6091 - *Galenica / Fresenius Medical Care / Vifor Fresenius Medical Care Renal Pharma JV*).

¹⁰ See Case No COMP/M.4010 - *Fresenius / Helios*.

¹¹ Case No COMP/M.2505 – *Tyco/CR Bard*, para. 7.

¹² See responses to question 16 of questionnaire Q2 – Questionnaire to customers (HD) and to question 12 of questionnaire Q3 – Questionnaire to customers (CRRT). The choice between CRRT and HD to treat an acute patient depends to a great extent on the clinical status of the patient (including, blood pressure, need for artificial respiration, haemostability or instability).

¹³ The market investigation revealed that approximately 20% of the acute patients are treated with HD.

¹⁴ See responses to question 16 of questionnaire Q2 – Questionnaire to customers (HD) and to question 12 of questionnaire Q3 – Questionnaire to customers (CRRT).

¹⁵ See responses to question 8.2 of questionnaire Q2 – Questionnaire to customers (HD).

¹⁶ See responses to question 16 of questionnaire Q2 – Questionnaire to customers (HD) and to question 12 of questionnaire Q3 – Questionnaire to customers (CRRT).

¹⁷ Only a very small proportion of chronic patients treated with HD receive that treatment at home. The vast majority is treated in healthcare centres.

¹⁸ See responses to question 11 of questionnaire Q2 – Questionnaire to customers (HD).

between PD and HD do not appear to be a significant criterion for the treatment prescription by the physician¹⁹.

24. Therefore, a small but significant increase in the price of HD products would be unlikely to induce a significant number of customers to switch to PD to treat chronic patients, and vice-versa. In light of the above, the Commission considers that PD products and HD products belong to separate product markets.
25. Finally, CRRT and PD products are fundamentally different and used for treatments applying to two very distinct categories of patients (acute and chronic patients respectively). Therefore, the Commission considers that these products also belong to two separate product markets.
26. In view of the above, the Commission concludes that CRRT, HD and PD products belong to separate product markets.
27. The extent to which, for each of CRRT and HD, the relevant product market should encompass all or several types of devices and consumables considered together as forming a single "system", or whether the market should be defined on the basis of each main type of device and consumable ("components") is considered in the following two sections. As the merging Parties' activities do not overlap in PD, this treatment method is not further assessed in this respect.

2. HD: system versus components

28. Baxter submits that it would not be appropriate to treat the individual components of an HD system as each constituting a distinct product market. It notes that customers often do not purchase monitors, disposables and fluids separately. In some cases, they conclude a "pay per treatment" contract²⁰. Furthermore, according to Baxter, CRRT suppliers typically offer all (or most) CRRT components.
29. In previous decisions dealing with medical devices²¹ in fields other than RRT, where the Commission assessed the relevance of defining markets on the basis of whole medical systems rather than individual "components" forming such systems, technical interoperability between components of different suppliers was an important criterion taken into consideration in such assessment. The following considerations may be relevant to such assessment: whether the main device in a system is a low value product - sometimes given for free by suppliers and the extent to which the choice of the main device is a key factor in determining the choice of the supplier.²²
30. In the present case, Baxter provided detailed information about the compatibility of dialysers, fluids and bloodlines with different HD monitors²³. The information

¹⁹ See responses to question 11 of questionnaire Q2 – Questionnaire to customers (HD).

²⁰ Under pay per treatment contracts (PPT) the supplier makes available the entire HD system, including monitors, disposables and fluids, for the number of treatments agreed. The customer pays an amount specified in the contract for each treatment performed with the equipment and consumables in question.

²¹ Case No COMP/M.3304 – *GE / Amersham*, Case No COMP/M.4569 - *GE / Abbott Diagnostics Division*, para 19, Case No COMP/M.3687 – *Johnson&Johnson / Guidant*, para 58.

²² Case No COMP/M.3687 – *Johnson&Johnson / Guidant*, para 58.

²³ See Annex 6.10 to the Form CO.

indicates that various HD components originating from different suppliers appear to be generally interoperable. This fact was confirmed in the market investigation.²⁴ Dialysers and fluids are generally compatible with various suppliers' monitors. Although bloodlines are generally monitor specific, as they are designed for the monitor model in question, they can be produced by different manufacturers²⁵. Exceptionally, there are a few HD monitors that work exclusively with pre-connected sets and cassettes.²⁶

31. The market investigation indicated that the majority of customers buy monitors²⁷, dialysers and fluids separately, in most instances from different providers.²⁸ The reason indicated for such choice was customers' desire to maintain a degree of independence and to have some protection against production problems. Certain customers believe that if they buy items individually they are able to procure the best products at the best prices. Hospitals and clinics generally conclude agreements allowing them to buy at least some of the consumables (dialysers and fluids) from different suppliers when technically possible.²⁹
32. Furthermore, an analysis of the tendering data provided by Baxter indicates that although the purchasing pattern varies among EEA countries, tenders are generally organised in lots and competitors bid for different lots, containing specific components or sets. This way of structuring tenders allows customers to select different providers for different HD products if they see fit.
33. Although, the system-based market definition proposed by Baxter is not strongly supported by the market investigation, for the purposes of the present case, the market definition can be left open in this respect as the Transaction does not raise serious doubts on the HD markets under both the "system" and "components" scenario.

²⁴ Agreed minutes of the teleconference call of 25 May 2013 with Asahi and agreed minutes of the teleconference call of 6 June 2013 with Nipro.

²⁵ Agreed minutes of the teleconference call of 19 June 2013 with EffeEmme and agreed minutes of the teleconference call of 24 June 2013 with Meise. With the exception of cassettes (see following footnote), a given model of such dedicated bloodlines can be – and often is, to a significant extent - produced and supplied by manufacturers other than the manufactures* of the monitors for which this bloodline model has been designed. Indeed, there appears to be no significant technical obstacle to this practice, and no significant obstacle in terms of intellectual property rights.

* *should read: manufacturers*

²⁶ Gambro's Artis and Innova monitors, Fresenius' 5008 monitor, and NxStage's SystemOne, that is to say a minority of HD monitors supplied on the market. A cassette is a pre-connected unit of bloodlines. The operator can mount the cassette onto the monitor, and the pre-configured arrangement of the bloodlines facilitates the correct connection of the various bloodlines on the shell to the monitor. This provides the operator with a ready-to-use circuit that can easily be connected. As to NxStage's SystemOne, the monitor functions with a pre-connected set of bloodlines and a dialyser.

²⁷ Usually, customers acquire monitors together with after-sales services (technical and maintenance services, training for nurses operating the monitors) associated with the monitors, either directly from the manufacturer or from the manufacturer's distributors, unless when they have the in-house capability to perform such operations themselves. In the remainder of this decision, the supply of monitors will be considered as encompassing the supply of such after-sale services, both for HD and CRRT.

²⁸ See responses to question 24 of questionnaire Q2 – Questionnaire to customers (HD).

²⁹ See responses to questions 26 and 27 of questionnaire Q2 – Questionnaire to customers (HD).

3. CRRT: systems versus components

34. As in the case of HD, Baxter submits that it would be inappropriate to further segment the CRRT market according to its various components. First, almost all CRRT suppliers offer the entire range of CRRT components. Second, hospitals and other purchasers often purchase at least bloodlines and dialysers from the monitor's producer because they are "sets" dedicated to that particular type of monitor. According to the Parties, bloodlines and dialysers in CRRT are dedicated and possibly proprietary to a specific monitor.³⁰ Universal bloodlines do not exist in CRRT. Also, Baxter explains that CRRT bloodlines are only offered by the manufacturers of the corresponding CRRT monitors.
35. As regards fluids, Baxter submits that CRRT fluids are typically not technically linked to the use of specific monitors or dialysers and that each fluid could be used with all or most of the other CRRT components. However, Baxter also mentions that differences in the fluid bags exist, which may discourage to some extent the use of another supplier's fluids. Firstly, different types of connections between fluid bags and monitors exist, which then require an adaptor for the use of the solution of another manufacturer. Secondly, the bag can be attached to the monitor in different ways (for example Gambro's Prismaflex monitor carries bags by three hooks to improve stability, instead of one hook per bag as, for instance, Baxter's Aquarius monitor).
36. The result of the market investigation indicated that bloodlines and dialysers ("CRRT sets") are generally technically linked (dedicated) to the CRRT monitor.³¹
37. As regards fluids, the results of the market investigation are mixed. First, it seems that fluids are generally compatible with third-party CRRT sets.³² Second, in some cases, a different department within the hospital deals with the purchasing of CRRT fluids as they are considered as pharmaceutical products.³³ Third, out of all responding customers, only one third said they would have PPT contracts (typically requiring them to source all components from one supplier).³⁴
38. However, a number of elements point towards CRRT fluids being part of an overall CRRT system market. First, in practice, the majority of customers that replied to the Commission's market investigation buy all disposables from the same supplier, even though fluids could in principle be purchased from different suppliers according to usual contractual arrangements.³⁵ Second, the majority of customers prefer to source all main categories of CRRT products from the same provider.³⁶ Third, the majority of

³⁰ This is the case with Gambro's Prismaflex system. Fresenius and Belco operate on the basis of the same model.

³¹ See responses to question 15 of questionnaire Q3 – Questionnaire to customers (CRRT).

³² See agreed minutes of the teleconference call of 13 May 2013 with B Braun, responses to question 15.1 of questionnaire Q3 – Questionnaire to customers (CRRT) and responses to question 10 of questionnaire Q4 – Questionnaire to distributors.

³³ See responses to questions 15 and 15.1 of questionnaire Q3 – Questionnaire to customers (CRRT).

³⁴ See responses to question 17 of questionnaire Q3 – Questionnaire to customers (CRRT).

³⁵ See responses to question 17 of questionnaire Q3 – Questionnaire to customers (CRRT) and agreed minutes of the teleconference call of 14 May 2013 with Fresenius.

³⁶ See responses to question 31 of questionnaire Q3 – Questionnaire to customers (CRRT).

the competitors indicated that the ability to provide all main categories of CRRT products is a crucial aspect of being successful in this market.³⁷

39. In view of the above, the Commission will assess the effects of the Transaction on the markets for CRRT products on the basis of two possible alternative market definitions: (i) a single product market for CRRT systems, comprising all CRRT components, and (ii) two product markets, one encompassing CRRT monitors and sets (including bloodlines and dialysers) and another including CRRT fluids and other disposables. In the present case, the precise product market definition can be left open in this respect because the Transaction raises serious doubts as to its compatibility with the internal market in a number of EEA countries on all these alternative product market definitions.

4. Adjacent markets

40. The Parties' activities overlap in water treatment systems and therapeutic plasma exchange.

a. Water treatment systems

41. Water treatment systems generate purified pre-treated water that is used by HD machines to produce dialysate and replacement fluids. Baxter submits that water treatment systems should be considered as forming one single product market, without it being necessary to distinguish between large-scale water treatment systems such as those serving a large HD treatment unit (renal wards or large dialysis centres) and smaller units such as those used by individual patients for home HD treatments or for in-centre treatment in small dialysis centres.
42. In previous cases the Commission examined water treatment systems used among others for healthcare applications, but did not define the product or geographic market for water treatment systems related to dialysis, and more generally to healthcare applications.³⁸
43. For the purposes of the present case, the precise market definition can be left open as the Transaction does not raise serious doubts irrespective of the market definition considered.

b. Therapeutic plasma exchange (TPE) therapy

44. Therapeutic plasma exchange ("TPE") is an extracorporeal therapy used to filter large molecular weight substances from the blood plasma. TPE can be used to treat a large variety of disorders, mainly neurological or haematological. Baxter submits that TPE is not as such a renal replacement therapy and should therefore not be considered part of the HD and/or CRRT market.
45. For the purposes of assessing the competitive effects of the Transaction, the Commission will consider the narrowest plausible market, namely that of TPE.

³⁷ See responses to question 39 of questionnaire Q1 – Questionnaire to competitors.

³⁸ Case No. COMP/M.3551 – *CD&R/ Culligan*.

C. Geographic market definition

1. HD and CRRT markets

a. Baxter's view

46. Baxter submits that in previous cases,³⁹ the Commission has dealt with the provision of dialysis treatment services (rather than the supply of equipment to providers of dialysis services as is the case here), and left open whether the geographic market was regional/local or national. In another decision related to the dialysis market⁴⁰ among others, and more particularly to “haemodialysis catheters/kits” the Commission had considered an EEA wide geographic market.
47. Baxter also submits that although some characteristics of the HD and CRRT sectors may point towards a national definition, these markets should be regarded as EEA-wide in scope for several reasons.
48. First, public hospitals often issue EEA-wide tenders for the supply of these products and there are no geographic limitations for suppliers invited to participate. Second, the main HD and CRRT suppliers are all active across the EEA and have centralized R&D and production facilities by product categories, shipping these products across the EEA (or worldwide), with transportation costs representing a minor proportion of the overall sales price.
49. Third, there are no regulatory barriers impeding cross-border trade within the EEA. Monitors, dialysers and bloodlines are subject to the Medical Devices Directive⁴¹ and once a CE marking has been obtained, a product can be sold throughout the EEA. This would also be true for fluids, including - though to a more limited extent - fluids that can be used to generate replacement fluids, which qualify as medicinal products under the Community Code (that is to say CRRT replacement fluids which enter the patient's blood stream),⁴² whose marketing authorisations are granted at national level but which benefit from a decentralized⁴³ or mutual recognition procedure.⁴⁴
50. Fourth, Baxter claims that local presence is not a crucial factor in the award of a tender/contract, even though some customers may require some form of local presence, for instance to provide technical support and/or training services. Fifth, Baxter argues that reimbursement schemes in EEA countries do not in any way affect the ability of suppliers to compete with their products in any EEA country as HD or

³⁹ Case No COMP/M.6091 – *Galenica/Fresenius Medical Care/Vifor Fresenius Medical Care Renal Pharma JV*, para. 49 *et seq.*

⁴⁰ Case No COMP/M.2505 – *Tyco/CR Bard*, para. 9 *et seq.*

⁴¹ Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12.7.1993, p. 1.

⁴² Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67.

⁴³ Where marketing authorizations are applied for simultaneously in several Member States with one of them functioning as the reference Member State, and at the end of the procedure, all authorities involved grant marketing authorizations.

⁴⁴ Where marketing authorization is obtained first in one Member State and mutual recognition is then sought in other Member States and can only be refused for narrow public health reasons.

CRRT suppliers do not have to apply separately for reimbursement status in each EEA country.

51. Sixth, Baxter claims that the fact that suppliers' market shares may vary from one EEA country to another is to a large extent due to historic reasons which does not in any way impair other suppliers' ability to compete in the same market.

b. The Commission's assessment

52. The market investigation does not support Baxter's views.
53. A majority of the customers that replied to the Commission's market investigation indicated, for both HD and CRRT, that when purchasing devices and consumables, they attach importance to the local presence or local sales force of the supplier or its distributors, as well as to the reputation of the supplier in their country. In particular, elements such as the potential supplier's local training and maintenance team are among the important factors influencing the customers' choice, given the importance of these after-sales services for monitor users⁴⁵.
54. Regarding the supply of monitors, customers generally require the presence of a maintenance representative working for the supplier in the country where they are located⁴⁶. Regarding the supply of consumables (fluids, dialysers and bloodlines), customers also expressed a preference to have locally active suppliers. The main reason is the need for short delivery times and for hospitals and clinics to have rapid response in case of problems with the products.⁴⁷ Distributors confirmed that regarding consumables, local warehouses are necessary in order to be able to meet customers' time-of-delivery requirements.⁴⁸ Local warehouses are generally situated at a distance ranging from 150 to 400 km from the customer's premises.⁴⁹ As to monitors, distributors emphasised the importance of having permanently available maintenance support teams for training and technical service.⁵⁰
55. The market investigation in this case indicated that competitors generally do not respond to public tenders in EEA countries where they do not have a direct or indirect presence, both for HD and CRRT.⁵¹ For example, Nikkiso Europe stated that it "*is not responding to requests from markets where [they] have no partners*".⁵² Moreover, the market investigation indicated that almost all competitors and distributors have a sale

⁴⁵ See responses to question 32 of questionnaire Q2 – Questionnaire to customers (HD) and responses to questions 23 and 24 of questionnaire Q3- Questionnaire to customers (CRRT).

⁴⁶ See responses to question 33 of questionnaire Q2 – questionnaire to customers (HD).

⁴⁷ See responses to question 34 of questionnaire Q2 – Questionnaire to customers (HD) (see for example [...] response to that question) and responses to questions 23 and 24 of questionnaire Q3- Questionnaire to customers (CRRT).

⁴⁸ See responses to question 16.1 of questionnaire Q 4 – Questionnaires to distributors.

⁴⁹ See responses to question 16.3 of questionnaire Q 4 – Questionnaires to distributors.

⁵⁰ See responses to question 17.1 of questionnaire Q4 – Questionnaires to distributors.

⁵¹ See responses to questions 24.4, 27 and 28 of questionnaire Q1 – Questionnaire to competitors.

⁵² See Nikkiso Europe's response to question 27.2 of questionnaire Q1 – Questionnaire to competitors.

or distribution network organized at national level, or even at sub-national / local level.⁵³

56. In addition, the bidding data submitted by Baxter indicates that tenders are organized at national level and market conditions vary from country to country.
57. Furthermore, the market investigation has indicated the existence of significant differences as regard the final price of the product, namely price fluctuations of more than 10-20% between EEA countries for HD. Competitors explain this fluctuation by the different reimbursement rates applicable under the various national reimbursement schemes, which are taken into account by suppliers when proposing or negotiating prices.⁵⁴ As regards national reimbursement system for CRRT, the market investigation indicates that modalities vary from country to country.⁵⁵
58. Finally, as regards regulatory barriers, while having a CE mark is sufficient to sell CRRT or HD medical device products across the EEA, this does not apply to fluids that can be used to generate replacement fluids as these are considered pharmaceutical products and are subject to approval by national authorities under the Community Code. Moreover, additional notification or registration is necessary for medical devices in some countries such as Spain or Greece⁵⁶. Besides, language differences may be an additional burden when applying for regulatory approvals for the pharmaceutical products as all necessary documentation has to be translated.⁵⁷

c. Conclusion

59. In view of the foregoing, the relevant geographic markets for HD systems and components are likely to be national in scope, rather than EEA-wide. For the purposes of the present case, however, the precise definition can be left open as the Transaction does not raise serious doubts with respect to HD under any alternative geographic market definition.
60. Similarly, the relevant geographic markets for CRRT systems, sets and disposables are likely to be national in scope, rather than EEA-wide. For the purposes of the present case, however, the precise definition can be left open as the Transaction raises serious doubts under the alternative geographic market definitions.

⁵³ See responses to questions 20 and 21 of questionnaire Q1 – Questionnaire to competitors and responses to question 12 of questionnaire Q4-Questionnaire to distributors.

⁵⁴ See responses to question 22 of questionnaire Q1 – Questionnaire to competitors.

⁵⁵ See responses to question 48 of questionnaire Q1 – Questionnaire to competitors and responses to question 39 of questionnaire Q4 – Questionnaire to distributors. See also B. Braun's response to question 23 of questionnaire Q1 – Questionnaire to competitors and agreed minutes of the teleconference call of 8 May 2013 with Bellco.

⁵⁶ See responses to question 22 of questionnaire Q1 – Questionnaire to competitors, responses to question 15 of questionnaire Q4 – Questionnaire to distributors, and the Parties' response to question 28 c. of the request for information regarding the draft commitment proposal of 1 April 2013.

⁵⁷ As regards pharmaceutical products (such as CRRT replacement fluids), it should be noted that the marketing authorisation holder also has to register at the local chamber of commerce and the manufacturing site has to be authorised by the competent authority of the EEA member state. See the Parties' response to question 28 c. of the request for information regarding the draft commitment proposal of 1 April 2013.

2. Adjacent markets

a. Water treatment systems

61. Baxter submits that the relevant geographic market for water treatment systems is (at least) EEA-wide in scope.
62. For the purposes of the present case, however, the precise market definition can be left open since the Transaction does not raise serious doubts whether the market is considered to be national or EEA-wide in scope.

b. Therapeutic plasma exchange

63. Baxter submits that the TPE market should be considered as EEA-wide.
64. For the purposes of the present case, however, the precise market definition can be left open since the Transaction does not raise serious doubts whether the market is considered to be national or EEA-wide in scope.

IV. COMPETITIVE ASSESSMENT

A. Haemodialysis (HD) Therapy equipment and consumables - Horizontal overlaps

1. EEA level

65. The Parties estimate that the overall EEA HD market (encompassing all HD equipment and consumables) was worth EUR [...] billion in 2012.
66. Gambro produces and sells HD monitors, associated technical services, disposables, and fluids. Whilst Baxter also sells all these products, it only manufactures fluids and sources the other components from third parties. Baxter supplies monitors in eight EEA countries, namely Denmark, Finland, Ireland, Italy, the Netherlands, Spain, Sweden, and the United Kingdom. These monitors are manufactured for Baxter by Nikkiso and bear Nikkiso's label. Until recently, Baxter offered dialysers [...].⁵⁸ Baxter offers bloodlines dedicated for use with Nikkiso's monitors, which are [...]. It also sources dedicated bloodlines [...]. Moreover, it distributes bloodlines dedicated for use with competing monitors (such as those manufactured by Gambro or Fresenius) [...].
67. However, [*Baxter's supply agreements*].⁵⁹
68. The Parties supply HD products either directly to end-customers or through distributors, depending on the country concerned.

⁵⁸ To a lesser extent, it also supplies dialysers [...], in two Member States only, namely Italy and the Netherlands.

⁵⁹ Baxter's submission of 17 June 2013 *Supplement to country analyses*.

a. HD systems

Market Structure – Market shares

69. The market shares estimated by the Parties on the EEA HD systems market (comprising monitors, bloodlines, dialysers, fluids and other disposables) are as follows:

Table 1: Market shares for the EEA HD systems market (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Gambro	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[20-30]%
Combined	[40-50]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
Fresenius	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
B. Braun	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Bellco	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[0-5]%
Nipro	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Nikkiso	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Toray	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Asahi	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

70. Baxter submits that the Parties' combined EEA market share is moderate (approximately [30-40]%) and that the increment is small ([0-5]%). Baxter stresses that it is currently the [...] largest player, behind B. Braun ([5-10]%), while Gambro currently ranks second with a market share of [20-30]%. Baxter also stresses that the combined entity will still only rank [...] behind the leading player Fresenius Medical Care ("Fresenius" or "FMC"), which has a market share of [30-40]%.
71. In the Commission's view, the market shares indeed suggest that on an EEA-wide basis, the combined entity will continue to face competition from several strong market players, first and foremost Fresenius, which achieves a [...] share than the Parties' combined market share, but also B. Braun and to a lesser extent, Bellco, Nipro and Nikkiso. In addition, while Baxter's market share has remained stable over the past six years at some [0-5]%, Gambro's market share has been declining significantly over the same period, and this decrease is correlated to a significant increase in Fresenius', and to a lesser extent, B. Braun's market share. This suggests that Fresenius and B. Braun are dynamic competitors in the HD markets and would have the potential to attract a significant number of customers should the combined entity attempt to raise prices or decrease quality post-Transaction.
72. In addition, the increment is relatively limited, which is indicative of limited merger-specific effects on the competitive dynamics.
73. In the course of the market investigation, a majority of customers and competitors indicated that the combined entity would continue to face significant competition from other HD product suppliers post-Transaction. A large majority of the competitors that took this view identified Fresenius as a source of competitive pressure. Other suppliers

mentioned as a source of competitive pressure on the merged entity included B. Braun, Bellco, Nipro, Nikkiso and Asahi⁶⁰. Other elements collected in the course of the market investigation tend to confirm the strength of Fresenius and B. Braun, and the non-negligible role played by other market participants such as Bellco and Nipro. In particular, customers were asked to score the strength of Baxter, Gambro, Fresenius and B. Braun with respect to various criteria, namely price, quality, range of products offered, technical assistance, capacity to offer innovative products and local presence. Fresenius appears to be viewed as the strongest supplier with respect to all criteria while Gambro ranks second. Baxter and B. Braun have similar scores and are viewed as significantly weaker than both Gambro and Fresenius, notably with respect to quality and the range of products offered. Furthermore, a significant number of respondents mentioned Bellco and Nipro and gave them relatively high scores⁶¹. The results are largely corroborated by the views expressed by competitors as regards the respective strengths of the main market participants⁶².

Closeness of competition

74. Furthermore, the Parties do not appear to be particularly close competitors. Asked to identify Gambro's closest competitor in regard to HD systems, a large majority of customers named Fresenius. All the other market participants were each either mentioned by a minority or not mentioned at all. Baxter and B. Braun were identified by a similar number of customers, and were followed by Bellco and Nipro⁶³. The same outcome emerges from the views conveyed by competitors as regards Gambro's closest competitor⁶⁴. In addition, customers overall see Gambro and Fresenius as similarly strong competitors with respect to product quality and the range of products offered, with all other competitors, including Baxter, being significantly weaker in respect of these two criteria⁶⁵. This is consistent with the views expressed by Baxter, according to which the Parties are not particularly close competitors notably because Gambro, for which HD is a key market, strives to differentiate itself from rivals by innovation and quality whereas Baxter – [...]⁶⁶.
75. Information provided by customers about the switching events that occurred over the last three years further supports the conclusion that the Parties are not particularly close competitors. Indeed, out of all the switching events reported by customers, only a small minority relates to switching between the Parties. Twice as many switching events involved one of the Parties and Fresenius. Moreover, out of all the switching events involving Gambro, only 20% also involved Baxter while almost 45% involved

⁶⁰ See responses to question 33 of questionnaire Q1 - Questionnaire to competitors and question 54 of questionnaire Q2- Questionnaire to customers (HD).

⁶¹ See responses to question 51 of questionnaire Q2 - Questionnaire to customers (HD).

⁶² See responses to question 30 of questionnaire Q1 - Questionnaire to competitors.

⁶³ See responses to question 53.1 of questionnaire Q2 - Questionnaire to customers (HD). Some customers named several competitors, suggesting that they were equally close to Gambro.

⁶⁴ See responses to question 32.1 of questionnaire Q1 - Questionnaire to competitors.

⁶⁵ See responses to question 51 of questionnaire Q2 - Questionnaire to customers (HD).

⁶⁶ This claim by Baxter is also consistent with the fact that Gambro manufactures itself all the categories of products and can thus influence the quality and technical functionalities of all these products. By contrast, Baxter [...].

Fresenius, 20% involved B. Braun and 35% involved other competitors such as Nipro and Bellco in particular⁶⁷.

76. The Commission also analysed the extent to which the Parties may be close competitors with respect to the development of new or upgraded products. It appears that the Parties are not particularly close competitors in this respect either, since Baxter is focussing on the development of [...] whereas Gambro is dedicating its R&D resources to the development of [...]. This is consistently confirmed by internal documents obtained from the Parties⁶⁸.

Customer's ability to switch to other suppliers

77. The market investigation indicates that switching from one supplier to another as a result of a price increase would encounter some barriers in particular if switching involves the HD monitor. These barriers, however, may ultimately not prevent HD customers from switching.
78. Overall, competitors consider that switching supplier is easy for consumables (including fluids, bloodlines, dialysers and other disposables) if the customers' monitors are not technically bundled to disposables exclusively produced by the manufacturer of the monitors, which is generally not the case⁶⁹, and if the customer does not prefer to purchase them as part of a package including monitors and associated technical services, such as a "pay-per-treatment" contract. As regards monitors, switching supplier is more burdensome in the eyes of competitors because customers need to test the new monitor model, modify their operational processes and retrain their staff. According to competitors, overall, switching the supplier entails the same difficulties for disposables as for monitors when the customer is technically and/or contractually prevented from buying disposables from a supplier other than the supplier of the monitors.⁷⁰
79. Customers' comments suggest that switching is not excessively difficult. A majority of the customers consider that switching supplier does not entail significant lead time or costs for dialysers, fluids and bloodlines⁷¹. Responses are more nuanced when it comes to monitors or whole HD systems. Respondents referred to the need to retrain staff, and to a lesser extent, test the new equipment and get used to new operating and maintenance processes⁷². However, even if switching supplier requires adaptations and entails costs when it involves a change of monitor model, those obstacles appear to be surmountable without major difficulties for HD customers. First, the time indicated by customers as necessary to test the new products and retrain staff broadly ranges from 3

⁶⁷ See responses to question 48 of questionnaire Q2 – Questionnaire to customers (HD) (including sub-questions).

⁶⁸ See for instance Baxter's internal document [...] and Gambro's internal document [...].

⁶⁹ See section III.B.2, in particular paragraph 30. A customer usually is contractually prevented from buying (certain) HD disposables from third parties when it procures disposables as part of a "package" contract including monitors.

⁷⁰ See responses to question 44 of questionnaire Q1 - Questionnaire to competitors.

⁷¹ Several respondents nevertheless noted that with respect to bloodlines, the fact that bloodlines may be linked to a specific monitor model may be a hurdle to switching.

⁷² See responses to questions 45 to 47 of questionnaire Q2 - Questionnaire to customers (HD).

to 12 months. According to certain customers, it can even be a matter of a few weeks only⁷³. Second, switching does not appear to entail disproportionate costs⁷⁴. Third and importantly, it appears easier to convince a HD customer to switch at the end of a contract period than a CRRT customer,⁷⁵ based on a cost/ benefit analysis of switching. Nurses in (HD) dialysis centres or clinics typically exclusively work on dialysis treatment and therefore HD equipment is used routinely and constantly by them.⁷⁶ The cost and time to retrain specialised dialysis nurses on a different monitor is therefore more rapidly amortised. Moreover, the benefits of switching are higher as the various HD components determine a large part of the cost for equipment and consumables in such centres / clinics.⁷⁷ Taken together, these factors therefore explain why the barriers to switching that exist are unlikely to act as major deterrents.

80. Besides, long-term contracts are not widespread in the HD markets, irrespective of the categories of products included in the scope of the contracts, which provides customers with frequent opportunities to switch. Indeed, according to a majority of competitors, the typical duration of supply agreements does not exceed two to three years⁷⁸. Switching is further fostered in national markets where formal tenders constitute a standard purchasing pattern, since tenders lead customers to conduct in-depth reviews and comparisons of the various propositions of the main suppliers. Furthermore, on the basis of the outcome of the market investigation, it appears that customers are not particularly inclined to maintain a long-term relationship with a single supplier in the HD markets⁷⁹.
81. Customers' replies to the Commission's requests for information show that switching is far from uncommon. Around one third of the respondents indicated that they switched supplier for HD systems or for one or more categories of HD products in the last three years⁸⁰. Around half of the switching events concerned one category of products only and a large majority of the switching events concerned one or more categories of consumables, excluding monitors⁸¹. This outcome reflects the possibility enjoyed by HD customers to switch the supplier for only part of the HD products. This possibility, which stems from the high degree of interoperability of the various HD devices and consumables – and which does not exist in the area of CRRT or is much more limited – facilitates switching to a significant extent. In addition, for a majority of reported

⁷³ See responses to question 45 of questionnaire Q2 - Questionnaire to customers (HD).

⁷⁴ See responses to question 46 of questionnaire Q2 - Questionnaire to customers (HD).

⁷⁵ See agreed minutes of the conference call of 24 May 2013 with NxStage, paragraph 26.

⁷⁶ See agreed minutes of conference call with Fresenius on 14 May 2013.

⁷⁷ By contrast, CRRT is a therapy confined to a small population of critically ill patients treated in the intensive care unit and nurses in such units only occasionally administer CRRT treatment. Moreover, CRRT monitors and consumables are only one of many cost items in intensive care units. Therefore, the benefits of switching are less important from the perspective of an intensive care unit (see paragraph 497 *et seq.* for switching by CRRT customers).

⁷⁸ See responses to question 45 of questionnaire Q1 - Questionnaire to competitors.

⁷⁹ In particular, elements of this nature have not been mentioned as capable of deterring customers from switching (see responses to question 47 of questionnaire Q2 - Questionnaire to customers (HD)).

⁸⁰ See responses to question 48 of questionnaire Q2 – Questionnaire to customers (HD).

⁸¹ See responses to question 48 of questionnaire Q2 – Questionnaire to customers (HD) (including sub-questions).

switching events, customers indicated that they had experienced no significant difficulties and that they incurred no significant costs⁸².

82. Therefore, even though there are hurdles to switching supplier in particular for monitors, and in certain circumstances, for disposables, these hurdles would not be sufficient to prevent a significant number of customers from switching away from the combined entity relatively quickly, if the latter were to raise prices, to alternative suppliers.

Competitive significance of Baxter

83. Market share data show that Gambro is a much more significant competitor than Baxter, which has had a modest and stable market share of around [0-5]% only over the last six years and which in addition, only manufactures itself [...] of the categories of HD products [...] and depends on third party manufacturers for [...]. Switching events reported by customers in the framework of the market investigation tend to confirm the limited competitive constraint exerted by Baxter on other competitors, in particular Gambro. Indeed, for only [...]% of these switching events⁸³, the relevant customers switched to Baxter. The corresponding figures for Gambro, B. Braun and Fresenius are respectively [...]%, [...]% and [...]%.⁸⁴ As regards B. Braun, which has much lower market shares than Gambro and Fresenius, but to which an equivalent number of customers switched in recent years, this figure shows that it is a dynamic competitor, likely to continue to grow in the near future. There is no similar indication concerning Baxter, whether in market share developments, switching events or any other elements collected in the course of the market investigation.
84. Therefore, the Transaction would not eliminate an important competitive force on the HD systems market at EEA level.

Barriers to entry and expansion

85. The market investigation indicates that barriers to entry into the EEA HD market appear to be high. This is the case in particular for monitors, for which customers' brand loyalty, the need to conduct significant research and development programmes, obtain regulatory approvals and intellectual property rights and the need for a local presence at national level with qualified sales forces constitute major obstacles to entry. For consumables, the outcome of the market investigation indicates that barriers to entry are substantial, in particular in view of the importance of economies of scale, which implies that a manufacturer needs to produce and sell large volumes in order to be competitive⁸⁵. According to competitors, overall, a company would need between two to four years to launch consumables on the market and around five years to launch a monitor⁸⁶.

82 See responses to question 48 of questionnaire Q2 – Questionnaire to customers (HD) (including sub-questions).

83 Customers were invited to report switching events that occurred over the last three years.

84 See responses to question 48 of questionnaire Q2- Questionnaire to competitors (HD) (including sub-questions).

85 See responses to question 50 of questionnaire Q1 - Questionnaire to competitors.

86 See responses to question 52 of questionnaire Q1 - Questionnaire to competitors.

86. For a company already supplying HD products in certain countries (whether within or outside the EEA) and willing to enter into an EEA country where it is not yet present, barriers to entry would, according to respondents, also be significant. The main obstacles relate to the need to advertise products, build up a good reputation, and set up local technical, training, marketing and sales teams.⁸⁷
87. Therefore, barriers to entry into the markets for HD system, whether at EEA or national level, are generally significant.

Buyer power

88. Baxter argues that the Parties face sophisticated customers which increasingly join forces through purchasing consortia or similar structures with a view to enhancing their bargaining power vis-à-vis suppliers. It also argues that customers pursue a number of strategies in order to increase the number of companies that compete against each other and to ensure that they are in a position to select multiple suppliers. Finally, it argues that customers can easily switch supplier, that their procurement processes are increasingly professionalised and that they are under rising pressure by national security systems to drive prices down through negotiations with suppliers.
89. The Commission notes that the value of customers' procurement contracts appears to vary significantly from one customer to another⁸⁸. Whereas certain contracts cover the needs of a large share of the whole market of individual countries, many others are much more modest, especially when they cover a single healthcare centre, which still occurs to a significant extent. Since prices are individually negotiated and not set by suppliers for the whole of their customer portfolio, it is unlikely that the possible buyer power enjoyed by large consortia and hospitals could protect smaller customers against hypothetical price rises rendered possible as a result of the Transaction.
90. Yet, the question of whether buyer power would be sufficient to offset hypothetical negative effects of the Transaction can be left open since the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to an EEA market for HD systems.

Conclusion

91. In view of the Parties' respective market shares and their development over recent years, the strength of competitors such as Fresenius, B. Braun, Bellco and Nipro, the fact that the Parties are not close competitors and the possibility for customers to switch supplier relatively quickly and without major costs, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to an EEA market for HD systems.

⁸⁷ See responses to questions 60 and 61 of questionnaire Q1 - Questionnaire to competitors.

⁸⁸ See Annexes HD 8.6.1 and HD 8.6.2 to the Form CO, which provide, respectively for Baxter and Gambro, the value of the contracts with customers whose contact details have been provided to the Commission, as a percentage of the sales of Baxter and Gambro respectively.

b. HD monitors

Market Structure – Market shares

92. The market shares estimated by the Parties on an EEA market for HD monitors are as follows:

Table 2: Market shares in the EEA HD monitor market (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Gambro	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[30-40]%	[30-40]%
Combined	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[30-40]%
FMC	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[40-50]%	[40-50]%
B. Braun	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Nikkiso	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Bellco	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

93. Baxter stresses that its market share only amounted to [0-5]% in 2012 and that consequently very limited merger-specific effects can be expected. Baxter argues that the combined entity will continue to face strong competition notably from Fresenius, B. Braun, Nikkiso, and Bellco. Baxter further remarks that Nipro and NxStage managed to expand their HD activities also with regard to HD monitors. Besides, Baxter considers that it does not exert a particularly important competitive constraint on Gambro.
94. Gambro's market share has been declining over recent years. Baxter's market share has never exceeded [0-5]% over the last six years nor is this share likely to grow significantly.
95. Indeed, [Baxter's supply agreements]. Furthermore, a majority of customers sourcing monitors from Baxter (or having sourced monitors from Baxter in the last 12 months), these monitors being all manufactured by Nikkiso, indicated that they would be ready to source the same monitors through an alternative distribution channel that would not involve Baxter.⁸⁹ This means that if Nikkiso started to distribute its monitors directly or through a distributor other than Baxter, this would not deter customers from continuing to buy these monitors.
96. [...] is likely to expand its operations in the markets for HD monitors in Denmark, Sweden, Finland and the Netherlands in the next few months and is likely to capture a very significant proportion of Baxter's customers. This element will be discussed as appropriate in the assessment of the effects of the Transaction on the national markets concerned.

⁸⁹ See responses to question 43.1 of questionnaire Q2 - Questionnaire to customers (HD).

Conclusion

97. In view of the foregoing, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to an EEA market for HD monitors.

c. HD bloodlines

98. The market shares estimated by the Parties on the EEA-wide market for HD bloodlines are as follows:

Table 3: Market shares in the EEA HD bloodlines market (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Gambro	[40-50]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[20-30]%
Combined	[40-50]%	[40-50]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
FMC	[30-40]%	[30-40]%	[30-40]%	[40-50]%	[40-50]%	[40-50]%
B. Braun	[0-5]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Bellco	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[0-5]%	[0-5]%
Nipro	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[5-10]%	[5-10]%
Nikkiso	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Hemodia	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[10-20]%	[10-20]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

99. As in the case of monitors, Gambro's market share has been declining over recent years. The increment is also small: Baxter's market share has never exceeded [0-5]% over the last six years.

100. Furthermore, [*Baxter's supply agreement*]. This element will be discussed as appropriate in the assessment of the effects of the Transaction on the national markets concerned.

101. In view of the foregoing, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to an EEA market for HD bloodlines.

d. HD dialysers

Market Structure – Market shares

102. The market shares estimated by the Parties on an EEA-wide market for HD dialysers are as follows:

Table 4: Market shares in the EEA HD dialysers market (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Gambro	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[20-30]%	[20-30]%
Combined	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
FMC	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
B. Braun	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Nipro	[0-5]%	[0-5]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Bellco	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[0-5]%
Toray	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Asahi	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Nikkiso	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

103. The Parties' combined market share does not exceed [30-40]% and the increment is small, with Baxter's market share not exceeding [0-5]% over the last two years and never more than [0-5]% in any of the last six years.
104. Furthermore, [...] ⁹⁰, [...]. [...] has indicated that it has already developed its own distribution network.⁹¹ Besides, in response to the Commission's requests for information, a large majority of customers sourcing dialysers from Baxter (or having sourced dialysers from Baxter in the last 12 months) indicated that they would be ready to source dialysers through an alternative distribution channel⁹².
105. As indicated at paragraph 66 above, whereas the monitors produced by [...] and sold by Baxter [*Baxter's manufacturing and sourcing strategy*], dialysers manufactured by [...] and sold by Baxter [*Baxter's manufacturing and sourcing strategy*]. However, customers' responses to the Commission's requests for information indicate that for a large majority of the respondents, a label on HD products is in itself of limited importance. By contrast, customers attach importance both to the actual identity of the manufacturer (which has an impact on the quality of the product) and the identity of the distributor (which has an impact on the quality of the distribution and after-sales services)⁹³, which can be independent of the label borne by the product. A large majority of the respondents are aware of the identity of the actual manufacturer of the HD products that they purchase even if its label is not on these products⁹⁴ and responses show that customers base their selection of a manufacturer (and the associated distribution channel) on the basis of a relatively thorough knowledge of both the manufacturer and the distributor, going far beyond the information provided

⁹⁰ Baxter's submission of 17 June 2013, [...].

⁹¹ See [...] response to question 70.2 of questionnaire Q1 – Questionnaire to competitors and agreed minutes of the teleconference call of 6 June 2013 with [...], paragraph 5.

⁹² See responses to question 43.3 of questionnaire Q2 - Questionnaire to customers (HD).

⁹³ See responses to questions 40.1 and 40.2 of questionnaire Q2 - Questionnaire to customers (HD).

⁹⁴ See responses to question 39 of questionnaire Q2 - Questionnaire to customers (HD).

by the label. For instance, [...] indicated that it "needs to know the country where the resold product is manufactured and the quality standards applied in that country"⁹⁵.

106. Therefore, if dialysers originating from [...] started to be sold under a different [...] than Baxter's one, this change of [...] would be unlikely to have a significant impact on the customer's decisions to continue to buy these dialysers or not.
107. In view of these elements, [...] is likely to expand its operations on the markets for HD dialysers in the EEA in the next few months and is likely to capture a significant proportion of Baxter's customers. This element will be discussed as appropriate in the assessment of the effects of the Transaction on national markets.

Conclusion

108. In view of the foregoing, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to an EEA market for HD dialysers.

e. HD fluids

Market Structure – Market shares

109. The market shares estimated by the Parties on a EEA market for HD fluids are as follows:

Table 5: Market shares in the EEA-wide market for HD fluids (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Gambro	[30-40]%	[30-40]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%
Combined	[40-50]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[20-30]%
FMC	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[40-50]%	[40-50]%
B. Braun	[5-10]%	[5-10]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
Bellco	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
MTN Neubrandenburg		[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Nipro	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Unipharm	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[5-10]%	[10-20]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

110. Baxter submits that Fresenius is the market leader with a [40-50]% share in 2012, followed by Gambro ([20-30]%), B. Braun ([10-20]%), Bellco ([5-10]%), Baxter ([5-10]%), and others. According to Baxter, the Transaction will not materially alter the competitive situation as the new entity will not be able to close the gap with Fresenius, Baxter being only a smaller player and a number of other competitors will remain active in HD fluids. In the near future, Baxter also expects increased competition from Nipro, which allegedly is already a viable competitor in some EEA countries, such as

⁹⁵ See [...] response to question 40.2 of questionnaire Q2 - Questionnaire to customers (HD) ("*Besoin de connaître le pays de fabrication du produit revendu ainsi que les normes de qualité appliquées dans ce pays*").

Greece ([5-10]%), Portugal ([0-5]%), and Slovakia ([10-20]%), and is expected to expand its activities into other EEA countries.

111. In the Commission's view, the market shares suggest that on an EEA-wide market, the combined entity will face significant competition from several strong market players, first and foremost Fresenius, which achieves a significantly higher market share than the Parties' combined market share, but also B. Braun and to a lesser extent, Bellco. In addition, while Baxter's market shares have remained stable, Gambro's shares have been declining considerably over the last six years, and this decrease is correlated to a significant increase in Fresenius', and to a lesser extent, B. Braun's market shares. This suggests that Fresenius and B. Braun are dynamic competitors which would have the potential to attract customers should the combined entity attempt to raise prices or decrease quality post-Transaction.

Closeness of competition

112. In addition, the Parties do not appear to be particularly close competitors. Asked to identify Gambro's closest competitor in regard to HD fluids, a large majority of customers named Fresenius. All the other market participants were each either mentioned by a minority or not mentioned at all. Baxter and B. Braun were identified by a similar number of respondents, and were followed by Bellco, Dirinco and Nipro⁹⁶. The same outcome emerges from the views conveyed by competitors as regards Gambro's closest competitor⁹⁷. Therefore, the Parties are not close competitors on an EEA market for HD fluids.

Conclusion

113. In view of the foregoing as well as the findings regarding barriers to switching for disposables (including fluids), it is likely that if the combined entity were to raise prices for fluids post-Transaction, customers would switch to strong competitors such as Fresenius and B. Braun.
114. Consequently, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to an EEA- market for HD fluids.

2. National level

115. The Parties' HD supply activities overlap in 24 EEA countries: Austria, Belgium, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.
116. The merged entity's market shares are below 15% on all possible product markets in six of these EEA countries (the Czech Republic, Estonia, Greece, Hungary, Romania and Slovakia). Consequently, the Transaction does not give rise to affected markets in any of these EEA countries. This also holds true for the Irish monitors market, which is not affected either.

⁹⁶ See responses to question 53.5 of questionnaire Q2 - Questionnaire to customers (HD). Some customers named several competitors, suggesting that they were equally close to Gambro.

⁹⁷ See responses to question 32.5 of questionnaire Q1 - Questionnaire to competitors.

117. For the purposes of the competitive assessment in this case, the various national product markets that are horizontally affected were allocated to one of three categories:⁹⁸
- i. Group 1 markets: where the Parties' combined market share exceeds 35% and the increment exceeds 1%;
 - ii. Group 2 markets: where the Parties' combined market share exceeds 35% but the increment does not exceed 1%;
 - iii. Group 3 markets: where the Parties' combined market share does not exceed 35%.
118. The Norwegian markets for HD systems and HD dialysers⁹⁹ fall within Group 2 as the Parties' combined market shares exceeded 35% in 2012 and the increment did not exceed 1% on these two markets. Given the insignificant increment, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in respect of these possible markets.
119. All the possible HD markets in the following countries fall within Group 3: Belgium and Luxembourg¹⁰⁰, Germany, Lithuania, Poland, Portugal and Slovenia.¹⁰¹ In addition the HD markets in the following countries also fall within Group 3: Finland (HD systems, bloodlines and fluids); Ireland (HD systems and bloodlines); Spain (dialysers) and the United Kingdom (HD systems, bloodlines and fluids).
120. In most of the various product markets in these countries, the increment is minimal, not exceeding 1%. When this is the case, the Transaction is not likely to result in a significant increase in market power. In the few markets where the increment is higher than 1%, the Parties' combined market share does not exceed 34% and the combined

⁹⁸ This approach has also been applied in other cases in the area of medical devices and pharmaceutical products. See Case COMP/M.6293 – *Thermo Fisher/Phadia*, recitals 26-27, Case COMP/M.6266 – *Johnson & Johnson/Synthes*, recitals 139-140, Case COMP/M.5865 *Teva/Ratiopharm* and Case COMP/M.5778 *Novartis/Alcon*. In the present case, the Commission carried out this categorisation based on the Parties' combined market shares for 2012. As the markets under consideration are bidding markets, the Commission also reviewed market share data from preceding years to confirm that the Parties' market shares had not fluctuated significantly in comparison to 2012 in order to confirm that the classification of products into Group 1, 2 or 3 markets was appropriate.

⁹⁹ In Norway, Baxter does not supply [...].

¹⁰⁰ The Parties provided market share estimates on the basis of sales encompassing both Belgium and Luxembourg. Neither Baxter nor Gambro records sales separately for Luxembourg, since both have limited activities in that country, which in addition, are carried out through their respective sales forces based in Belgium. Baxter [...] sells disposables in Luxembourg and estimates that its market shares in Luxembourg are very likely to be even lower than its market shares provided for the Belgium / Luxembourg cluster. Gambro, for its part, only has [...] sales of HD [...] in two Luxembourgish hospitals through occasional and *ad hoc* sales, and estimates its HD market share to be significantly below [5-10]% in 2012. As regards Belgium, the Parties consider that in view of the relative sizes of Belgium and Luxembourg, their market shares in Belgium are unlikely to differ materially from those calculated for the Belgium / Luxembourg cluster. In view of these elements as well as the market share estimates provided by the Parties for the Belgium / Luxembourg cluster, the Commission estimates that the Parties' combined market shares are unlikely to have exceeded 35% on any possible product market in each of these two countries in 2012.

¹⁰¹ In addition to combined market shares not exceeding 35%, the increment for each HD product market, which arises as a result of Baxter's very limited presence in each of Germany, Lithuania, Poland, Portugal and Slovenia, is well below 1%.

entity will face very significant competition from Fresenius (which in all cases has a market share higher than [30-40]%) but also from a range of other competitors¹⁰². In addition, no substantiated concerns have been raised by customers in the course of the market investigation as regards these markets. The Commission therefore concludes that the Transaction is unlikely to raise serious doubts as to its compatibility with the internal market in respect of any possible HD market in Belgium, Luxembourg, Germany, Lithuania, Poland, Portugal and Slovenia or in Finland with respect to HD systems, bloodlines and fluids, in Ireland with respect to HD systems and bloodlines, in Spain with respect to dialysers and in the United Kingdom with respect to HD systems, bloodlines and fluids.

a. Group 1 markets - Introduction

121. The following section therefore focuses on markets in ten Member States (Austria, Denmark, Finland, France, Ireland, Italy, the Netherlands, Spain, Sweden and the United Kingdom) that fall within Group 1, referring as appropriate to the findings of the assessment of the effects of the Transaction at EEA level, insofar as these findings are applicable to the relevant national market.
122. For the purposes of assessing the closeness of competition between the Parties, the Commission requested the Parties to submit bidding data for these ten EEA countries covering their participation in competitive processes, including both formal tenders and informal requests for quotes¹⁰³. Generally, information gathered in this way may constitute relevant evidence for assessing the degree of competition between the merging parties especially in markets such as the ones in the current case where products are differentiated and the duration of contracts is generally longer than one year. Diversion ratios based on tender data are informative about the actual competition taking place when bidding for contracts. In particular, quantifying the proportion of bids lost by one of the Parties and attributing them proportionally to the winners provides a real positioning of the competitors of that party in the market.
123. The bidding data submitted by the Parties cover a period of five years (2008-2012), and is structured into two separate files for each EEA country, one including the tenders which Baxter is aware of and another the tenders of which Gambro is aware.
124. The Commission analysed these bidding data on a country-by-country basis. The results of this analysis are presented below when assessing the effects of the Transaction on the various national markets.

¹⁰² Such as Bellco and Sterima on the HD system market in Belgium and Luxembourg, where these competitors have market shares of [5-10]% and [0-5]% respectively and Bellco and Nipro on the dialysers market in Belgium and Luxembourg, where these competitors have market shares of [5-10]% and [5-10]% respectively. In the Irish market for bloodlines, which is the market where the merged entity's share just falls within Group 3, its market share is [30-40]% whilst that of Fresenius is [30-40]%. In addition, B. Braun has recently entered this market and captured [20-30]% market share in 2012.

¹⁰³ See paragraph 29, Horizontal Mergers Guidelines: "*In bidding markets it may be possible to measure whether historically the submitted bids by one of the merging parties have been constrained by the presence of the other merging party*".

b. Austria

125. The Parties estimate that the market for HD systems, encompassing all the HD equipment and consumables, was worth EUR [...] million in Austria in 2012.
126. Gambro sells a full range of HD products. It supplies them [*Gambro's distribution system*]. Baxter [*Composition of Baxter's monitor sales*]. In Austria, Baxter sells dialysers originating from [...], bloodlines for older generation Baxter monitors as well as for monitors manufactured by other players, and fluids. Baxter sells these products [*Baxter's distribution system*].
127. The Parties' main competitors in Austria are Fresenius, B. Braun, and to a lesser extent, Nikkiso and Nipro. Fresenius and B. Braun offer the full range of HD products in Austria. [...] has recently acquired two dialysis clinics (in [...] and in [...], in the province of [...]).
128. Baxter submits that its own position in the Austrian HD market as the [...] largest supplier is very limited. Also, Gambro's market shares have been steadily decreasing over the past years.
129. Baxter submits that the small increment brought about by the Transaction will not significantly impede competition. Baxter claims that it is not a close competitor of Gambro, and that the Parties will continue to face fierce competition from other players. Baxter adds that there are no Austria-specific barriers to entry or expansion, and that customers can exercise significant countervailing power.

HD systems

Market structure – Market shares

130. The market shares estimated by the Parties on an Austrian market for HD systems are as follows:

Table 6: Market shares in the Austrian market for HD systems (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Gambro	[40-50]%	[50-60]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%
Combined	[50-60]%	[50-60]%	[50-60]%	[40-50]%	[40-50]%	[40-50]%
FMC	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
B. Braun	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Nipro	[5-10]%	[5-10]%	[5-10]%	[0-5]%	[0-5]%	[0-5]%
Nikkiso	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

131. The increment is insignificant (approximately [0-5]%). In addition, Gambro's market share has been decreasing substantially over the last years, whereas Fresenius' market share has been increasing significantly. Post-Transaction, the combined entity is expected to continue to face significant competition from a range of dynamic market participants, first and foremost Fresenius but also B. Braun and to a more limited extent, Nikkiso and Nipro.

Closeness of competition

132. Also, the Parties do not appear to be particularly close competitors. A majority of Austrian customers replying to the Commission's requests for information named Fresenius as Gambro's closest competitor. B. Braun was also mentioned whilst Baxter was not¹⁰⁴. This, in addition, to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, confirms Baxter's view that it is not a close competitor of Gambro.

Competitive significance of Baxter - customers' ability to switch to other suppliers

133. In view of the development of Baxter's market shares over recent years and the fact that it only manufactures fluids and depends on third party manufacturers for other products, Baxter does not appear as a source of significant competitive constraint to Gambro. By contrast, Fresenius and B. Braun appear as strong competitors. The fact that [...] has recently opened clinics in Austria (providing an outlet for its HD products) tends to indicate that this company is likely to expand in Austria in the near future.
134. Furthermore, the general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs, if the combined entity were to increase prices post-Transaction applies also to the current assessment.

Conclusion

135. Therefore, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Austrian market for HD systems.

HD monitors

136. The market shares estimated by the Parties on the Austrian market for HD monitors are as follows:

Table 7: Market shares in the Austrian market for HD monitors (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Gambro	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[40-50]%	[40-50]%
Combined	[50-60]%	[60-70]%	[50-60]%	[50-60]%	[40-50]%	[50-60]%
FMC	[30-40]%	[30-40]%	[40-50]%	[30-40]%	[40-50]%	[40-50]%
Nikkiso	[5-10]%	[0-5]%	[0-5]%	[0-5]%	[5-10]%	[5-10]%
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

137. The increment is very limited. In addition, [*Composition of Baxter's sales*]. Therefore, Baxter's modest market share overstates its role in the competitive dynamics. This

¹⁰⁴ See responses to question 53.1 of questionnaire Q2 - Questionnaire to customers (HD). Some customers named several competitors, suggesting that they were equally close to Gambro.

means that the increment ([0-5]%) overstates the merger-specific effects. Besides, Gambro's market share has been declining significantly over the last three years.

138. Therefore, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Austrian market for HD monitors.

HD bloodlines

139. The market shares estimated by the Parties on the Austrian market for HD bloodlines are as follows:

Table 8: Market shares in the Austrian market for HD bloodlines (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Gambro	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[40-50]%
Combined	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[40-50]%
FMC	[20-30]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[40-50]%
Nikkiso	[5-10]%	[5-10]%	[5-10]%	[5-10]%		[5-10]%
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[5-10]%
Dimedico	[5-10]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

140. The increment is rather small (approximately [0-5]%). In addition, Gambro's market share has been decreasing substantially over the last years, whereas Fresenius' market share has been increasing significantly. Post-Transaction, the combined entity is expected to face significant competition from a range of dynamic market participants, first and foremost Fresenius but also B. Braun and Nikkiso.
141. In addition, the Parties do not appear to be particularly close competitors. A majority of customers replying to the Commission's requests for information named Fresenius as Gambro's closest competitor. B. Braun was also mentioned whilst Baxter was not¹⁰⁵. This, in addition, to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, confirms Baxter's view that it is not a close competitor of Gambro.
142. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.
143. Therefore, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Austrian market for HD bloodlines.

HD dialysers

144. The market shares estimated by the Parties on the Austrian market for HD dialysers are as follows:

¹⁰⁵ See responses to question 53.3 of questionnaire Q2 - Questionnaire to customers (HD).

Table 9: Market shares in the Austrian market for HD dialysers (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Gambro	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%
Combined	[50-60]%	[50-60]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%
FMC	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[40-50]%	[40-50]%
Nipro	[10-20]%	[10-20]%	[10-20]%	[5-10]%	[5-10]%	[5-10]%
B. Braun	[0-5]%	[0-5]%	[0-5]%	[5-10]%	[0-5]%	[0-5]%
Asahi	[0-5]%	[0-5]%	[0-5]%	[0-5]%		
Others	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

145. The increment is small (approximately [0-5]%). In addition, Gambro's market share has been decreasing over the last years, whereas Fresenius' market share has been increasing significantly. Post-Transaction, the combined entity is expected to face significant competition from a range of significant market participants, first and foremost Fresenius but also Nipro and B. Braun.
146. In addition, the Parties do not appear to be particularly close competitors. A majority of customers replying to the Commission's requests for information named Fresenius as Gambro's closest competitor. B.Braun and Nipro were also mentioned whilst Baxter was not¹⁰⁶. This, in addition, to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, confirms Baxter's view that it is not a close competitor of Gambro.
147. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs, if the combined entity were to increase prices post-Transaction also applies to this assessment.
148. Therefore, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Austrian market for HD dialysers.

HD fluids

149. The market shares estimated by the Parties on the Austrian market for HD fluids are as follows:

¹⁰⁶ See responses to question 53.4 of questionnaire Q2 - Questionnaire to customers (HD).

Table 10: Market shares in the Austrian market for HD fluids (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Gambro	[50-60]%	[50-60]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%
Combined	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[40-50]%
FMC	[20-30]%	[20-30]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
B. Braun	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
Nikkiso	[0-5]%	[0-5]%	[0-5]%	[0-5]%		[0-5]%
Others	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

150. The increment, (approximately [0-5]%) is small. In addition, Gambro's market share has been decreasing over the last years, whereas Fresenius' market share has been increasing significantly. Post-Transaction, the combined entity is expected to face significant competition from a range of significant market participants, first and foremost Fresenius but also B. Braun, which has had a market share of around [10-20]% over the last six years, and Nikkiso.
151. In addition, the Parties do not appear to be particularly close competitors. A majority of customers replying to the Commission's requests for information named Fresenius as Gambro's closest competitor. B. Braun was also mentioned whilst Baxter was not¹⁰⁷. This, in addition, to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, confirms Baxter's view that it is not a close competitor of Gambro.
152. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs, if the combined entity were to increase prices post-Transaction also applies to this assessment.
153. Therefore, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Austrian market for HD fluids.

c. Denmark

154. The Parties estimate that the market for HD systems, encompassing all the HD equipment and consumables, was worth EUR [...] million in Denmark in 2012.
155. Gambro offers the same HD products in Denmark as EEA-wide¹⁰⁸, that is monitors, associated technical services, disposables, and fluids. It supplies them [*Gambro's distribution system*]. Baxter offers the same categories of HD products in Denmark as EEA-wide including monitors and bloodlines originating from [...] and dialysers manufactured by [...], as well as its own fluids. Baxter sells its HD products in Denmark [*Baxter's distribution system*].

¹⁰⁷ See responses to question 53.5 of questionnaire Q2 - Questionnaire to customers (HD).

¹⁰⁸ See paragraph 66.

156. The Parties' main competitors in Denmark are Fresenius and B. Braun. Fresenius offers all categories of HD products. B. Braun offers the main consumables, and has a direct sales force in Denmark.
157. According to Baxter, the Transaction will not significantly impede effective competition in HD in Denmark because Baxter's share in HD and in each HD segment in Denmark is small, and continues to decrease, and the combined entity will continue to face fierce and increasing competition from other suppliers, including Gambro's closest competitor Fresenius. Baxter further notes that Denmark is extremely tender driven, as almost 100% of the purchases of HD products are made via tenders, providing significant buyer power to hospitals and regions. According to Baxter, four of five regions source the HD demand for the entire region in one large tender.

HD systems

Market structure – market shares

158. The market shares estimated by the Parties on the Danish market for HD systems are as follows:

Table 11: Market shares in the Danish market for HD systems (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[0-5]%	[0-5]%
Gambro	[40-50]%	[40-50]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%
Combined	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[60-70]%
FMC	[40-50]%	[30-40]%	[30-40]%	[40-50]%	[30-40]%	[30-40]%
Asahi	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

159. The Transaction combines the leading HD supplier, Gambro (with HD sales in 2012 of approximately EUR [...] million and a share of [50-60]%) with the number [...] Baxter (with HD sales in 2012 of approximately EUR [...] and a share of [0-5]%). Fresenius is the number two with a share of [30-40]%.
160. Baxter submits that Fresenius has been competing aggressively and has won a series of important tenders across Denmark. For example, in 2012, Gambro lost a tender for the supply of [...] in the [...] to Fresenius. According to Baxter, this tender accounted for approximately [...] % of the total Danish HD demand.
161. Baxter also emphasised the role of B. Braun, which has further expanded its activities in Denmark in 2011 and 2012. According to Baxter, B. Braun competes vigorously in tenders against Gambro and Fresenius. Baxter indicated that B. Braun had won (part of) a tender in 2013 for the [...] for [...].
162. The Danish market appears to be fairly concentrated, with the Parties and Fresenius accounting together for [90-100]% of the sales in 2012. Gambro and Fresenius appear to be strong suppliers compared to all the other market participants. The Parties' combined market share is high and Gambro's market share has been increasing, whereas Baxter's market share has been decreasing over the same period.

Closeness of competition

163. The market investigation has not yielded fully reliable results as regards the closeness of competition between the Parties. For HD systems, half of the respondents identified Baxter as Gambro's closest competitor and the other half identified Fresenius. However, for HD monitors, HD bloodlines, HD dialysers and HD fluids considered separately, all respondents named Fresenius and none mentioned Baxter¹⁰⁹. This is a first indication that Baxter is a more remote competitor to Gambro than Fresenius.
164. Moreover, the bidding analysis carried out by the Commission and summarised below confirms that the Parties are not close competitors¹¹⁰.

Bidding analysis

(i) Gambro's bidding data

165. Gambro, participated in [...] tenders organised between 2008 and 2012 (overall [...] events) in Denmark, where approximately [...] of Gambro's sales are made via tenders.
166. For those cases where the presence of a competitor in tenders was recorded by Gambro's sales workforce, Fresenius was mentioned by far most often, followed by Baxter and Scan-Med¹¹¹ both mentioned with the same frequency. Other competitors that were present in the tenders include Vingmed, Globe Medical, NordiaTech and Covidien¹¹². Amongst the events for which the bid value is available, Fresenius is by far the competitor who participated in the highest value bids.
167. As regards the effective pressure exerted by these competitors on Gambro, measured by the number of competitive events won from Gambro, information is limited. However, out of the [...] events lost by Gambro for which the winner's name is identified, Baxter won [...] tenders, [...] within tenders which include a wide range of products. The other events lost by Gambro were won by Fresenius ([...] cases, for [...]), Scan-Med ([...] cases), Vingmed ([...] cases), Globe Medical, Bard and Nordic Medcom each in [...].
168. Therefore, Gambro's bidding data in Denmark confirms Baxter's weak position as well as the presence of many other viable competitors that effectively win tenders lost by Gambro. Moreover, since the bidding data extends only to 2012, it does not cover B. Braun's more recent successes in Denmark.

¹⁰⁹ See responses to question 53 of questionnaire Q2- Questionnaire to customers (HD).

¹¹⁰ In addition, two switching events were reported by Danish customers. One was a switch from Fresenius to Gambro for whole systems and the other one was a switch from Baxter to Fresenius for monitors - see responses to question 48 of questionnaire Q2 –Questionnaire to customers (HD) (including sub-questions). These events tend to illustrate the finding that Fresenius is closer to each Party than the other Party.

¹¹¹ Scan-Med is a large distributor in the Nordic area, which distributes HD products among others from B. Braun and Nikkiso.

¹¹² Essentially distributors, the main exception being Covidien, which manufactures vascular access products (see Covidien's response to question 1.1 of questionnaire Q1 – Questionnaire to competitors).

(ii) Baxter's bidding data

169. Baxter only participated in [...] tenders over the relevant period, comprising [...] competitive events (lots). Baxter only made an offer for [...] of the lots.
170. Baxter's dataset confirms the information from Gambro's bidding data according to which Baxter won only [...] of the lots lost by Gambro, [...] for [...] and [...] for [...]. The [...] competitive events (lots) lost by Baxter were won by Fresenius ([...]), Gambro ([...]) and Scan-Med ([...]). Although Scan-Med won less frequently than the other two large competitors, it participated in tenders for a wide range of products including dialysis systems/monitors and fluids. Therefore, its effective presence on the Danish market is largely disregarded by the market shares calculated on the basis of annual sales on a manufacturer basis.

(iii) Conclusion of the bidding analysis

171. On the basis of the bidding analysis, the Danish market for HD systems appears to be characterised by two large suppliers (Fresenius and Gambro) and a number of medium and smaller rivals (including not only Baxter but also Scan-Med, Vingmed, Nordic Medcom and, based on its recent success, B. Braun). Therefore the loss of independent competition from Baxter cannot be expected to have a material impact on the vigour of competition on the market post-Transaction.

Competitive significance of Baxter - customers' ability to switch to other suppliers

172. Moreover, [...], the actual market share increment would be lower than Baxter's current [0-5]%. As explained in paragraph 67 above, both Nikkiso and Nipro are expected to expand their operations significantly in the countries where [...], which include Denmark, and are likely to capture a very significant part of Baxter's customers for the relevant product.¹¹³
173. Furthermore, the general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs, if the combined entity were to increase prices post-Transaction applies also to the current assessment.

Conclusion

174. Therefore, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Danish market for HD systems.

¹¹³ These aspects will be dealt with in more detail in the assessment of the effects of the Transaction on the Danish markets for monitors, bloodlines and dialysers, but they are also relevant to the Danish market for systems, since Baxter's sales of monitors, bloodlines and dialysers account for more than [...] % of Baxter's total HD sales in Denmark.

HD monitors

175. The market shares estimated by the Parties on the Danish market for HD monitors are as follows:

Table 12: Market shares in the Danish market for HD monitors (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[0-5]%	[5-10]%	[0-5]%	[0-5]%
Gambro	[40-50]%	[30-40]%	[50-60]%	[30-40]%	[40-50]%	[60-70]%
Combined	[40-50]%	[30-40]%	[50-60]%	[40-50]%	[40-50]%	[60-70]%
FMC	[50-60]%	[60-70]%	[40-50]%	[50-60]%	[50-60]%	[30-40]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

176. Baxter argues that it only had [...] sales in 2012 and that the market shares in 2012 do not accurately reflect the competitive landscape in the monitors segment in Denmark, which would essentially be split between Gambro and Fresenius. Baxter indicated that most of Denmark's requirements for HD monitors have been tendered by four regions and that of these, Gambro has won the [...] and [...] while Fresenius supplies the [...].
177. Furthermore, Baxter indicated that it could not participate in most tenders that also involved HD monitors in Denmark, since [*Details of Baxter's products*]. Baxter indicated that it only participated in [...] in 2012, in which no central regional purchasing takes place.
178. The Danish market for HD monitors appears to be highly concentrated, with only the Parties and Fresenius being active. The Parties' combined market share is high and has been increasing very significantly since 2007 as a result of Gambro's growing market share, whereas Fresenius' market shares has decreased significantly.
179. However, the increment is small and the market investigation¹¹⁴ and the Commission's bidding analysis indicated that the Parties are not particularly close competitors.
180. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.
181. The Commission therefore concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Danish market for HD monitors.

HD bloodlines

182. The market shares estimated by the Parties on the Danish market for HD bloodlines are as follows:

¹¹⁴ As indicated above, all Danish customers identified Fresenius as Gambro's closest competitor for monitors (see responses to question 53.2 of questionnaire Q2 – Questionnaire to customers (HD)).

Table 13: Market shares in the Danish market for HD bloodlines (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Gambro	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[40-50]%	[40-50]%
Combined	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[40-50]%	[40-50]%
FMC	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[50-60]%	[50-60]%
Others						[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

183. The increment is minimal ([0-5]%). Fresenius appears as a strong competitor, with a market share above [50-60]% in each of the last two years. Moreover, the market investigation and the bidding analysis (the results of which have been presented above) indicate that the Parties are not particularly close competitors. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.
184. The Commission therefore concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Danish market for HD bloodlines.

HD dialysers

185. The market shares estimated by the Parties on the Danish market for HD dialysers are as follows:

Table 14: Market shares in the Danish market for HD dialysers (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Gambro	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%
Combined	[50-60]%	[60-70]%	[60-70]%	[60-70]%	[60-70]%	[60-70]%
FMC	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[20-30]%
Asahi	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Others					[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

186. Baxter submits that Post-Transaction, Danish customers will still have a choice of at least two other existing dialyser suppliers in Denmark - Fresenius with a [20-30]% share in 2012 and Asahi with [5-10]%. Baxter further submits that the static view of the market shares in 2012 does not adequately reflect the fierce competition in this segment. Baxter explained that it expected to lose dialyser sales in the near future because of the loss of important contracts. For example, Fresenius won a [...] in [...], for which Baxter currently supplies [...]. Baxter considers that it may well lose its [...] business in [...] to Fresenius. Besides, Baxter claims that it has lost significant business to Fresenius when the latter won the [...], respectively, which is not yet reflected in the value shares provided above.
187. Baxter further believes that the market shares do not reflect the competitive pressure exerted by B. Braun. For example, according to Baxter, B. Braun participated [...] in

at least [...] tenders, which included [...] in 2011 ([...]) and 2012 ([...]) and its efforts to win such tenders are expected to continue.

188. The Parties' combined market share is high and growing. However, the Parties do not appear to be particularly close competitors in view of the market investigation¹¹⁵ and more importantly, in view of the bidding analysis. Moreover, as it results from the conclusions of the bidding analysis, the market shares are not fully representative of the competitive interactions on the Danish market for dialysers. In particular, they tend to overstate Baxter's role.
189. Furthermore, post-Transaction, in Denmark, the actual market share increment would be lower than Baxter's current market share since [...]. An expansion by Nipro is likely to occur in the next few months. Nipro's expansion on the Danish market for dialysers appears sufficiently likely and timely and sufficient in scope for Nipro to exert a significant constraint on the combined entity. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.
190. The Commission therefore concludes that Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Danish market for HD dialysers.

HD fluids

191. The market shares estimated by the Parties on the Danish market for HD fluids are as follows:

Table 15: Market shares in the Danish market for HD fluids (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[5-10]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Gambro	[40-50]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%
Combined	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%
FMC	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%
B. Braun		[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

192. The increment is very limited (approximately [0-5]%) and Fresenius appears as a significant competitor, with a market share above [40-50]% in each of the last six years. Moreover, the market investigation and the bidding analysis, which has been presented above, indicate that the Parties are not close competitors. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.
193. The Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Danish market for HD fluids.

¹¹⁵ As indicated above, all Danish customers identified Fresenius as Gambro's closest competitor for dialysers (see responses to question 53.4 of questionnaire Q2 – Questionnaire to customers (HD)).

d. Finland

194. The Parties estimate that the market for HD systems, encompassing all the HD equipment and consumables, was worth EUR [...] million in Finland in 2012.
195. Gambro offers a full HD product range in Finland. It supplies them [*Gambro's distribution system*]. Baxter offers the same HD products and brands in Finland as EEA-wide, including monitors and bloodlines originating from [...] and dialysers manufactured by [...], as well as its own fluids. Baxter sells its HD products in Finland [*Baxter's distribution system*].
196. The Parties' main competitors in Finland are Fresenius and B. Braun. Fresenius offers a full HD product range in Finland. So does B. Braun, which has a dedicated HD sales force in Finland and in addition, owns two private HD clinics in Helsinki.
197. In Finland, only the markets for monitors and dialysers are Group 1 markets.¹¹⁶

HD monitors

198. The market shares estimated by the Parties on the Finnish market for HD monitors are as follows:

Table 16: Market shares in the Finnish market for HD monitors (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[5-10]%	[5-10]%	[10-20]%	[0-5]%	[0-5]%	[0-5]%
Gambro	[30-40]%	[20-30]%	[20-30]%	[30-40]%	[40-50]%	[30-40]%
Combined	[40-50]%	[30-40]%	[40-50]%	[40-50]%	[40-50]%	[30-40]%
FMC	[30-40]%	[50-60]%	[40-50]%	[40-50]%	[30-40]%	[40-50]%
B. Braun	[0-5]%	[0-5]%	[0-5]%	[5-10]%	[5-10]%	[5-10]%
Others	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

199. As a result of the steep decline in Baxter's market shares since 2009, the increment is small.
200. Post-Transaction, the combined entity is expected to face significant competition from Fresenius, whose market share has been growing and which is expected to remain the market leader, and to a lesser extent, B. Braun. The bidding analysis carried out by the Commission indicates that the Parties are not particularly close competitors.

(i) Gambro's bidding data

201. [...] Gambro's sales in Finland are made through tenders. Gambro has participated in more than [...]% of the tenders over the relevant period but lost more than [...] of them. According to Gambro's bidding data, Fresenius and B. Braun are the closest competitors of Gambro in Finland, winning most of the bids lost by Gambro or being identified by Gambro as runner-ups in the bids won by Gambro. Fresenius won [...] of the bids lost by Gambro, B. Braun more than [...]% and Baxter [...]%. This ranking is roughly consistent with the position of these three competitors of Gambro in Finland

¹¹⁶ The markets for systems, bloodlines and fluids are Group 3 markets. See paragraphs 119 and 120 above.

in terms of market shares. Moreover, a number of fringe players (such as Carbonex and Bard) are also effective competitors winning some of the bids lost by Gambro.

(ii) Baxter's bidding data

202. Baxter participated in slightly less tenders than Gambro. Its sales are also made [...] through tenders.
203. The presence of Baxter in tenders decreased considerably in the last few years (2009-2010: [...] tenders and 2011-2012: [...] tenders). This is consistent with the decrease in its market shares. Overall Baxter lost [...]% of the tenders where it participated and in 2012 it won only [...] of them. The competitive events lost by Baxter were won by Fresenius in [...]% of the cases, Gambro in [...]%, B. Braun in [...]% and the rest by multiple suppliers.
204. Moreover, the actual market share increment would be lower than Baxter's current market share since [...], Nikkiso is expected to expand its operations significantly in Finland. Nikkiso's entry is likely to occur in the next few months. For the reasons explained at paragraphs 95 and 96, Nikkiso's entry appears sufficient in scope and sufficiently likely and timely for Nikkiso to constitute a source of significant competitive pressure on the combined entity.
205. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.
206. In light of the above, the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Finnish market for HD monitors.

HD dialysers

207. The market shares estimated by the Parties on the Finnish market for HD dialysers are as follows:

Table 17: Market shares in the Finnish market for HD dialysers (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[20-30]%	[20-30]%	[20-30]%	[10-20]%	[10-20]%	[10-20]%
Gambro	[30-40]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%
Combined	[60-70]%	[50-60]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%
FMC	[30-40]%	[30-40]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%
B. Braun	[5-10]%	[5-10]%	[5-10]%	[10-20]%	[10-20]%	[10-20]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

208. The increment ([10-20]%) is large and the Parties' combined market share is higher than the market shares of their competitors. However, overall, the market shares of both Baxter and Gambro have been declining substantially over the last six years whereas the market shares of each of Fresenius and B. Braun have been increasing. Post-Transaction, the combined entity is expected to face significant competition from these competitors.

209. The Commission's bidding analysis also indicated that Fresenius and B. Braun are Gambro's closest competitors and that Baxter lost strength significantly in the last few years.
210. Also, the actual market share increment would be lower than Baxter's current market share as [...]. Entry by [...] is likely to occur in the next few months. For the reasons explained at paragraphs 104 to 107, [...] expansion appears sufficient in scope and sufficiently likely and timely for [...] to exert a significant constraint on the combined entity.
211. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.
212. In light of the above, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Finnish market for HD dialysers.

e. France

213. The Parties estimate that the market for HD systems, encompassing all the HD equipment and consumables, was worth EUR [...] million in France in 2012.
214. Gambro offers a full HD product range in France. According to Baxter, Gambro historically has a strong position in France, notably due to its acquisition of Hospal in 1987, which is still a separate brand in France. Baxter submits that Hospal has been strong since the 1970s, because of local production capabilities and close relationships with local hospitals. In France, Gambro only sells its products through [*Gambro's distribution system*].
215. In France, Baxter offers the same HD product range as at the EEA level, with the exception of [...], which it no longer distributes in that country. Baxter sells HD products in France through [*Baxter's distribution system*].
216. According to Baxter, there are numerous suppliers of HD products in France in addition to the Parties, including Fresenius, B. Braun, Nikkiso, Asahi, Toray, Bellco, Nipro, and Hemodia. Fresenius and B. Braun offer a full HD product range in France. Bellco offers monitors, dialysers and fluids.

HD systems

Market structure – market shares

217. The market shares estimated by the Parties on the French market for HD systems are as follows:

Table 18: Market shares in the French market for HD systems (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Gambro	[40-50]%	[40-50]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
Combined	[50-60]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%
FMC	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%
Toray	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Bellco	[5-10]%	[5-10]%	[5-10]%	[0-5]%	[5-10]%	[0-5]%
Asahi	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[5-10]%	[5-10]%
Nikkiso	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[5-10]%	[5-10]%
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[5-10]%	[5-10]%
Nipro	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Hemodia	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

218. Baxter argues that it is not a particularly close competitor of Gambro, claiming that the HD products that Baxter and Gambro sell in France are not regarded as close substitutes. Baxter considers that the combined entity will continue to face fierce competition from strong rivals. Baxter further argues that customers are strong and can exercise significant countervailing power.
219. The combined entity would remain the market leader. Yet, while Baxter's market share has been fairly stable over the last six years, Gambro's market share has been decreasing significantly over the same period, to the benefit of a range of other competitors. Market shares suggest that post-Transaction, the combined entity would face significant competition from Fresenius but also from a range of smaller competitors, including Toray, B. Braun, Nikkiso, Asahi, Nipro and Bellco.

Closeness of competition

220. In addition, the Parties do not appear to be particularly close competitors. A majority of French customers named Fresenius as Gambro's closest competitor. Baxter was mentioned by only a limited minority¹¹⁷.
221. Switching events reported by French customers tend to confirm that the Parties are not close competitors. [...] of these switching events involved Gambro. However, only [...]% of the events involving Gambro also involved Baxter, whilst the other events involved other competitors such as Fresenius, Nipro and Hemotech¹¹⁸.

Competitive significance of Baxter – Customers' ability to switch to other suppliers

222. Furthermore, Nipro [...] and is expected to expand its operations significantly in France in the coming months. Since dialysers sales account for almost [...]% of Baxter's total HD sales in France, this means that the post-merger increment is likely

¹¹⁷ See responses to question 53.1 of questionnaire Q2 - Questionnaire to customers (HD).

¹¹⁸ See responses to question 48 of questionnaire Q2 – Questionnaire to customers (HD) (including sub-questions).

to overstate the magnitude of the merger-specific effects on the French market for HD systems.

223. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.
224. In light of the above, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the French market for HD systems.

HD dialysers¹¹⁹

225. The market shares estimated by the Parties on the French market for HD dialysers are as follows:

Table 19: Market shares in the French market for HD dialysers (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[0-5]%	[5-10]%
Gambro	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
Combined	[40-50]%	[40-50]%	[40-50]%	[30-40]%	[30-40]%	[30-40]%
FMC	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%
Toray	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
Asahi	[5-10]%	[5-10]%	[5-10]%	[10-20]%	[10-20]%	[10-20]%
Nipro	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Nikkiso	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Bellco	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

226. Post-Transaction, the combined entity would remain the market leader. However, Gambro's market share has been decreasing substantially, a trend which has benefitted a range of competitors which do not include Baxter, whose market share has remained almost constant over the last six years. Market shares suggest that post-Transaction, the combined entity would face significant competition from Fresenius, Toray, Asahi, and to a lesser but non-negligible extent, Nipro, Nikkiso and B. Braun.
227. Furthermore, Nipro [...] and is expected to expand its operations significantly in France. This implies that the post-merger increment likely to overstate the magnitude of the Transaction, for the reasons explained at paragraphs 104 to 107.
228. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.

¹¹⁹ Baxter had no sales or [...] sales of monitors and bloodlines in France in the last two years, so that there is no overlap (or a [...]) on the French monitors and bloodlines markets. Therefore, the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to these two markets.

229. In light of the above, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the French market for HD dialysers.

HD fluids

Market structure – market shares

230. The market shares estimated by the Parties on the French market for HD fluids are as follows:

Table 20: Market shares in the French market for HD fluids (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[10-20]%	[10-20]%	[20-30]%	[20-30]%	[10-20]%	[10-20]%
Gambro	[20-30]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
Combined	[40-50]%	[40-50]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%
FMC	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%
Bellco	[20-30]%	[20-30]%	[20-30]%	[10-20]%	[10-20]%	[10-20]%
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Aguettant	[5-10]%	[0-5]%	[0-5]%			
Others				[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

231. Baxter argues that the product offerings of the Parties are largely complementary, because in France Baxter is mainly active in the supply of concentrates in liquid form whereas Gambro is mainly active in the supply of concentrates in powder form¹²⁰. Baxter provided information according to which, by volume, Baxter has the [...] in liquid concentrates ([30-40]%), [...] Fresenius ([30-40]%) and Bellco ([20-30]%), while Gambro only has a share of [5-10]%. By contrast, when it comes to powders, Gambro's share by volume in France is [40-50]%, while Baxter is one of the smallest suppliers with a share of [0-5]%. Baxter also indicated that Fresenius had significant powder activities in France, with a share of [30-40]%.
232. Baxter infers from those elements that the Transaction would not eliminate Gambro's closest competitor in the HD fluids segment. Baxter submits that post-Transaction the combined entity would continue to face vigorous competition and would be constrained by a number of existing competitors, including Fresenius, B. Braun and Bellco.
233. Post-Transaction, the combined entity would be the clear market leader, well ahead of all the other competitors. The Parties' combined market share has been on a general upward trend over the last six years, whereas Bellco's market share has declined and Fresenius' market share has remained relatively stable. Market shares suggest that post-Transaction, while enjoying a strong position, the combined entity would face significant competition from Fresenius and Bellco (with market shares of respectively [20-30]% and [10-20]%) and to a lesser extent, B. Braun. In the framework of the market investigation, a large majority of the French customers indicated that they

¹²⁰ See footnote 4.

would switch to B. Braun if the combined entity raised prices¹²¹. This suggests that B. Braun is a significant competitor to the Parties.

Closeness of competition

234. In addition, the Parties do appear to have different focuses in their respective fluid operations in France, with Gambro focussing on powders and Baxter on liquid concentrates. The market investigation has not yielded unequivocal results as to the customers' views on the identity of Gambro's closest competitors¹²² but as shown below, the Commission's bidding analysis supports Baxter's view that the Parties are not particularly close competitors.

Bidding analysis

235. Overall, the bidding data confirms that Fresenius, Bellco, B. Braun, Hemotech (which distributes Asahi and Nikkiso's products) and Meditor (which distributes Toray's products) would be important remaining rivals for HD tenders post-merger. Moreover, although each of the Parties has a presence in relation to fluids in France, the tender data shows that there will remain a range of strong rivals in the fluid segment post-Transaction. These rivals include Fresenius, Bellco, B. Braun, Hemotech and Nipro, all of which contest and also win fluid lots.
236. Gambro's dataset does not allow for a meaningful analysis of winners due to the lack of information. However, Baxter's database shows the effective competitive constraint imposed by at least five competitors that actively participate and win the bids lost by Baxter in [*HD product*]. For the last two years where information is available for the tenders concerning fluids, Gambro won [...]% of the bids, Bellco [...]%, B. Braun [...]%, Nipro [...]%, Fresenius [...]%, Hemotech [...]% and other competitors won the remaining contracts.
237. Gambro won much less competitive events in 2012 than in 2011 (both in absolute and in relative terms). In 2012 Gambro won in [...] cases (out of [...]) compared to [...] cases (out of [...]) in 2011. Moreover, Baxter bidding data clearly confirms the significant presence of Nipro as a competitor in fluids, which is disregarded by the market share data. Besides its real presence in the market through bids won, the tender data also informs about the increasing participation of Nipro, in terms of number of competitive events where it submitted a bid, which went up from [...]% in 2010 to [...]% in 2012.
238. Therefore, the bidding analysis shows that the Parties are not particularly close competitors and that they face significant competition from a number of other market participants.

Conclusion

239. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs applies also to this analysis.

¹²¹ See responses to question 55 of questionnaire Q2 - Questionnaire to customers (HD).

¹²² See responses to question 53.5 of questionnaire Q2 - Questionnaire to customers (HD).

240. In view of the foregoing, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the French market for HD fluids.

f. Ireland

241. The Parties estimate that the market for HD systems, encompassing all the HD equipment and consumables, was worth EUR [...] million in Ireland in 2012.

242. Gambro offers a full HD product range in Ireland. Gambro supplies these products through [*Gambro's distribution system*]. Baxter offers the same HD products in Ireland as at the EEA level, including monitors and bloodlines manufactured by[...], dialysers manufactured by [...], as well as its own fluids. Baxter sells its HD products in Ireland [*Baxter's distribution system*].

243. According to Baxter, apart from the Parties, the main HD suppliers active in Ireland are Fresenius and B. Braun. B. Braun is a recent entrant. It entered into the Irish market in 2011. B. Braun offers a full range of HD products in that country. So does Fresenius.

244. The Health Service Executive (HSE) acts a central procurement entity in Ireland, purchasing HD equipment and consumables on behalf of public hospitals and HD private "satellite" units, namely, privately owned healthcare centres which are also subject to the HSE tender process. The HSE enters into framework agreements with HD suppliers following tenders. Once a framework agreement has been concluded (and eligible suppliers have been selected), public hospitals and private HD satellite units may then contact eligible suppliers and ask for the submission of bids. The HSE distinguishes three main regions for tenders: the Southwest, the Midwest and the Dublin regions.

245. In Ireland, only the market for dialysers falls within Group 1.¹²³

HD dialysers

246. The market shares estimated by the Parties on the Irish market for HD dialysers are as follows:

Table 21: Market shares in the Irish market for HD dialysers (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[30-40]%	[30-40]%
Gambro	[30-40]%	[40-50]%	[30-40]%	[20-30]%	[20-30]%	[5-10]%
Combined	[50-60]%	[60-70]%	[50-60]%	[50-60]%	[50-60]%	[40-50]%
FMC	[40-50]%	[30-40]%	[30-40]%	[40-50]%	[40-50]%	[30-40]%
B. Braun						[20-30]%
Kimal	[0-5]%		[5-10]%	[5-10]%		
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

¹²³ The markets for HD systems and bloodlines are Group 3 markets. See paragraphs 119 and 120 above. The market for monitors is not affected.

247. On the basis of this data, it appears that post-Transaction, the combined entity would rank first. However, Gambro's market share has declined significantly over the years (especially since 2011), whereas B. Braun has achieved a significant market share of [20-30]% since its entry into the market.
248. Also, the Commission's bidding data analysis indicates that the Parties participated in very few tenders over the relevant period and lost [...] of them. Gambro participated in [...] tenders in total over the relevant period. It lost [...] of them, [...] to Fresenius, [...] to B. Braun and [...] to Baxter. Baxter participated in [...] tenders where the outcome is known and also lost [...] of them: [...] to B. Braun, [...] to Fresenius and [...] to both of them. The [...] tender won by Baxter was with a customer where [...].
249. Moreover, B. Braun and Fresenius' strength has been confirmed by the [...], which identified these two competitors as both Baxter and Gambro's closest competitors¹²⁴. Furthermore, the [...] reported various recent switching events. In all cases, the [...] switched either to Fresenius or to B. Braun. In certain cases, Gambro was the previous supplier¹²⁵. This illustrates that the Parties are not particularly close competitors (no reported switching events involved both of them), as well as the strength of Fresenius and B. Braun.
250. These elements, in addition, to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment (see paragraphs 74 and following) confirm that the Parties are not close competitors.
251. Moreover, [...] it also appears that the actual post-Transaction increment may be overstated, for the reasons explained at paragraphs 104 to 107.
252. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.
253. In light of the above, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Irish market for HD dialysers¹²⁶.

g. Italy

254. The Parties estimate that the market for HD systems, encompassing all the HD equipment and consumables, was worth EUR [...] million in Italy in 2012.
255. Gambro offers the full HD product range in Italy. Gambro does not offer [...], but it does offer technical support and maintenance services. It relies on [*Gambro's distribution system*].

¹²⁴ With respect to HD systems as well as to each of the categories of HD products. See [...] response to questions 52 and 53 of questionnaire Q2 - Questionnaire to customers (HD).

¹²⁵ See [...] response to question 48 of questionnaire Q2 – Questionnaire to customers (HD) (including sub-questions).

¹²⁶ Gambro's revenues in the Irish fluids market have declined significantly and steadily over the last 6 years with sales [...] in 2012. Consequently, this market is not affected.

- 256. Baxter offers the same HD products as at the EEA level, including monitors and bloodlines manufactured by [...], dialysers manufactured by [...], as well as its own fluids. In addition, Baxter offers synthetic dialysers manufactured by [...]. Regarding HD monitors, Baxter offers the [...] monitors, but [...]. Baxter thus sources the [...] monitors it offers from [...]. Baxter uses a [*Baxter's distribution system*] for HD sales in Italy, [...]. Baxter does not [...] in HD.
- 257. According to Baxter, the Parties' main competitors are Fresenius, Bellco (an Italian company which according to Baxter enjoys a strong and stable presence in its home country), B. Braun as well as Nipro, Nikkiso, Toray and Asahi.
- 258. Fresenius, B. Braun and Bellco offer a full range of HD products in Italy.

HD systems

Market structure – market shares

- 259. The market shares estimated by the Parties on the Italian market for HD systems are as follows:

Table 22: Market shares in the Italian market for HD systems (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[5-10]%	[5-10]%	[5-10]%	[0-5]%	[0-5]%	[5-10]%
Gambro	[50-60]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%
Combined	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[40-50]%
FMC	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%
Bellco	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Toray	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Nikkiso	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Asahi	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

- 260. According to Baxter, Fresenius is the main challenger to Gambro with a share of [20-30]%, and it will continue to be the combined entity's closest competitor post-Transaction. Baxter also puts emphasis on the role of Bellco, B. Braun, Toray and Nikkiso. According to Baxter, Fresenius aggressively targets HD in Italy and is understood to participate in virtually all Italian tenders with great success.
- 261. Post-Transaction, the combined entity would be the clear market leader (as Gambro currently is), well ahead of all the other competitors. However, while Baxter and Bellco's market share is fairly stable, Gambro's market share has been decreasing significantly over the last six years, mirroring a sizable increase in Fresenius' market share. Market shares suggest that post-Transaction, the combined entity would face significant competition from Fresenius and Bellco (with market shares of respectively [20-30]% and [10-20]%) – which are able to satisfy the needs of customers which want to buy all the HD products as a package -, but also competition from a range of other players, notably B. Braun, Toray and Nikkiso.

Closeness of competition

262. In addition, the Parties do not appear to be particularly close competitors. Asked to identify Gambro's closest competitor in HD systems, a large majority of Italian customers named Fresenius. B. Braun and Bellco were each identified by a limited minority and no respondent referred to Baxter¹²⁷. This, in addition, to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, tends to confirm Baxter's view that it is not a close competitor of Gambro.

Competitive significance of Baxter – Customers' ability to switch to other suppliers

263. Moreover [...], the actual market share increment would be lower than Baxter's current [5-10]%. As explained in paragraph 67 above, Nipro is expected to expand its operations significantly in the countries [...], which include Italy, and is likely to capture a very significant part of Baxter's customers.
264. Furthermore, the general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs, if the combined entity were to increase prices post-Transaction applies also to the current assessment.

Conclusion

265. Therefore, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Italian market for HD systems.

HD bloodlines¹²⁸

266. The market shares estimated by the Parties on the Italian market for HD bloodlines are as follows:

¹²⁷ See responses to question 53.1 of questionnaire Q2 - Questionnaire to customers (HD).

¹²⁸ Baxter had no sales or only [...] sales of monitors in Italy in 2012, so that there is no overlap (or [...]) on the Italian monitors markets. Therefore, the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to this market.

Table 23: Market shares in the Italian market for HD bloodlines (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Gambro	[50-60]%	[50-60]%	[50-60]%	[40-50]%	[50-60]%	[50-60]%
Combined	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%
FMC	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%
Bellco	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Nikkiso	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Midial	[0-5]%	[0-5]%				
Others						[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

267. The increment in market share is limited at [0-5]% reflecting Baxter's marginal presence on this market. Consequently, the Transaction would not result in a significant change to the structure of the market. In addition, the merged entity would continue to face competition from a number of long-established suppliers such as Fresenius, Bellco, B. Braun and Nikkiso. Therefore, taking these elements into account and in the absence of substantiated concerns during the market investigation, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Italian market for HD bloodlines.

HD dialysers

268. The market shares estimated by the Parties on the Italian market for HD dialysers are as follows:

Table 24: Market shares in the Italian market for HD dialysers (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[0-5]%	[0-5]%
Gambro	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[30-40]%	[30-40]%
Combined	[50-60]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%
FMC	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%
Bellco	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
Toray	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Asahi	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Nikkiso	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Nipro	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

269. Post-Transaction, the combined entity would be the clear market leader (as Gambro currently is), well ahead of all the other competitors. However, while Baxter and Bellco's market share is fairly stable, Gambro's market share has been decreasing over the last six years, mirroring an increase in Fresenius' market share. Market shares suggest that post-Transaction, the combined entity would face significant competition from Fresenius and Bellco (with market shares of respectively [20-30]% and [10-20]%) but also competition from a range of other players, notably Toray and Asahi.

270. In addition, the Parties do not appear to be particularly close competitors. Asked to identify Gambro's closest competitor in HD dialysers, a large majority of Italian customers named Fresenius. B. Braun and Bellco were each identified by a limited minority and no respondent referred to Baxter¹²⁹. This, in addition, to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, tends to confirm Baxter's view that the Parties are not close competitors.
271. Furthermore, post-Transaction, in Italy, the actual market share increment would be lower than Baxter's current market share since [...]. An expansion by Nipro is likely to occur in the next few months. For the reasons explained at paragraphs 104 to 107, Nipro's expansion on the Italian market for dialysers appears sufficiently likely and timely and sufficient in scope for Nipro to exert a significant constraint on the combined entity. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.
272. The Commission therefore concludes that Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Italian market for HD dialysers.

HD fluids

273. The market shares estimated by the Parties on the Italian market for HD fluids are as follows:

Table 25: Market shares in the Italian market for HD fluids (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[10-20]%	[10-20]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Gambro	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%
Combined	[50-60]%	[50-60]%	[50-60]%	[40-50]%	[40-50]%	[40-50]%
FMC	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[30-40]%	[20-30]%
Bellco	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

274. Baxter stresses the important role of Fresenius on the Italian market for HD fluids and its own limited presence on that market. Baxter further argues that the Parties are not close competitors, and that they in fact only directly compete in a very limited number of HD tenders/lots in that country. In support of its claim that the Parties are not close competitors, Baxter also submits that its HD fluid offering is [...] than that of Gambro, because it does [...] - while Gambro and Fresenius do¹³⁰.

¹²⁹ See responses to question 53.4 of questionnaire Q2 - Questionnaire to customers (HD).

¹³⁰ Baxter's submission of 17 June 2013 *Supplement to HD country analyses*.

275. Post-Transaction, the combined entity would be the clear market leader (as Gambro currently is), well ahead of all the other competitors. However, Baxter's market share has been decreasing significantly over the last six years. Fresenius' market share, on the other hand, follows a growing trend. Market shares suggest that post-Transaction, the combined entity would face significant competition from Fresenius and Bellco (with market shares of respectively [20-30]% and [10-20]%).
276. In addition, the Parties do not appear to be particularly close competitors. Asked to identify Gambro's closest competitor in regard to HD fluids, a large majority of Italian customers named Fresenius. B. Braun and Baxter were each mentioned by a limited minority (and by a similar number of respondents) and Bellco was also mentioned¹³¹. This, in addition, to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, tends to confirm Baxter's view that the Parties are not close competitors.
277. The analysis of the Parties' bidding data, discussed below, supports this finding.

Bidding analysis

278. The tender data provided by the Parties for fluids in Italy reveals that the Parties face significant competitive pressure in HD from rivals such as Bellco, Nipro, Fresenius and B. Braun.
279. An analysis of the tender data shows that Baxter bids for HD fluid lots considerably less frequently than Gambro, which suggests that Baxter does not exert a very strong constraint on Gambro.
280. In order to get a better insight into the extent to which the Parties compete head-to-head in the market for HD fluids, the Parties' economic consultants combined their individual datasets. This exercise indicates that it is relatively rare for Baxter and Gambro to bid for the same lots within a tender, even where they both participate in the bidding process for the same tender. For the [...] tenders ([...] lots) involving [HD product], where full tender details are available in both Parties' tender datasets, Baxter and Gambro only bid for the same lot in [...] of the [...] cases. In addition, in more than [...]% of the cases ([...] lots out of [...]) where Baxter and Gambro competed against each other the lots were won by another competitor (the identity of the winner(s) being unknown).
281. There is thus an important proportion of bids for which Baxter and Gambro do not face each other as competitors. In the few instances where both Gambro and Baxter participate in the same tenders, the tender data shows that competitively strong and credible alternatives will remain post-Transaction.

Conclusion

282. Furthermore, the general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs, if the combined entity were to increase prices post-Transaction applies also to the current assessment.

¹³¹ See responses to question 53.5 of questionnaire Q2 - Questionnaire to customers (HD).

283. Therefore, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Italian market for HD fluids.

h. Netherlands

284. The Parties estimate that the market for HD systems, encompassing all the HD equipment and consumables, was worth EUR [...] million in the Netherlands in 2012.

285. Gambro offers a full range of HD products in the Netherlands. It supplies them [*Gambro's distribution system*]. Baxter also offers a full range of HD products including monitors manufactured by [...], dialysers manufactured by [...], bloodlines for [...] monitors, which are sourced in particular from [...], as well as its own fluids. In addition, Baxter offers dialysers manufactured by [...]. However, [...] ¹³². Baxter sells its HD products in the Netherlands [*Baxter's distribution system*].

286. According to Baxter, the main HD suppliers active in the Netherlands are Fresenius, Gambro, Baxter, B. Braun, Medcomp, Dirinco, Nipro and MTN Neubrandenburg.

287. Fresenius and B. Braun offer a full range of HD products. Medcomp does not particularly focus on RRT products but is specialized in vascular access products for various medical applications¹³³. Dirinco, for its part, is not involved in the manufacture of any HD product but distributes monitors, bloodlines and dialysers manufactured by NxStage as well as fluids originating from SALF and HAAS, dialysers from Medica and Toray, bloodlines from Effe Emme and vascular access products from Joline, Kimal and JMS¹³⁴. In the HD area, MTN Neubrandenburg is only involved in the production and distribution of fluids¹³⁵.

HD systems

288. The market shares estimated by the Parties on the Dutch market for HD systems are as follows:

¹³² Baxter's submission of 17 June 2013 *Supplement to HD country analyses*.

¹³³ Form CO, paragraphs 213 and 257.

¹³⁴ See Dirinco's response to question 1.1 of questionnaire Q1 – Questionnaire to competitors.

¹³⁵ See MTN Neubrandenburg's response to question 1.1 of questionnaire Q1 – Questionnaire to competitors.

Table 26: Market shares in the Dutch market for HD systems (in value)¹³⁶

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[10-20]%	[20-30]%
Gambro	[40-50]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
Combined	[40-50]%	[40-50]%	[30-40]%	[30-40]%	[40-50]%	[50-60]%
FMC	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
Nikkiso	[0-5]%	[5-10]%	[0-5]%	[5-10]%		
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[5-10]%
Medcomp	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Dirinco	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Nipro	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
MTN Neubrandenburg		[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[5-10]%	[5-10]%	[10-20]%	[10-20]%	[5-10]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

289. Baxter stresses that Fresenius currently ranks [...] with a share of [30-40]% while B. Braun, ranks fourth (with a share of [5-10]%). Baxter further notes that Gambro's position has continuously decreased over recent years, due in particular to Fresenius' aggressive pricing policy. Baxter argues that Gambro's closest competitor is Fresenius. Baxter considers that its own current position is due to the relatively recent acquisition of a distributor – Cablon – and its success in [...] tenders in 2011, whereas its position was much more limited prior to 2011. Baxter notes that the main competitors in the HD market are active globally, market several specialized HD products and could easily expand their operations in the Netherlands if the combined entity were to attempt to raise prices post-Transaction. Baxter refers in that respect to various examples of expansion into HD in the Netherlands, such as the recent opening of a sales office in the Netherlands by Bellco, the recent hiring of additional sales representatives by Nipro, and NxStage's relatively recent entry.
290. The Parties' combined market shares are significant and the increment is large ([20-30]%) and increasing due to Baxter's increasing market shares. By contrast, Gambro's market share has gone down substantially since 2007. Market shares suggest that the Parties will face significant competition by Fresenius (which has a market share of [30-40]%), and to a much lesser extent, B. Braun, all the more since both competitors offer a comprehensive range of HD products and are thus able to satisfy the needs of the customers that want to buy all these products as a single package. Other competitors only have a modest presence.

Closeness of competition

291. The Parties do not appear to be particularly close competitors. Asked to identify Gambro's closest competitor in regard to HD systems, a large majority of Dutch customers named Fresenius. Baxter was identified by a minority and no other competitor was mentioned¹³⁷. This, in addition, to the general findings reached as

¹³⁶ Corrected version provided as part of Baxter's submission of 17 June 2013 *Supplement to country analyses*.

¹³⁷ See responses to question 53.1 of questionnaire Q2 - Questionnaire to customers (HD). Some customers named several competitors, suggesting that they were equally close to Gambro.

regards closeness of competition between the Parties in the EEA-wide assessment, tends to confirm Baxter's view that it is not a close competitor of Gambro.

292. The analysis of the Parties' bidding data, described below, supports this finding.

Bidding analysis

(i) Gambro's bidding data

293. According to information gathered by Gambro, it participated in approximately [...]% of the tenders in the Netherlands, a country where [...]% of its sales are made via tenders. Therefore, the information provided by this bidding analysis is fairly representative.
294. In terms of participation in tenders over the years, it seems that Gambro submitted a bid in [...] tenders in the last two years as compared to the previous period. Given that the total number of tenders in the Netherlands does not seem to have changed considerably, it can be inferred that Gambro became less active.
295. Tenders are generally split into lots including product categories or sets of product categories. Generally the lots represent the competitive events where competition takes place. The dataset identifies the companies that were invited to the tender. Also information on the outcome as well as the winner is available in general. However, information on the volume and price is too scarce to allow for a systematic quantitative analysis.
296. Fresenius is the rival most frequently seen by Gambro in the Netherlands, followed by Baxter, B. Braun, Nipro and Dirinco. Baxter's participation in bids was very low before 2011 (less than [...]% of bids) and only increased after that year (to approximately [...]% of bids) due to its acquisition of Cablon. Over the last five years, Baxter was the unique other competitor invited in only [...]% of the events where Gambro participated (and for [...] of the events recorded for 2012). In the vast majority of the competitive events, a set of at least three to four competitors was invited.
297. For the tenders where the ranking of competitors was recorded, Fresenius was identified (as perceived by Gambro's sales workforce) as the closest competitor of Gambro in almost [...]% of the cases. Baxter is rather perceived as the second closest competitor of Gambro in the majority of events.
298. As regards the tenders lost by Gambro¹³⁸ where information on the winner is available, approximately [...] of them were won by Fresenius. Baxter won slightly less than [...]% of the tenders lost by Gambro, B. Braun [...], Nipro [...] and Dirinco [...]. However, the success of Baxter mainly predates its acquisition of Cablon in 2011. Subsequently, Baxter won only [...] of the events lost by Gambro (approximately [...]). Therefore, the increasing participation of Baxter in tenders did not trigger high winning rates, but the opposite. These percentages suggest that Baxter's market share ([20-30]% in 2012) overstates the current competitive constraint it exerts on Gambro based on the number of wins in the tender data. Furthermore,

¹³⁸ Gambro lost approximately [...]% of the competitive events where it participated and won (or partly won) more than [...] of them. The rest of the tenders were cancelled, postponed or are still on-going.

other competitors' market shares (B. Braun – [5-10]%, Nipro and Dirinco – [0-5]% each) seem to underestimate their effective constraint imposed on Gambro, reflected in the contracts won in Gambro's tenders.

(ii) Baxter's bidding data

299. The dataset of Baxter is much smaller than the one of Gambro; it includes approximately [...] tenders ("final" offers) for the last five years. However, tenders cover [...] of the sales made by Baxter; therefore, this bidding data has some relevance.
300. Consistent with the evidence from Gambro's data set, the number of tenders in which Baxter participated increased in the last few years (reflecting the acquisition of Cablon). However, Baxter has not managed to [...] in the last two years as all the tenders won by Baxter in 2011-2012 concern [...].
301. The tenders lost by Baxter were won by Fresenius ([...] events) and Gambro ([...] events). The tender [...] (more than EUR [...] million, for [...]) was lost by Baxter to Fresenius and the [...] tender (more than EUR [...] million, again for [...]) was lost by Baxter to Gambro in 2011. In both cases the stated reason for losing was the price.

(iii) Conclusion of the bidding analysis

302. The tender data of both Parties suggests therefore that Fresenius is the main competitor of both Parties, in line with the outcome of the market investigation. Furthermore, Baxter is not a strong or dynamic competitor. Despite its acquisition of Cablon in 2011, Baxter did not manage to increase its success in tenders. Moreover, other competitors such as B. Braun, Nipro and Dirinco all exert a significant competitive constraint on the Parties, effectively winning competitive events at a rate much higher than what their market shares might indicate.

Competitive significance of Baxter – Customers' ability to switch to other suppliers

303. Moreover, [...], the actual market share increment would be lower than Baxter's current [20-30]%. For the reasons explained at paragraphs 95 and 96 and paragraphs 104 to 107, both Nikkiso and [...] are expected to expand their operations significantly in the countries [...], which include the Netherlands, and are likely to capture a very significant part of Baxter's customers for the relevant product.¹³⁹
304. Furthermore, the general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs, if the combined entity were to increase prices post-Transaction applies also to the current assessment.

¹³⁹ These aspects will be dealt with in more detail in the assessment of the effects of the Transaction on the Dutch markets for monitors, bloodlines and dialysers, but they are also relevant to the Dutch market for systems, since Baxter's sales of monitors, bloodlines and dialysers account for more than [...]% of Baxter's total HD sales in the Netherlands.

Conclusion

305. Therefore, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Dutch market for HD systems.

HD monitors

Market structure – market shares

306. The market shares estimated by the Parties on the Dutch market for HD monitors are as follows:

Table 27: Market shares in the Dutch market for HD monitors (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter				[0-5]%	[10-20]%	[30-40]%
Gambro	[30-40]%	[30-40]%	[40-50]%	[40-50]%	[30-40]%	[20-30]%
Combined	[30-40]%	[30-40]%	[40-50]%	[40-50]%	[50-60]%	[60-70]%
FMC	[30-40]%	[30-40]%	[50-60]%	[50-60]%	[30-40]%	[20-30]%
Nikkiso	[10-20]%	[20-30]%	[0-5]%	[5-10]%		
B. Braun	[10-20]%	[0-5]%	[0-5]%	[0-5]%	[5-10]%	[5-10]%
Others					[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

307. According to Baxter, the sudden increase in its own shares illustrates that market shares may significantly fluctuate by winning or losing a few tenders. Moreover, the Parties expect Fresenius to further expand its market share in the future as a result of its aggressive pricing strategy and close relationships with physicians.

308. The Parties' combined market share is significant and the increment is large ([20-30]%). The Parties' combined market share has increased very significantly since 2007 as a result of Baxter's growing shares since its acquisition of Cablon. Market shares suggest that Fresenius will continue to be a significant competitor, nonetheless far more modest than the combined entity. B. Braun, for its part, with a market share of [5-10]%, is expected to play an important role. Besides, the Dutch market appears to be quite concentrated, with the Parties, Fresenius, Nikkiso and B. Braun having a combined market share of [90-100]% in 2012 and [90-100]% in previous years.

Closeness of competition

309. However, the Parties do not appear to be particularly close competitors. Asked to identify Gambro's closest competitor in regard to HD monitors, a large majority of Dutch customers named Fresenius. Baxter was identified by a minority and no other competitor was mentioned¹⁴⁰. This, in addition, to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, and the findings of the bidding analysis presented in the assessment of the effects of the Transaction on the Dutch market for HD systems, tends to confirm Baxter's view that it is not a close competitor of Gambro. It further appears from the bidding analysis that

¹⁴⁰ See responses to question 53.2 of questionnaire Q2 - Questionnaire to customers (HD).

competitors such as B. Braun, Nipro and Dirinco, have a much more significant role on this market than their market shares would suggest.

Competitive significance of Baxter – Customers' ability to switch to other suppliers

310. Moreover, [...], the combined entity's market share would be lower than the Parties' combined market share. Indeed, for the reasons explained at paragraphs 95 and 96, Nikkiso is expected to expand its monitors sales significantly in the countries [...], which include the Netherlands, and is likely to capture a very significant part of Baxter's customers.
311. Furthermore, the general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs, if the combined entity were to increase prices post-Transaction applies also to the current assessment.

Conclusion

312. Therefore, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Dutch market for HD monitors.

HD bloodlines

313. The market shares estimated by the Parties on the Dutch market for HD bloodlines are as follows:

Table 28: Market shares in the Dutch market for HD bloodlines (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter					[20-30]%	[20-30]%
Gambro	[50-60]%	[50-60]%	[40-50]%	[40-50]%	[30-40]%	[30-40]%
Combined	[50-60]%	[50-60]%	[40-50]%	[40-50]%	[50-60]%	[60-70]%
FMC	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
Nikkiso	[5-10]%	[5-10]%	[10-20]%	[10-20]%		
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Meise	[0-5]%	[0-5]%	[5-10]%	[0-5]%	[0-5]%	[0-5]%
Dirinco	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

314. Baxter stresses that Fresenius ranks [...] ([30-40]%), [...] [...] Gambro ([30-40]%), whereas Baxter ranks [...] ([20-30]%), and B. Braun [...] ([0-5]%). Baxter notes that Gambro' share considerably decreased from [50-60]% in 2007, and that there are other active players such as Meise and Dirinco. Baxter considers that Gambro and Baxter are not close competitors in the area of HD bloodlines (with Gambro offering captive cassettes for its Artis monitors and dedicated bloodlines for its other HD monitors).
315. The Parties' combined market shares are significant and the increment is large ([20-30]%). The Parties' combined market share has increased very significantly since 2010 as a result of Baxter's growing share since its acquisition of Cablon. The market share data suggest that Fresenius will continue to be a significant competitor, nonetheless far

more modest than the combined entity. As in the case of monitors, the Dutch bloodlines market appears to be very concentrated, with the Parties and Fresenius accounting together for [90-100]% of sales.

316. However, the Parties do not appear to be particularly close competitors. Asked to identify Gambro's closest competitor in regard to HD bloodlines, a large majority of Dutch customers named Fresenius. Baxter was not identified at all¹⁴¹. This, in addition, to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, and the findings of the bidding analysis presented in the assessment of the effects of the Transaction on the Dutch market for HD systems, tends to confirm Baxter's view that it is not a close competitor of Gambro. It further appears from the bidding analysis that competitors such as B. Braun and Dirinco, have a much more significant role on this market than their market shares would suggest.
317. Moreover, post-Transaction, in the Netherlands, the combined entity's market share is expected to be lower than the Parties' current combined market share [...].
318. Furthermore, the general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs, if the combined entity were to increase prices post-Transaction applies also to the current assessment.
319. Therefore, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Dutch market for HD bloodlines.

HD dialysers

320. The market shares estimated by the Parties on the Dutch market for HD dialysers are as follows:

Table 29: Market shares in the Dutch market for HD dialysers (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Gambro	[40-50]%	[40-50]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
Combined	[50-60]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%
FMC	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%
Nipro	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[5-10]%
Dirinco	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	
Asahi	[0-5]%	[0-5]%	[0-5]%	[0-5]%		
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

321. Baxter stresses that Fresenius is the [...] supplier (with a market share of [40-50]%) whereas Gambro ranks [...] [30-40]%), having lost 10 percentage points from 2007 to 2012, Baxter ranks [...] ([5-10]%), B. Braun ranks [...] ([5-10]%), and Nipro [...] ([0-5]%).

¹⁴¹ See responses to question 53.3 of questionnaire Q2 - Questionnaire to customers (HD).

322. The Parties' combined market shares is significant but has been decreasing over recent years, due to a significant reduction in Gambro's market share, correlated to an increase in Fresenius and B. Braun's market shares. Market shares suggest that Fresenius will continue to be a significant competitor of a similar size as the combined entity, and even a greater size if trends observed in recent years persist. B. Braun is also expected to act as a non-negligible constraint on the combined entity.
323. In addition, the Parties do not appear to be particularly close competitors. Asked to identify Gambro's closest competitor in regard to HD dialysers, a large majority of Dutch customers named Fresenius¹⁴². This, in addition, to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, and the findings of the bidding analysis presented in the assessment of the effects of the Transaction on the Dutch market for HD systems, tends to confirm Baxter's view that it is not a close competitor of Gambro. It further appears from the bidding analysis that competitors such as B. Braun have a much more significant role on this market than their market shares would suggest.

Competitive significance of Baxter – Customers' ability to switch to other suppliers

324. Furthermore, post-Transaction, in the Netherlands, the actual market share increment would be lower than Baxter's current market share since [...]. Indeed, in 2012, around [...] %¹⁴³ of Baxter's sales of dialysers in the Netherlands were made up of dialysers originating from and supplied [...]. An expansion by [...] is likely to occur in the next few months. For the reasons explained at paragraphs 104 to 107, [...] expansion on the Dutch market for dialysers appears sufficiently likely and timely and sufficient in scope for [...] to exert a significant constraint on the combined entity.
325. Moreover, the general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.

Conclusion

326. Therefore, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Dutch market for HD dialysers.

HD fluids

327. The market shares estimated by the Parties on the Dutch market for HD fluids are as follows:

¹⁴² See responses to question 53.4 of questionnaire Q2 - Questionnaire to customers (HD).

¹⁴³ Baxter's submission of 17 June 2013 *Supplement to country analyses* and Form CO, paragraph 872.

Table 30: Market shares in the Dutch market for HD fluids (in value)¹⁴⁴

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter					[0-5]%	[5-10]%
Gambro	[50-60]%	[30-40]%	[30-40]%	[20-30]%	[30-40]%	[30-40]%
Combined	[50-60]%	[30-40]%	[30-40]%	[20-30]%	[30-40]%	[30-40]%
FMC	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[40-50]%	[40-50]%
MTN Neubrandenburg		[10-20]%	[10-20]%	[10-20]%	[10-20]%	[5-10]%
Dirinco	[10-20]%	[10-20]%	[10-20]%	[5-10]%	[5-10]%	[0-5]%
Nikkiso	[0-5]%	[5-10]%	[5-10]%	[5-10]%		
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

328. Baxter stresses that Fresenius would remain the leading supplier post-merger and refers to the role of other suppliers such as MTN Neubrandenburg, B. Braun and Dirinco.
329. The Parties' combined market share is significantly lower than that of Fresenius, which has been going up very substantially over the last five years, while Gambro's market share has decreased significantly. The Parties' combined market share has not exceeded [40-50]% since 2008. Moreover, MTN Neubrandenburg appears to be an important source of competitive constraint.
330. In addition, the Parties do not appear to be particularly close competitors. Asked to identify Gambro's closest competitor in regard to HD fluids, a large majority of Dutch customers named Fresenius¹⁴⁵. This, in addition, to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, and the findings of the bidding analysis presented in the assessment of the effects of the Transaction on the Dutch market for HD systems, tends to confirm Baxter's view that it is not a close competitor of Gambro. It further appears from the bidding analysis that competitors such as B. Braun and Dirinco have a much more significant role on this market than their market shares would suggest.
331. In view of the foregoing as well as the general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs, the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Dutch market for HD fluids.

i. Spain

332. The Parties estimate that the market for HD systems, encompassing all the HD equipment and consumables, was worth EUR [...] million in Spain in 2012.
333. Gambro offers a full HD product range in Spain and the same brands as at the EEA-level. It sells its products through [*Gambro's distribution system*]. Baxter also

¹⁴⁴ Corrected version provided as part of Baxter's submission of 17 June 2013 *Supplement to country analyses*.

¹⁴⁵ See responses to question 53.5 of questionnaire Q2 - Questionnaire to customers (HD).

offers a full HD product range in Spain, including monitors and bloodlines manufactured by [...], dialysers manufactured by [...] and its own fluids. Baxter operates [*Baxter's distribution system*] in Spain.

334. Fresenius, Nipro, and to a lesser extent, Bellco and B. Braun are the Parties' main competitors in Spain. Fresenius offers a full HD product range in Spain. Nipro also supplies a full range of HD products in Spain, where it has its own sales forces¹⁴⁶.
335. In Spain, the markets for HD systems, bloodlines and fluids are Group 1 markets.¹⁴⁷

HD systems

Market structure – market shares

336. The market shares estimated by the Parties on the Spanish market for HD systems are as follows:

Table 31: Market shares in the Spanish market for HD systems (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Gambro	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%
Combined	[40-50]%	[40-50]%	[40-50]%	[30-40]%	[30-40]%	[30-40]%
FMC	[30-40]%	[40-50]%	[40-50]%	[30-40]%	[40-50]%	[30-40]%
Nipro	[0-5]%	[0-5]%	[0-5]%	[5-10]%	[5-10]%	[5-10]%
Asahi	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Bellco	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Toray	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

337. Baxter notes that the Transaction will combine the current number [...] Gambro (with a market share of [30-40]% in 2012) and the number [...] Baxter (with a market share of [5-10]% in 2012), whereas Fresenius is the current [...] (with a market share of [30-40]% in 2012), and will [...]. Baxter considers that Fresenius, but also Nipro, Bellco, B. Braun, and Asahi will continue to exert competitive pressure on the combined entity. Baxter claims that all of those competitors actively participate in tenders in Spain, including the largest tenders such as those organised in 2011 by [...], the [...] and [...].
338. The Parties' combined market share is in the same order of magnitude as that of the market leader, Fresenius. The market share data suggest that the Parties will face significant competition by Fresenius but also from a range of smaller competitors, notably Nipro, which has a market share of [5-10]% and which, as Fresenius, offers a full range of HD products and is thus able to satisfy the customers that want to buy all

¹⁴⁶ See Nipro's response to question 40 of questionnaire Q1 – Questionnaire to competitors.

¹⁴⁷ The Spanish market for dialysers is a Group 3 market. See paragraphs 119 and 120 above.

these products as a package. Moreover, other competitors such as B. Braun and Bellco, have a non-negligible presence.

339. In addition, whereas the market shares of Baxter, Bellco, Fresenius and B. Braun have remained relatively stable, Gambro's market share has been declining significantly over the last six years, whereas Nipro's market share has been increasing significantly, suggesting that it is a very dynamic competitor.

Closeness of competition

340. Furthermore, the Parties do not appear to be particularly close competitors. Asked to identify Gambro's closest competitor in regard to HD systems, a large majority of Spanish customers named Fresenius. Other competitors were mentioned at best by a very small minority¹⁴⁸. This, in addition, to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, tends to confirm Baxter's view that it is not a close competitor of Gambro.
341. The analysis of the Parties' bidding data, described below, supports this finding.

Bidding analysis

342. In Spain, Gambro has maintained the separate Hospal brand under which it offers mainly CRRT products but also HD products. Therefore, two separate datasets were provided by Gambro. In both of them the presence of Baxter is marginal or inexistent.
343. Amongst the HD tenders in the Hospal database that were lost, [...] was won by Baxter. In the Gambro database which contains about [...] competitive events over the relevant period, Baxter won only [...] of the bids lost by Gambro and [...] of them were for [HD product].
344. The tender data provided by Baxter reveals the strength of Nipro, which won [...]% of the bids lost by Baxter. This competitive constraint exerted by Nipro is definitely higher than what the market shares might indicate. Nipro's market share has been increasing constantly over the last five years, but the effective competitive strength that Nipro will exhibit in Spain in the future is clearly grasped by the high number of contracts won recently.
345. Furthermore, Gambro together with Hospal won another [...]% of the bids lost by Baxter, followed by Fresenius with only [...]%. Many other players were identified as winners in Baxter's database, including Diaverum, B. Braun, Bellco, Zento Medical, Palex Medica and Izasa among others.
346. Therefore, the bidding data available for Spain reveal a market with a large number of suppliers, all actively present and effectively constraining the Parties in tenders. Gambro, Fresenius and Nipro are the main players, whereas Baxter has only a marginal effective presence, even lower than what is indicated by its market share.

¹⁴⁸ See responses to question 53.1 of questionnaire Q2- Questionnaire to customers (HD). Some customers named several competitors, suggesting that they were equally close to Gambro.

Competitive significance of Baxter – Customers' ability to switch to other suppliers

347. Furthermore, post-Transaction, in Spain, the actual market share increment would be lower than Baxter's current market share ([5-10]%) since [...]. An expansion by Nipro is likely to occur in the next few months. Nipro's expansion on the Spanish market for dialysers appears sufficiently likely and timely and sufficient in scope for Nipro to exert a significant constraint on the combined entity¹⁴⁹. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.

Conclusion

348. The Commission therefore concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Spanish market for HD systems.

HD bloodlines¹⁵⁰

349. The market shares estimated by the Parties on the Spanish market for HD bloodlines are as follows:

Table 32: Market shares in the Spanish market for HD bloodlines (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Gambro	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[30-40]%	[30-40]%
Combined	[50-60]%	[50-60]%	[50-60]%	[40-50]%	[40-50]%	[40-50]%
FMC	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[40-50]%
Nipro				[5-10]%	[5-10]%	[5-10]%
Bellco	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

350. The Parties' combined market share is in the same order of magnitude as that of the [...], Fresenius. The market shares suggest that the Parties will face significant competition from Fresenius but also from a range of smaller competitors, notably Nipro, which has a market share of [5-10]%.

351. In addition, whereas Baxter's market share has remained relatively stable, Gambro's market share has been declining significantly over the last six years. Over the same period, both Nipro and Fresenius' market shares have been growing.

352. Furthermore, the Parties do not appear to be particularly close competitors. Asked to identify Gambro's closest competitor in regard to HD bloodlines, a large majority of

¹⁴⁹ These aspects are relevant to the Spanish market for systems, since sales of dialysers account for more than [...] % of Baxter's total HD sales in Spain.

¹⁵⁰ Baxter's monitor revenues were [...] in 2012 meaning that this market is not affected. Baxter's position has been similar in previous years.

Spanish customers named Fresenius. Other competitors were mentioned at best by a very small minority¹⁵¹. This, in addition to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, tends to confirm Baxter's view that it is not a close competitor of Gambro.

353. Moreover, as already indicated, bidding data available for Spain reveals a market with a large number of suppliers, all actively present and effectively constraining the Parties in tenders, in addition to Fresenius. Besides, the general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.
354. The Commission therefore concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Spanish market for HD bloodlines.

HD fluids

355. The market shares estimated by the Parties on the Spanish market for HD fluids are as follows:

Table 33: Market shares in the Spanish market for HD fluids (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Gambro	[40-50]%	[40-50]%	[40-50]%	[30-40]%	[30-40]%	[30-40]%
Combined	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%
FMC	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[40-50]%
B. Braun	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Bellco	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[5-10]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

356. The Transaction would enable the combined entity to reach [...] market share as that of Fresenius, the [...]. Market shares suggest that the Parties will face significant competition by Fresenius but also from other competitors, notably B. Braun, which has a market share of [5-10]%.
357. In addition, whereas Baxter and B. Braun's market shares have remained relatively stable, Gambro's market share has been declining significantly over the last six years, mirroring a substantial increase in Fresenius' market share.
358. Furthermore, the Parties do not appear to be particularly close competitors. Asked to identify Gambro's closest competitor in regard to HD fluids, a large majority of Spanish customers named Fresenius. Other competitors were mentioned at best by a very small minority¹⁵². This, in addition to the general findings reached as regards

¹⁵¹ See responses to question 53.3 of questionnaire Q2 - Questionnaire to customers (HD).

¹⁵² See responses to question 53.5 of questionnaire Q2 - Questionnaire to customers (HD).

closeness of competition between the Parties in the EEA-wide assessment, tends to confirm that Fresenius is a closer competitor to Gambro than Baxter.

359. Moreover, as already indicated, bidding data available for Spain reveals a market with a large number of suppliers, all actively present and effectively constraining the Parties in tenders, in addition to Fresenius.
360. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.
361. The Commission therefore concludes that Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Spanish market for HD fluids.

j. Sweden

362. The Parties estimate that the market for HD systems, encompassing all the HD equipment and consumables, was worth EUR [...] million in Sweden in 2012.
363. Gambro offers a full HD product range in Sweden and the same brands as at the EEA level. It sells its products through [*Gambro's distribution system*].
364. Baxter offers a full HD product range in Sweden including monitors and bloodlines manufactured by [...], dialysers manufactured by [...], as well as its own fluids. Baxter sells its HD products in Sweden [*Baxter's distribution system*].
365. According to Baxter, the main HD suppliers active in Sweden are Gambro, Fresenius, Baxter, and B. Braun and additional suppliers are active in certain HD segments. Fresenius offers a full HD product range in Sweden and markets its products directly. B. Braun has significant HD sales in Sweden only in the fluid market. B. Braun has a direct sales force in Sweden but also uses distributors.

HD systems

Market structure – market shares

366. The market shares estimated by the Parties on the Swedish market for HD systems are as follows:

Table 34: Market shares in the Swedish market for HD systems (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[5-10]%	[10-20]%
Gambro	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[40-50]%	[40-50]%
Combined	[70-80]%	[70-80]%	[60-70]%	[60-70]%	[50-60]%	[50-60]%
FMC	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[40-50]%	[30-40]%
Meda	[0-5]%	[0-5]%	[0-5]%	[0-5]%		
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

367. Baxter argues that it is not a close competitor of Gambro, the HD products that Baxter and Gambro sell in Sweden not being regarded as close substitutes. According to Baxter, the combined entity will continue to face fierce competition from strong rivals, in particular Fresenius, as well as from B. Braun and other growing players.
368. Baxter indicates that Fresenius has expanded its Swedish business successfully in recent years at the expense of the Parties, in particular through aggressive pricing. An illustration of this success would be a tender organised in [...] by [...] covering [...] that is [...], which was won by Fresenius.
369. As regards B. Braun, Baxter notes that it has been present in Sweden for some years but only recently further expanded its HD activities in that country (in 2011-2012). In spite of B. Braun's currently minor market position, Baxter expects this competitor, in light of its experience and position in other Nordic countries, such as Finland, to gain a significant position also in Sweden in the near future.
370. Baxter also notes that Bellco is active on the Swedish HD market with bicarbonate-based fluids and dialysers, which are distributed by Nordic Medcom, a large distributor present in the Nordic countries. Besides, Baxter believes that Bellco is currently looking to expand its activities and to increase its presence in Sweden.
371. On the basis of the market share data, the Swedish market appears to be fairly concentrated, with only three suppliers – the Parties and Fresenius – enjoying a significant market presence. The Parties' combined market share is significant, well above Fresenius' market share.
372. However, the Parties' combined market share has been decreasing significantly over the last six years, primarily due to the declining path followed by Gambro's market share. This decrease has been mirrored by a significant increase in the market share of Fresenius, which has reached almost [40-50]%. Fresenius thus emerges as a strong and dynamic competitor, all the more since it offers a full HD product range and is thus able to satisfy the needs of customers willing to purchase all these products as a single package.

Closeness of competition

373. Moreover, in the framework of the market investigation, Fresenius has been identified by a large majority of Swedish customers as Gambro's closest competitor whereas Baxter has been identified by around half of the respondents and B. Braun by a minority¹⁵³. This, in addition, to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, is a first indication that the Parties are not particularly close competitors and that Fresenius is a closer competitor to Gambro than Baxter.
374. The analysis of the Parties' bidding data, described below, supports this finding.

¹⁵³ See responses to question 53.1 of questionnaire Q2 - Questionnaire to customers (HD).

Bidding analysis

(i) Gambro's bidding data

375. According to information gathered by Gambro, the latter participated in [...] tenders in Sweden, a country where [...]% of its sales are made via tenders (hence the highly informative nature of the information provided by the bidding analysis). Overall, the bidding dataset reveals the presence of many active competitors in Sweden. For the vast majority of competitive events, more than two and up to five competitors were mentioned. Moreover, where the information on the incumbent supplier was available, it showed that the vast majority of contracts were served by multi-sourcing. Customers source generally every component / consumable from various suppliers.
376. In terms of ranking of competitors present in a tender, Fresenius was perceived by Gambro's sales forces as its closest rival in [...]% of the cases. Nordic Medcom, which distributes products originating in particular from Bellco, was named as Gambro's closest competitor in [...]% of the cases and Baxter only in [...]%. Baxter is rather viewed as the second closest competitor on the Swedish market in the majority of the tenders.
377. In 2012 Gambro won [...]% of the competitive events where it participated, much less than its average winning rate of almost [...]% for the last 5 years. For those tenders where both Parties won part of the contract, there were other winners as well, showing again a market preference by Swedish customers to procure from multiple suppliers.
378. When Gambro lost a competitive event, the winner was Fresenius in more than [...]% of the cases followed by Baxter and Nordic Medcom, each winning in approximately [...]% of the cases. Moreover, Baxter [...] event lost by Gambro in 2012. Of the [...] events lost by Gambro in 2012, [...] were won by Fresenius and [...] by Nordic Medcom. Since the sales data show a market share for Nordic Medcom that is much smaller than the market share of Baxter (even if the entirety of Bellco sales as estimated by the Parties is attributed to Nordic Medcom), the tender data suggests that historical market share data may understate the growing significance of Nordic Medcom in the competition for tenders and its future competitive position.

(ii) Baxter's bidding data

379. Baxter's dataset is relatively smaller than Gambro's dataset but nevertheless it is believed to cover all tenders where Baxter participated in the relevant period. Moreover, as already indicated, [...]% of its sales in Sweden are made through tenders.
380. Baxter's position seems to weaken over time on the Swedish market. It lost considerably more events in 2012 ([...]%) than on average in previous years ([...]%).
381. Even if its market share is smaller than Gambro's, Fresenius is perceived as Baxter's main competitor in more than [...] of the competitive events where Baxter participated, much ahead of Gambro. Fresenius also won more than [...]% of the tenders lost by Baxter whereas Gambro won only [...] of them.
382. Baxter tender data also reveals the presence of two other strong effective competitors: Nordic Medcom and Scandinavian Medical, which distributes products originating from B. Braun and Nipro among others. They won together [...]% of the tenders lost by Baxter.

(iii) Conclusion of the bidding analysis

383. The tender data suggests that Fresenius is the main competitor of both Parties in Sweden. Both Gambro and Baxter are losing strength at the expense of solid distributors supplying products originating from well-known manufacturers, which are increasing their effective presence. Both datasets identify Nordic Medcom and Scandinavian Medical as winners in a considerable number of bids, showing them as a much stronger competitive constraint to both Parties than it is indicated by the market shares of the Parties' competitors.

Competitive significance of Baxter – Customers' ability to switch to other suppliers

384. Moreover, [...], the actual market share increment would be lower than Baxter's current [10-20]%. As explained in paragraphs 95 above and 104 above, both Nikkiso and [...] are expected to expand their operations significantly in the countries [...], which include Sweden, and are likely to capture a very significant part of Baxter's customers for the relevant product.¹⁵⁴

385. Furthermore, the general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs, if the combined entity were to increase prices post-Transaction applies also to the current assessment.

386. Therefore, the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Swedish HD system market.

HD monitors

387. The market shares estimated by the Parties on the Swedish market for HD monitors are as follows:

Table 35: Market shares in the Swedish market for HD monitors (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[5-10]%	[5-10]%	[5-10]%	[10-20]%	[0-5]%	[5-10]%
Gambro	[70-80]%	[60-70]%	[60-70]%	[70-80]%	[20-30]%	[50-60]%
Combined	[80-90]%	[70-80]%	[70-80]%	[80-90]%	[30-40]%	[60-70]%
FMC	[10-20]%	[20-30]%	[20-30]%	[10-20]%	[60-70]%	[30-40]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

388. Baxter expects B. Braun and Bellco to expand their activities in Sweden further, including into the monitors segment. Baxter further stresses that NxStage has expanded into Sweden in 2010. According to Baxter, NxStage sells its products in Sweden through the distributor Nordic Medcom, which actively participates in tenders and for instance, was one of the winners of the tender organized by [...]. Baxter

¹⁵⁴ These aspects will be dealt with in more detail in the assessment of the effects of the Transaction on the Swedish markets for monitors, bloodlines and dialysers, but they are also relevant to the Swedish market for systems, since Baxter's sales of monitors, bloodlines and dialysers account for more than [...] % of Baxter's total HD sales in Sweden.

considers it likely that NxStage's presence in Sweden will be more visible in the future.

389. The Swedish market for monitors appears to be very concentrated in light of the market share data, with only three significant suppliers, namely the Parties and Fresenius. Moreover, the Parties have a high combined market share, positioning the combined entity well ahead of Fresenius in terms of revenues.
390. However, the Parties' combined market share has been severely declining over recent years. This sharp decline is mainly due to the decrease in Gambro's market share, correlated to a very marked growing trend followed by Fresenius' market share¹⁵⁵, which was [30-40]% in 2012. Fresenius thus emerges as a strong and dynamic competitor. In addition, as already indicated, it results from the bidding analysis that the competitive strengths of distributors such as Nordic Medcom and Scandinavian Medical, which distribute products originating from manufacturers other than the Parties and Fresenius, is significant and is not reflected in the market share data.
391. Furthermore, in the framework of the market investigation, Fresenius has been identified by a large majority of Swedish customers as Gambro's closest competitor whereas Baxter has been identified by around half of the respondents and B. Braun by a minority¹⁵⁶. This, in addition to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, and the findings of the bidding analysis presented in the assessment of the effects of the Transaction on the Swedish market for HD systems, tends to confirm Baxter's view that it is not a close competitor of Gambro.
392. Moreover, [...], the actual market share increment would be lower than Baxter's current [5-10]%. As explained in paragraph above, Nikkiso is expected to expand its operations significantly in the countries [...], which include Sweden, and is likely to capture a very significant part of Baxter's customers for HD monitors.
393. Furthermore, the general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs, if the combined entity were to increase prices post-Transaction applies also to the current assessment.
394. Therefore, the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Swedish HD monitors market.

HD bloodlines

395. The market shares estimated by the Parties on the Swedish market for HD bloodlines are as follows:

¹⁵⁵ The [60-70]% figure reached in 2011 was exceptional.

¹⁵⁶ See responses to question 53.2 of questionnaire Q2 - Questionnaire to customers (HD).

Table 36: Market shares in the Swedish market for HD bloodlines (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[5-10]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[5-10]%
Gambro	[60-70]%	[60-70]%	[60-70]%	[60-70]%	[50-60]%	[40-50]%
Combined	[70-80]%	[60-70]%	[60-70]%	[60-70]%	[50-60]%	[40-50]%
FMC	[20-30]%	[20-30]%	[20-30]%	[30-40]%	[40-50]%	[50-60]%
Berco	[0-5]%	[5-10]%	[5-10]%	[0-5]%		
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

396. Baxter puts emphasis on the leading role of Fresenius, which has a market share of [50-60]%, and claims that some smaller players such as MedTech, Scandinavian Medical and Nordic Medcom currently focus on the disposables segment.
397. As in the case of monitors, the Swedish market for bloodlines appears to be very concentrated in light of the market share data, with only three significant suppliers, namely the Parties and Fresenius. Moreover, the Parties have a high combined market share.
398. However, the Parties' combined market share has been declining over recent years. This sharp decline is mainly due to the decrease in Gambro's market share, correlated to a very marked increase in Fresenius' market share. Fresenius thus emerges as a strong and dynamic competitor. In addition, as already indicated, it results from the bidding analysis that the competitive strengths of distributors such as Nordic Medcom and Scandinavian Medical, which distribute products originating from manufacturers other than the Parties and Fresenius, is significant and is not reflected in the market share data.
399. Furthermore, in the framework of the market investigation, Fresenius has been identified by a large majority of Swedish customers as Gambro's closest competitor whereas Baxter has been identified by around half of the respondents and B. Braun by a minority¹⁵⁷. This, in addition to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, and the results of the bidding analysis presented in the assessment of the effects of the Transaction on the Swedish market for HD systems, tends to confirm that Fresenius is a closer competitor to Gambro than Baxter.
400. Moreover, [...], the actual market share increment would be lower than Baxter's current [5-10]%.
401. Furthermore, the general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs, if the combined entity were to increase prices post-Transaction applies also to the current assessment.
402. Therefore, the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Swedish HD bloodlines market.

¹⁵⁷ See responses to question 53.3 of questionnaire Q2 - Questionnaire to customers (HD).

HD dialysers

403. The market shares estimated by the Parties on the Swedish market for HD dialysers are as follows:

Table 37: Market shares in the Swedish market for HD dialysers (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[10-20]%	[10-20]%	[20-30]%	[10-20]%	[10-20]%	[10-20]%
Gambro	[40-50]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[40-50]%
Combined	[60-70]%	[60-70]%	[70-80]%	[70-80]%	[60-70]%	[50-60]%
FMC	[30-40]%	[30-40]%	[30-40]%	[30-40]%	[40-50]%	[40-50]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

404. As in the case of monitors and bloodlines, the Swedish market for dialysers appears to be very concentrated in light of the market share data, with only three significant suppliers, namely the Parties and Fresenius. The Parties' combined market share is significant but it has been decreasing over the last four years, due to a reduction in Baxter's market share. By contrast, Fresenius' market share has increased significantly over the same period. Market shares suggest that the combined entity will face significant competition from Fresenius, which is a strong and dynamic competitor in Sweden. In addition, as already indicated, it results from the bidding analysis that the competitive strengths of distributors such as Nordic Medcom and Scandinavian Medical, which distribute products originating from manufacturers other than the Parties and Fresenius, is significant and is not reflected in the market share data.
405. Furthermore, in the framework of the market investigation, Fresenius has been identified by a large majority of Swedish customers as Gambro's closest competitor whereas Baxter has been identified by around half of the respondents and B. Braun by a minority¹⁵⁸. This, in addition to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, and the results of the bidding analysis presented in the assessment of the effects of the Transaction on the Swedish market for HD systems, tends to confirm that Fresenius is a closer competitor to Gambro than Baxter.
406. Furthermore, post-Transaction, in Sweden, the actual market share increment would be lower than Baxter's current market share since [...]. An expansion by Nipro is likely to occur in the next few months. Nipro's expansion on the Swedish market for dialysers appears sufficiently likely and timely and sufficient in scope for Nipro to exert a significant constraint on the combined entity. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.
407. The Commission therefore concludes that Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Swedish market for HD dialysers.

¹⁵⁸ See responses to question 53.4 of questionnaire Q2 - Questionnaire to customers (HD).

HD fluids

408. The market shares estimated by the Parties on the Swedish market for HD fluids are as follows:

Table 38: Market shares in the Swedish market for HD fluids (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[5-10]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Gambro	[60-70]%	[60-70]%	[50-60]%	[50-60]%	[60-70]%	[50-60]%
Combined	[60-70]%	[60-70]%	[60-70]%	[60-70]%	[60-70]%	[50-60]%
FMC	[10-20]%	[20-30]%	[20-30]%	[20-30]%	[30-40]%	[30-40]%
B. Braun	[5-10]%	[0-5]%	[0-5]%	[0-5]%	[5-10]%	[5-10]%
Meda	[5-10]%	[5-10]%				
Serumwerk			[5-10]%	[5-10]%		
MTN Neubrandenburg			[5-10]%	[5-10]%		
Others		[5-10]%				
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

409. According to Baxter, over the past five years, Gambro and Baxter have gradually lost business in this segment, whereas Fresenius has expanded its business, from [10-20]% in 2007 to [30-40]% in 2012. Baxter expects Fresenius to continue to compete aggressively in this segment. In addition, it expects B. Braun to further grow.
410. As in the case of monitors, bloodlines and dialysers, the Swedish market for fluids appears to be very concentrated in light of the market share data, with only four significant suppliers, namely the Parties, Fresenius and B. Braun. The Parties' combined market share is high but has been decreasing over the six years, as the market shares of each of Baxter and Gambro have been decreasing, mirroring a substantial increase in Fresenius' market share. Market shares suggest that the combined entity will face significant competition from Fresenius, which is a strong and dynamic competitor in Sweden, and to a more limited but non negligible extent, from B. Braun. In addition, as already indicated, it results from the bidding analysis that the competitive strengths of distributors such as Nordic Medcom and Scandinavian Medical, which distribute products originating from manufacturers other than the Parties and Fresenius, is significant and is not reflected in the market share data.
411. Furthermore, in the framework of the market investigation, Fresenius has been identified by a large majority of Swedish customers as Gambro's closest competitor whereas Baxter has been identified by around half of the respondents and B. Braun by a minority¹⁵⁹. This, in addition to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, and the results of the bidding analysis presented in the assessment of the effects of the Transaction on the Swedish market for HD systems, tends to confirm that Fresenius is a closer competitor to Gambro than Baxter.

¹⁵⁹ See responses to question 53.5 of questionnaire Q2 - Questionnaire to customers (HD).

412. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.
413. The Commission therefore concludes that Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the Swedish market for HD fluids.

k. United Kingdom

414. The Parties estimate that the market for HD systems, encompassing all the HD equipment and consumables, was worth EUR [...] million in the United Kingdom in 2012.
415. Gambro offers a full HD product range in the United Kingdom. It sells its products [*Gambro's distribution system*]. Baxter also offers a full HD product range including monitors and bloodlines manufactured by [...], dialysers manufactured by [...], as well as its own fluids. However, Baxter's presence in HD in the United Kingdom is modest. Baxter is mainly active in relation to HD products for home HD products. Otherwise, Baxter's activities focus on Northern Ireland. Baxter does not have [*Baxter's distribution system*]. In Northern Ireland, Baxter provides repair and maintenance services for HD products. In the remainder of the United Kingdom, Baxter merely provides repair and maintenance services for home HD products.
416. According to Baxter, the main HD suppliers active in the United Kingdom are Gambro, Fresenius, B. Braun, Kimal and Nipro and there is a group of other, less significant, suppliers, which include Baxter and Allmed.
417. Fresenius offers a full HD product range in the United Kingdom, as well as dialysis services in partnership with the National Health Service (NHS). B. Braun also offers a full HD product range as well as dialysis services, alone or in cooperation with the NHS.
418. In the United Kingdom, only the market for dialysers falls within Group 1.¹⁶⁰

HD dialysers

419. The market shares estimated by the Parties on the United Kingdom market for HD dialysers are as follows:

¹⁶⁰ The markets for HD systems, bloodlines and fluids are Group 3 markets. See paragraphs 119 and 120 above. Baxter's sales of monitors were [...] in 2012 meaning that this market is not affected. Baxter's presence on the market has been limited in each of the past six years.

Table 39: Market shares in the United Kingdom market for HD dialysers (in value)

Competitor	Share of sales					
	2007	2008	2009	2010	2011	2012
Baxter	[5-10]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Gambro	[10-20]%	[10-20]%	[20-30]%	[30-40]%	[30-40]%	[30-40]%
Combined	[20-30]%	[20-30]%	[20-30]%	[40-50]%	[40-50]%	[30-40]%
FMC	[60-70]%	[50-60]%	[50-60]%	[40-50]%	[30-40]%	[30-40]%
Nipro	[5-10]%	[5-10]%	[10-20]%	[10-20]%	[5-10]%	[10-20]%
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Allmed					[5-10]%	[5-10]%
Asahi	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[0-5]%	[5-10]%	[5-10]%	[5-10]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

420. The Parties' combined market share is [...] to the one of Fresenius, the [...]. It has been growing significantly since 2007 mainly due to a significant increase in Gambro's market share, correlated to a very substantial decrease in Fresenius' market share.
421. Market share data indicate that post-Transaction, the combined entity would face significant competition not only from Fresenius, but also from a range of other market participants, notably Nipro (which has a market share of [10-20]%), Allmed and B. Braun.

Closeness of competition

422. Moreover, in the framework of the market investigation, Fresenius has been identified by a large majority of United Kingdom customers as Gambro's closest competitor whereas B. Braun has been identified by a limited minority and Baxter has not been mentioned at all¹⁶¹. This, in addition, to the general findings reached as regards closeness of competition between the Parties in the EEA-wide assessment, tends to confirm Baxter's view that the Parties are not close competitors and that Fresenius is a closer competitor to Gambro than Baxter.
423. The analysis of the Parties' bidding carried out by the Commission and summarised below confirms that the Parties are not close competitors.

Bidding analysis

(i) Gambro's bidding data

424. According to information gathered by Gambro, the latter participated in more than [...]% of the tenders in the United Kingdom, a country where approximately [...] of Gambro's sales are made via tenders.
425. The tender data reveals that the market in the United Kingdom is competitive with the presence of at least three strong players besides the Parties, namely Fresenius, B. Braun and Kimal and with price being the most important factor determining the

¹⁶¹ See responses to question 53.4 of questionnaire Q2 - Questionnaire to customers (HD).

outcome of a tender. These competitors participate in tenders for all components and consumables, which suggests that are well-established and fully-fledged players.

426. Gambro won less than [...] of the competitive events where it participated. The bids lost by Gambro were won mainly by Fresenius and B. Braun (each in more than [...]% of the cases). Bidding data shows the effective strength of B. Braun in the United Kingdom that goes much beyond what is shown by its market share. The rest of the bids lost by Gambro were won by Baxter and Kimal.

(ii) Baxter's bidding data

427. According to Baxter's data, Baxter participated in about [...] of the tenders organised in the United Kingdom during the relevant period and approximately [...]% of its sales are made through tenders. Baxter submitted a bid in [...] tenders and won only [...] of them. Baxter also partly won lots belonging to other [...] tenders, but these contracts were shared amongst 4-8 other suppliers. The [...] of competitive events lost by Baxter were won by Fresenius. Although with a lower frequency, the other individual bidders which won tenders lost by Baxter in many cases were B. Braun and Kimal. The dataset shows as well a considerable number of contracts where the winners were multiple suppliers (including Fresenius, Gambro, B. Braun, Nipro, Kimal, Health Tec Medical, Merit Medical, Covidien, Vygon and Asahi). Gambro was the single winner of an event lost by Baxter only in [...], namely in [...] for [HD product].

(iii) Conclusion of the bidding analysis

428. The bidding data obtained by the Commission in regard to the United Kingdom reveals a market with strong effective competition exerted by at least five solid players (Gambro, Fresenius, B. Braun, Baxter and Kimal), along with other smaller players. These competitors participate actively in tenders for all components. The removal of one competitor post-merger seems to leave sufficient real alternatives in the market so that competition is not affected.
429. Furthermore, in the framework of the market investigation, Fresenius has been identified as Gambro's closest competitor by a large majority of United Kingdom customers whereas all the other competitors have been mentioned at best by a small minority¹⁶².
430. Furthermore, post-Transaction, in the United Kingdom, the actual market share increment would be lower than Baxter's current market share ([0-5]%) since [...]. An expansion by Nipro is likely to occur in the next few months. Nipro's expansion on the United Kingdom market for dialysers appears sufficiently likely and timely and sufficient in scope for Nipro to exert a significant constraint on the combined entity. The general conclusions arrived at in the EEA-wide assessment as to the possibility for customers to switch supplier relatively quickly without incurring major costs also applies to this assessment.
431. The Commission therefore concludes that Transaction does not raise serious doubts as to its compatibility with the internal market with respect to the United Kingdom market for HD dialysers.

¹⁶² See responses to question 53.4 of questionnaire Q2 - Questionnaire to customers (HD).

B. Continuous Renal Replacement Therapy (CRRT) equipment and consumables - Horizontal overlaps

1. Market structure – Merging firms have large market shares

432. According to the Parties' estimates, the CRRT market size in value terms amounted to EUR [...] million in the EEA in 2012.
433. Both Parties supply CRRT monitors, fluids, bloodlines, dialysers and other disposables. Gambro manufactures all these products itself whilst Baxter only manufactures CRRT fluids and sources the other elements from third parties under OEM contracts. In particular, Baxter sources monitors from [...], bloodlines from [...], dialysers from [...] and other disposables (catheters) from [...]. With the exception of [...], all products have been Baxter-labelled.¹⁶³
434. The Parties operate either directly or through distributors in the various EEA countries where they are present. Gambro has a wide geographical footprint and is present in [...] EEA countries, with a direct sales force in [...] EEA countries¹⁶⁴, through distributors or agents in further [...] EEA countries¹⁶⁵, and both directly and through distributors in [...]. Baxter is present in CRRT in approximately [...] of the EEA countries. Baxter has a direct presence in [...] EEA countries,¹⁶⁶ distributes its products through distributors in a further [...] EEA countries¹⁶⁷, and uses both its own sales force as well as distributors in [...].
435. Gambro offers its full range of products in all the EEA countries. Baxter is also offering all CRRT components in all EEA countries where it is (directly or indirectly) present. However, as regards CRRT monitors, [*Details on Baxter's CRRT products*]¹⁶⁸
¹⁶⁹.

a. EEA level

CRRT systems

436. The Notifying Party submits that the Parties' market shares are substantial, but the increment would be relatively small. Moreover, in addition to Fresenius (Germany), there would be other players active in CRRT, including other system providers Bellco (Italy) and B. Braun (Germany), as well as providers of certain components such as Toray (Japan) constraining the Parties' ability to act independently. While their market shares would still be relatively small, the Parties would expect these other providers to continue to grow, for example as customers might switch to them in cases when they would previously have chosen Baxter.

¹⁶³ [...].

¹⁶⁴ Notably in [...].

¹⁶⁵ Notably in [...].

¹⁶⁶ [...].

¹⁶⁷ [...].

¹⁶⁸ [...].

¹⁶⁹ [...].

437. The Commission notes that with a 2012 market share of [50-60]%, Gambro is currently the market leader in the CRRT system market at EEA level, with Baxter being the third largest competitor ([10-20]%). The Transaction would thus lead to a significant increment and result in a combined market share of [60-70]%. The following table gives an overview of the market share estimates of the Parties for the past six calendar years.

Table 40: Market shares in the CRRT systems market in the EEA (by value)

Company	Market shares (in %)					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[5-10]%	[10-20]%	[10-20]%	[10-20]%
Gambro	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%
Combined	[50-60]%	[50-60]%	[50-60]%	[60-70]%	[60-70]%	[60-70]%
Fresenius	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[20-30]%
B. Braun	[5-10]%	[5-10]%	[5-10]%	[0-5]%	[0-5]%	[0-5]%
Edwards Lifesciences ¹⁷⁰	[5-10]%	[5-10]%	[5-10]%	[0-5]%		
Medcomp	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Toray		[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Bellco	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Arrow (Teleflex)	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Dirinco	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

438. Fresenius, with a 2012 market share of [20-30]% in 2012, would significantly lag behind the merged entity whose CRRT sales would be more than [...] those of Fresenius.

439. Other remaining competitors together would account for only [10-20]% of the market and none accounts for more than [0-5]%. Moreover, many of these smaller competitors offer only some components. For instance, Medcomp (with a market share of [0-5]%) is not a CRRT system provider but specialized in vascular access products (included in the category of other disposables) for various medical applications, not only RRT. Teleflex only offers disposables, namely a variety of vascular access products marketed under the Arrow brand. Toray only sells CRRT dialysers. Dirinco is a distributor and CRRT fluids producer that is only active in CRRT in the Netherlands and Belgium.

440. Therefore, post-Transaction, the merged entity and Fresenius are the only providers of CRRT systems at EEA level with a large footprint, with B. Braun and Bellco being the

¹⁷⁰ In 2009, Baxter acquired from Edwards Lifesciences Corporation ("Edwards") the assets that formed Edwards' CRRT business.

only alternative system providers active in the EEA but with so far very limited market shares of [0-5]% each.

CRRT monitors and sets (bloodlines and dialysers)

441. In the segment / market for CRRT monitors and sets (bloodlines and dialysers), the market structure is very similar to the overall systems market. In 2012, Gambro was the market leader with a share of [50-60]%, with Baxter being the third largest competitor ([10-20]%). The Transaction would thus lead to a significant increment and to a combined market share of [60-70]%. The following table gives an overview of the market share estimates of the Parties for the past six calendar years.

Table 41: Market shares in CRRT monitors and sets in the EEA (by value)

Competitor	Market shares (in %)					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[5-10]%	[10-20]%	[10-20]%	[10-20]%
Gambro	[60-70]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%
Combined	[60-70]%	[50-60]%	[60-70]%	[70-80]%	[60-70]%	[60-70]%
Fresenius	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[20-30]%	[20-30]%
Edwards Lifesciences	[10-20]%	[10-20]%	[10-20]%	[0-5]%		
Toray		[5-10]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Bellco	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
B. Braun	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Diamed	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

442. Over this period, Baxter gained considerable market share, whereas Gambro consistently lead the market with shares exceeding [50-60]%. Although Fresenius gained some share more recently and accounted, in 2012, for [20-30]% of the market, it would significantly lag behind the merged entity. Other competitors' shares are limited amounting to only [5-10]% in total. The two other CRRT system providers, B. Braun and Bellco, did not gain any significant share.

CRRT fluids

443. CRRT system providers that also manufacture and sell CRRT fluids are limited to the Parties with a combined market share of [70-80]% in 2012 (increment of [10-20]%), Fresenius ([20-30]%), and B. Braun ([0-5]%). Dirinco ([0-5]%) only manufactures and sells CRRT fluids in the Netherlands together with third party monitors and consumables. There are some other companies selling CRRT fluids in certain national markets but all of them together have a marginal market share in the EEA of less than [0-5]%.¹⁷¹ The following table gives an overview of the market share estimates of the Parties for the past six calendar years.

¹⁷¹ For instance, Bellco sells fluids mainly in Italy ([0-5]% of the Italian CRRT fluid market), the Czech Republic ([5-10]%) and Poland ([0-5]%). Medica sells fluids only in Italy ([0-5]% of the Italian market). All figures are for 2011.

Table 42: Market shares in CRRT fluids in the EEA (by value)

Competitor	Market shares (in %)					
	2007	2008	2009	2010	2011	2012
Baxter	[5-10]%	[5-10]%	[5-10]%	[10-20]%	[10-20]%	[10-20]%
Gambro	[50-60]%	[50-60]%	[50-60]%	[60-70]%	[60-70]%	[60-70]%
Combined	[60-70]%	[60-70]%	[60-70]%	[70-80]%	[70-80]%	[70-80]%
Fresenius	[10-20]%	[10-20]%	[10-20]%	[20-30]%	[20-30]%	[10-20]%
B. Braun	[10-20]%	[10-20]%	[10-20]%	[0-5]%	[0-5]%	[0-5]%
Edwards Lifesciences	[5-10]%	[5-10]%	[5-10]%			
Dirinco	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

444. Over this period, both Baxter and Gambro gained considerable market share. Fresenius also grew its fluids sales whereas B. Braun's sales dropped sharply after 2009.

CRRT other disposables

445. The Notifying Party submits that there is a broad range of suppliers of other disposables.
446. The Commission notes that the Parties have a combined market share of [30-40]% in 2012, with a large increment of [10-20]%. The principal competitors of the Parties in this segment/ market differ in that they are not other CRRT system providers but mostly specialised providers of vascular access product provider such as Medcomp (with a 2012 market share of [20-30]%), Arrow (Teleflex) ([10-20]%) or Covidien ([5-10]%). The following table gives an overview of the market share estimates of the Parties for the past six calendar years.

Table 43: Market shares in CRRT other disposables in the EEA (by value)

Competitor	Market shares (in %)					
	2007	2008	2009	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[5-10]%	[10-20]%	[10-20]%	[10-20]%
Gambro	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%
Combined	[20-30]%	[20-30]%	[30-40]%	[30-40]%	[40-50]%	[30-40]%
Medcomp	[5-10]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%
Arrow (Teleflex)	[20-30]%	[10-20]%	[10-20]%	[10-20]%	[5-10]%	[10-20]%
Covidien (Tyco/Quinton)	[10-20]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
VMP	[5-10]%	[5-10]%	[5-10]%	[0-5]%	[5-10]%	[5-10]%
Bard/Vascath	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[0-5]%	[0-5]%
Vygon	[5-10]%	[5-10]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Fresenius	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Cook	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	
Others	[5-10]%	[5-10]%	[5-10]%	[0-5]%	[5-10]%	[0-5]%
Total	100%	100%	100%	100%	100%	100%

Source: Parties' estimates

447. Over this period, Baxter is the only competitor among the top five suppliers that has considerably gained market share, whereas Gambro's share remained relatively constant, in most years [...] the market closely followed by Medcomp.

b. National level

448. For the purposes of the competitive assessment in this case, the various national product markets that are horizontally affected were grouped into three categories: (i) Group 1 markets: where the Parties' combined market share exceeds 35% and the increment exceeds 1%; (ii) Group 2 markets: where the Parties' combined market share exceeds 35% but the increment does not exceed 1%; and (iii) Group 3 markets: where the Parties' combined market share does not exceed 35%¹⁷².

CRRT systems

449. In the overall CRRT market, the merged entity would have very large combined shares – exceeding [50-60]% – in 12 EEA countries, in most cases with large increments.¹⁷³ In Ireland, the Parties would have a [...] and in the United Kingdom a [...]. In another three Member States, the merged entity has significant market shares (above 35%) in 2012,¹⁷⁴ so that there are a total of 15 Group 1 markets at CRRT system level, as listed in the following table:

¹⁷² Please refer to footnote 99 for a more detailed explanation of the methodology used for this categorisation.

¹⁷³ Austria, Belgium/Luxembourg, Denmark, France, Greece, Ireland, Italy, the Netherlands, Norway, Spain, Sweden and the United Kingdom. Belgium and Luxembourg are referred to as one market (see footnote 100 for further detail on this.).

¹⁷⁴ These are Germany, Poland and the Czech Republic.

Table 44: 2012 market shares in CRRT systems (by value)

	Baxter	Gambro	<i>Combined</i>	Fresenius	BBraun	Bellco	Other	Total
Group 1 Countries								
Austria	[0-5]%	[50-60]%	<i>[50-60]%</i>	[30-40]%			[5-10]%	100%
Belgium/ Luxembourg	[5-10]%	[80-90]%	<i>[80-90]%</i>	[10-20]%			[0-5]%	100%
Czech Republic	[40-50]%	[0-5]%	<i>[40-50]%</i>	[20-30]%	[5-10]%	[0-5]%	[20-30]%	100%
Denmark	[30-40]%	[40-50]%	<i>[70-80]%</i>	[10-20]%			[5-10]%	100%
France	[5-10]%	[50-60]%	<i>[60-70]%</i>	[10-20]%			[10-20]%	100%
Germany	[0-5]%	[40-50]%	<i>[40-50]%</i>	[40-50]%	[0-5]%		[10-20]%	100%
Greece	[40-50]%	[50-60]%	<i>[90-100]%</i>	[0-5]%			[5-10]%	100%
Ireland	[10-20]%	[80-90]%	<i>[90-100]%</i>	-			[0-5]%	100%
Italy	[10-20]%	[40-50]%	<i>[50-60]%</i>	[10-20]%	[0-5]%	[10-20]%	[10-20]%	100%
Netherlands	[5-10]%	[40-50]%	<i>[50-60]%</i>	[5-10]%			[30-40]%	100%
Norway	[20-30]%	[50-60]%	<i>[70-80]%</i>	[20-30]%			[5-10]%	100%
Poland	[0-5]%	[40-50]%	<i>[40-50]%</i>	[30-40]%	[10-20]%		[5-10]%	100%
Spain	[10-20]%	[60-70]%	<i>[80-90]%</i>	[10-20]%			[0-5]%	100%
Sweden	[10-20]%	[70-80]%	<i>[80-90]%</i>	[10-20]%			[5-10]%	100%
United Kingdom	[30-40]%	[60-70]%	<i>[90-100]%</i>	-			[0-5]%	100%
Group 2 Countries								
None								
Group 3 Countries								
Romania	[10-20]%	[5-10]%	<i>[20-30]%</i>	[40-50]%			[30-40]%	100%
Slovakia	[20-30]%	[5-10]%	<i>[20-30]%</i>	[40-50]%	[20-30]%		[5-10]%	100%

Source: Parties' estimates

Table 45: Historical market shares - 2011 (by value)

	Baxter	Gambro	Combined	Fresenius	BBraun	Bellco	Other	Total
Austria	[5-10]%	[50-60]%	[60-70]%	[30-40]%			[5-10]%	100%
Belgium/ Luxembourg	[5-10]%	[80-90]%	[90-100]%	[5-10]%			[0-5]%	100%
Czech Republic	[70-80]%	[0-5]%	[70-80]%	[10-20]%	[10-20]%	[0-5]%	[0-5]%	100%
Denmark	[40-50]%	[40-50]%	[80-90]%	[10-20]%				100%
France	[10-20]%	[50-60]%	[60-70]%	[10-20]%			[20-30]%	100%
Germany	[0-5]%	[30-40]%	[40-50]%	[40-50]%	[0-5]%		[10-20]%	100%
Greece	[30-40]%	[60-70]%	[90-100]%	[0-5]%			[0-5]%	100%
Ireland	[20-30]%	[70-80]%	[90-100]%	-			[0-5]%	100%
Italy	[10-20]%	[40-50]%	[50-60]%	[10-20]%	[0-5]%	[10-20]%	[20-30]%	100%
Netherlands	[5-10]%	[40-50]%	[50-60]%	[10-20]%			[30-40]%	100%
Norway	[20-30]%	[50-60]%	[70-80]%	[10-20]%			[5-10]%	100%
Poland	[0-5]%	[40-50]%	[50-60]%	[20-30]%	[10-20]%		[5-10]%	100%
Spain	[10-20]%	[70-80]%	[80-90]%	[10-20]%				100%
Sweden	[10-20]%	[70-80]%	[80-90]%	[10-20]%			[5-10]%	100%
United Kingdom	[40-50]%	[50-60]%	[90-100]%	-			[0-5]%	100%
Romania	[20-30]%	[5-10]%	[30-40]%	[50-60]%			[10-20]%	100%
Slovakia	[40-50]%	[5-10]%	[40-50]%	[40-50]%	[5-10]%			100%

Source: Parties' estimates

Table 46: Historical market shares - 2010 (by value)

	Baxter	Gambro	Combined	Fresenius	BBraun	Bellco	Other	Total
Austria	[10-20]%	[40-50]%	[60-70]%	[30-40]%			[5-10]%	100%
Belgium/ Luxembourg	[5-10]%	[80-90]%	[90-100]%	[5-10]%			[0-5]%	100%
Czech Republic	[40-50]%	[0-5]%	[40-50]%	[20-30]%	[5-10]%		[10-20]%	100%
Denmark	[20-30]%	[50-60]%	[70-80]%	[10-20]%			[10-20]%	100%
France	[10-20]%	[50-60]%	[60-70]%	[10-20]%			[10-20]%	100%
Germany	[5-10]%	[40-50]%	[50-60]%	[30-40]%	[0-5]%		[10-20]%	100%
Greece	[10-20]%	[80-90]%	[90-100]%	[0-5]%			[0-5]%	100%
Ireland	[20-30]%	[70-80]%	[90-100]%	-			[0-5]%	100%
Italy	[10-20]%	[40-50]%	[50-60]%	[10-20]%	[0-5]%	[10-20]%	[20-30]%	100%
Netherlands	[5-10]%	[40-50]%	[50-60]%	[10-20]%			[30-40]%	100%
Norway	[10-20]%	[50-60]%	[70-80]%	[10-20]%			[10-20]%	100%
Poland	[5-10]%	[40-50]%	[50-60]%	[30-40]%	[10-20]%		[0-5]%	100%
Spain	[10-20]%	[60-70]%	[80-90]%	[5-10]%			[5-10]%	100%
Sweden	[10-20]%	[60-70]%	[80-90]%	[10-20]%			[5-10]%	100%
United Kingdom	[40-50]%	[50-60]%	[90-100]%	[0-5]%			[5-10]%	100%
Romania	[20-30]%	[0-5]%	[20-30]%	[50-60]%			[10-20]%	100%
Slovakia	[0-5]%	[5-10]%	[10-20]%	[80-90]%				100%

Source: Parties' estimates

450. In the following EEA countries, only one party (Gambro) has sales, so that there is no overlap: Bulgaria, Estonia, Finland, Hungary, Latvia, Lithuania, Malta, Portugal and Slovenia. This equally applies to the CRRT component markets.

CRRT monitors and sets (bloodlines and dialysers)

451. The market structure is similar with respect to the possible component markets. The Transaction would result in a combined market share of over (or just under) [50-60]% in most affected national markets for CRRT monitors and sets.

Table 47: 2012 market shares in CRRT monitors and sets (by value)

	Baxter	Gambro	Combined	Fresenius	B. Braun	Bellco	Other	Total
Group 1 countries								
Austria	[0-5]%	[60-70]%	[60-70]%	[30-40]%			[0-5]%	100%
Belgium/ Luxembourg	[0-5]%	[80-90]%	[80-90]%	[10-20]%				100%
Czech Republic	[50-60]%	[0-5]%	[50-60]%	[30-40]%	[10-20]%	[0-5]%	[0-5]%	100%
Denmark	[30-40]%	[40-50]%	[70-80]%	[20-30]%				100%
France	[10-20]%	[60-70]%	[70-80]%	[20-30]%			[0-5]%	100%
Germany	[0-5]%	[30-40]%	[30-40]%	[50-60]%			[5-10]%	100%
Greece	[10-20]%	[70-80]%	[90-100]%	[5-10]%				100%
Ireland	[10-20]%	[80-90]%	[90-100]%					100%
Italy	[5-10]%	[40-50]%	[40-50]%	[10-20]%	[5-10]%	[20-30]%	[10-20]%	100%
Netherlands	[10-20]%	[70-80]%	[80-90]%	[10-20]%			[0-5]%	100%
Norway	[30-40]%	[40-50]%	[70-80]%	[20-30]%				100%
Poland	[5-10]%	[40-50]%	[40-50]%	[40-50]%	[0-5]%		[0-5]%	100%
Spain	[10-20]%	[70-80]%	[80-90]%	[10-20]%			[0-5]%	100%
Sweden	[10-20]%	[70-80]%	[80-90]%	[10-20]%				100%
United Kingdom	[30-40]%	[60-70]%	[90-100]%	[0-5]%			[0-5]%	100%
Group 2 countries								
None								
Group 3 countries								
Romania	[10-20]%	[10-20]%	[20-30]%	[60-70]%			[0-5]%	100%
Slovakia	[10-20]%	[0-5]%	[20-30]%	[50-60]%	[20-30]%			100%

Source: Parties' estimates¹⁷⁵

¹⁷⁵ In this one and the following tables, sales for individual competitors are only reported where their market share is above 1% within the country. Where a competitor's sales represent less than a 1% market share within the country, they are included within "Other".

Table 48: Historical market shares – 2011 (by value)

	Baxter	Gambro	Combined	Fresenius	B. Braun	Bellco	Others	Total
Austria	[5-10]%	[50-60]%	[60-70]%	[30-40]%			[0-5]%	100%
Belgium-Luxembourg	[0-5]%	[80-90]%	[80-90]%	[10-20]%				100%
Czech Republic	[70-80]%		[70-80]%	[5-10]%	[5-10]%	[0-5]%	[0-5]%	100%
Denmark	[40-50]%	[40-50]%	[80-90]%	[10-20]%				100%
France	[10-20]%	[50-60]%	[70-80]%	[20-30]%			[0-5]%	100%
Germany	[5-10]%	[30-40]%	[30-40]%	[50-60]%			[5-10]%	100%
Greece	[10-20]%	[80-90]%	[90-100]%	[0-5]%				100%
Ireland	[20-30]%	[80-90]%	[90-100]%					100%
Italy	[5-10]%	[30-40]%	[40-50]%	[10-20]%	[5-10]%	[10-20]%	[20-30]%	100%
Netherlands	[10-20]%	[70-80]%	[80-90]%	[10-20]%				100%
Norway	[20-30]%	[60-70]%	[80-90]%	[10-20]%			[0-5]%	100%
Poland	[5-10]%	[60-70]%	[70-80]%	[20-30]%	[0-5]%			100%
Spain	[10-20]%	[70-80]%	[80-90]%	[10-20]%			[0-5]%	100%
Sweden	[10-20]%	[70-80]%	[80-90]%	[10-20]%				100%
United Kingdom	[40-50]%	[50-60]%	[90-100]%	[0-5]%			[0-5]%	100%
Romania	[20-30]%	[5-10]%	[30-40]%	[40-50]%			[10-20]%	100%
Slovakia	[40-50]%	[5-10]%	[50-60]%	[30-40]%	[5-10]%			100%

Source: Parties' estimates

Table 49: Historical market shares – 2010 (by value)

	Baxter	Gambro	Combined	Fresenius	B. Braun	Bellco	Others	Total
Austria	[10-20]%	[50-60]%	[70-80]%	[20-30]%			[0-5]%	100%
Belgium-Luxembourg	[5-10]%	[80-90]%	[90-100]%	[10-20]%				100%
Czech Republic	[40-50]%		[40-50]%	[40-50]%	[10-20]%			100%
Denmark	[5-10]%	[70-80]%	[70-80]%	[20-30]%				100%
France	[20-30]%	[50-60]%	[70-80]%	[20-30]%			[0-5]%	100%
Germany	[10-20]%	[40-50]%	[50-60]%	[30-40]%			[5-10]%	100%
Greece	[0-5]%	[90-100]%	[90-100]%	[5-10]%			[0-5]%	100%
Ireland	[10-20]%	[80-90]%	[90-100]%					100%
Italy	[5-10]%	[30-40]%	[40-50]%	[10-20]%	[5-10]%	[10-20]%	[20-30]%	100%
Netherlands	[10-20]%	[60-70]%	[70-80]%	[20-30]%			[0-5]%	100%
Norway	[10-20]%	[60-70]%	[80-90]%	[10-20]%			[0-5]%	100%
Poland	[5-10]%	[50-60]%	[60-70]%	[30-40]%	[10-20]%			100%
Spain	[10-20]%	[70-80]%	[90-100]%	[5-10]%			[0-5]%	100%
Sweden	[20-30]%	[60-70]%	[80-90]%	[10-20]%				100%
United Kingdom	[40-50]%	[50-60]%	[90-100]%	[0-5]%			[0-5]%	100%
Romania	[10-20]%		[10-20]%	[60-70]%			[20-30]%	100%
Slovakia		[5-10]%	[5-10]%	[90-100]%				100%

Source: Parties' estimates

CRRT fluids

452. The Transaction would result in a combined market share of over (or just under) [50-60]% in most affected national markets for CRRT fluids.

Table 50: 2012 market shares in CRRT fluids (by value)

	Baxter	Gambro	<i>Combined</i>	Fresenius	B. Braun	Bellco	Other	Total
Group 1 countries								
Austria	[0-5]%	[50-60]%	<i>[50-60]%</i>	[30-40]%			[5-10]%	100%
Belgium/ Luxembourg	[0-5]%	[80-90]%	<i>[90-100]%</i>	[10-20]%				100%
Denmark	[30-40]%	[40-50]%	<i>[80-90]%</i>	[10-20]%				100%
Germany	[0-5]%	[50-60]%	<i>[60-70]%</i>	[30-40]%	[0-5]%			100%
Greece	[50-60]%	[40-50]%	<i>[90-100]%</i>				[0-5]%	100%
Ireland	[10-20]%	[80-90]%	<i>[90-100]%</i>					100%
Italy	[10-20]%	[60-70]%	<i>[70-80]%</i>	[10-20]%	[0-5]%	[5-10]%	[0-5]%	100%
Norway	[0-5]%	[70-80]%	<i>[80-90]%</i>	[20-30]%				100%
Poland	[0-5]%	[40-50]%	<i>[40-50]%</i>	[20-30]%	[20-30]%		[0-5]%	100%
Romania	[60-70]%	[5-10]%	<i>[60-70]%</i>	[20-30]%			[10-20]%	100%
Slovakia ¹⁷⁶	[50-60]%	[0-5]%	<i>[50-60]%</i>	[20-30]%	[10-20]%			100%
Spain	[0-5]%	[80-90]%	<i>[80-90]%</i>	[10-20]%				100%
Sweden	[5-10]%	[80-90]%	<i>[90-100]%</i>	[5-10]%				100%
United Kingdom	[30-40]%	[60-70]%	<i>[90-100]%</i>	[0-5]%				100%
Group 2 countries								
None								
Group 3 countries								
None								

Source: Parties' estimates

Table 51: Historical market shares – 2011 (by value)

	Baxter	Gambro	<i>Combined</i>	Fresenius	B. Braun	Bellco	Others	Total
Austria	[0-5]%	[50-60]%	<i>[50-60]%</i>	[40-50]%			[0-5]%	100%
Belgium- Luxembourg	[0-5]%	[80-90]%	<i>[90-100]%</i>	[5-10]%				100%
Denmark	[30-40]%	[50-60]%	<i>[90-100]%</i>	[10-20]%				100%
Germany	[0-5]%	[50-60]%	<i>[50-60]%</i>	[40-50]%	[0-5]%			100%
Greece	[40-50]%	[50-60]%	<i>[90-100]%</i>				[0-5]%	100%
Ireland	[10-20]%	[80-90]%	<i>[90-100]%</i>					100%
Italy	[10-20]%	[60-70]%	<i>[70-80]%</i>	[10-20]%	[0-5]%	[0-5]%	[0-5]%	100%
Norway	[10-20]%	[70-80]%	<i>[80-90]%</i>	[10-20]%				100%
Poland	[0-5]%	[40-50]%	<i>[40-50]%</i>	[30-40]%	[20-30]%			100%
Romania	[50-60]%		<i>[50-60]%</i>	[30-40]%			[10-20]%	100%
Slovakia	[70-80]%	[5-10]%	<i>[70-80]%</i>	[10-20]%	[0-5]%			100%
Spain	[0-5]%	[80-90]%	<i>[90-100]%</i>	[10-20]%				100%
Sweden	[5-10]%	[80-90]%	<i>[90-100]%</i>	[10-20]%				100%
United Kingdom	[40-50]%	[50-60]%	<i>[90-100]%</i>					100%

Source: Parties' estimates

¹⁷⁶ Gambro's fluid sales in Slovakia in 2012 were [...]. Notwithstanding this negligible increment, this bidding market has been analysed given the fluctuations observed in Gambro's market shares over the last few years.

Table 52: Historical market shares – 2010 (by value)

	Baxter	Gambro	Combined	Fresenius	B. Braun	Bellco	Others	Total
Austria	[5-10]%	[40-50]%	[50-60]%	[40-50]%			[0-5]%	100%
Belgium-Luxembourg	[0-5]%	[90-100]%	[90-100]%	[0-5]%				100%
Denmark	[30-40]%	[50-60]%	[80-90]%	[10-20]%				100%
Germany	[0-5]%	[50-60]%	[50-60]%	[40-50]%	[0-5]%			100%
Greece	[10-20]%	[80-90]%	[90-100]%				[0-5]%	100%
Ireland	[20-30]%	[70-80]%	[90-100]%					100%
Italy	[10-20]%	[60-70]%	[70-80]%	[10-20]%	[0-5]%	[0-5]%	[0-5]%	100%
Norway	[10-20]%	[60-70]%	[80-90]%	[10-20]%				100%
Poland	[0-5]%	[30-40]%	[40-50]%	[30-40]%	[20-30]%			100%
Romania	[60-70]%		[60-70]%	[20-30]%			[10-20]%	100%
Slovakia	[20-30]%	[5-10]%	[20-30]%	[70-80]%				100%
Spain	[0-5]%	[90-100]%	[90-100]%	[5-10]%				100%
Sweden	[0-5]%	[80-90]%	[80-90]%	[10-20]%				100%
United Kingdom	[40-50]%	[50-60]%	[90-100]%	[0-5]%				100%

Source: Parties' estimates

CRRT other disposables

453. As for other disposables, the Transaction would result in a combined market share of over [50-60]% in five countries (Belgium/Luxembourg, Denmark, Ireland, Spain, and the United Kingdom) in 2012, and there are five more Group 1 countries (Austria, Germany, Greece, Netherlands, Norway and Sweden).

Table 53: 2012 market shares in CRRT other disposables (by value)

	Baxter	Gambro	Combined	Med-comp	Arrow	Covidien	Bard/Vascath	Fresenius	B. Braun	Other	Total
Group 1 countries											
Austria	[5-10]%	[30-40]%	[40-50]%	[0-5]%	[20-30]%	[20-30]%		[0-5]%		[5-10]%	100%
Belgium/Luxembourg	[20-30]%	[60-70]%	[80-90]%	[0-5]%	[0-5]%			[0-5]%		[5-10]%	100%
Denmark	[10-20]%	[30-40]%	[50-60]%	[10-20]%		[5-10]%	[20-30]%	[0-5]%			100%
Germany	[0-5]%	[30-40]%	[40-50]%	[0-5]%	[10-20]%	[5-10]%		[0-5]%		[30-40]%	100%
Greece	[30-40]%	[0-5]%	[30-40]%	[20-30]%	[20-30]%			[0-5]%		[20-30]%	100%
Ireland	[50-60]%	[40-50]%	[90-100]%								100%
Netherlands	[10-20]%	[20-30]%	[40-50]%	[10-20]%	[10-20]%		[5-10]%			[10-20]%	100%
Norway	[20-30]%	[10-20]%	[40-50]%	[10-20]%		[10-20]%	[10-20]%	[0-5]%	[5-10]%	[5-10]%	100%
Spain	[40-50]%	[20-30]%	[60-70]%	[5-10]%	[10-20]%	[5-10]%		[0-5]%		[0-5]%	100%
Sweden	[5-10]%	[20-30]%	[30-40]%	[20-30]%		[20-30]%	[20-30]%	[0-5]%			100%
United Kingdom	[60-70]%	[30-40]%	[90-100]%							[0-5]%	100%
Group 2 countries											
None											
Group 3 countries											
Czech Republic	[10-20]%	[0-5]%	[20-30]%		[70-80]%			[0-5]%	[0-5]%	[0-5]%	100%
France	[5-10]%	[10-20]%	[20-30]%	[50-60]%	[5-10]%	[5-10]%	[0-5]%			[5-10]%	100%
Italy	[10-20]%	[10-20]%	[20-30]%	[20-30]%	[10-20]%	[10-20]%	[5-10]%			[10-20]%	100%
Poland	[0-5]%	[20-30]%	[20-30]%	[20-30]%	[0-5]%	[30-40]%		[0-5]%		[10-20]%	100%
Slovakia	[5-10]%	[20-30]%	[20-30]%	[50-60]%				[10-20]%	[5-10]%		100%

Source: Parties' estimates

Table 54: Historical market shares - 2011 (by value)

	Baxter	Gambro	Combined	Med-comp	Arrow (Teleflex)	Covidien (Tyco/Quinton)	Bard/Vascath	FMC	B. Braun	Others	Total
Austria	[10-20]%	[30-40]%	[40-50]%	[0-5]%	[20-30]%	[20-30]%		[0-5]%		[5-10]%	100%
Belgium-Luxembourg	[20-30]%	[60-70]%	[80-90]%	[0-5]%	[0-5]%			[0-5]%		[5-10]%	100%
Denmark	[10-20]%	[80-90]%	[90-100]%					[0-5]%			100%
Germany	[0-5]%	[30-40]%	[40-50]%	[0-5]%	[10-20]%	[5-10]%		[0-5]%		[30-40]%	100%
Greece	[60-70]%	[30-40]%	[90-100]%					[0-5]%			100%
Ireland	[50-60]%	[40-50]%	[90-100]%								100%
Netherlands	[10-20]%	[20-30]%	[40-50]%	[10-20]%	[20-30]%		[5-10]%			[10-20]%	100%
Norway	[10-20]%	[10-20]%	[30-40]%	[10-20]%		[10-20]%	[5-10]%	[0-5] %	[5-10]%	[20-30]%	100%
Spain	[40-50]%	[30-40]%	[80-90]%		[5-10]%	[5-10]%		[0-5]%		[5-10]%	100%
Sweden	[0-5]%	[30-40]%	[30-40]%	[20-30]%		[20-30]%	[20-30]%	[0-5]%			100%
United Kingdom	[60-70]%	[30-40]%	[90-100]%							[0-5]%	100%
Czech Republic	[70-80]%	[10-20]%	[90-100]%					[0-5]%	[0-5]%	[0-5]%	100%
France	[5-10]%	[10-20]%	[10-20]%	[50-60]%	[5-10]%	[5-10]%	[0-5]%			[5-10]%	100%
Italy	[10-20]%	[10-20]%	[20-30]%	[20-30]%	[10-20]%	[10-20]%	[5-10]%			[10-20]%	100%
Poland	[5-10]%	[30-40]%	[30-40]%			[40-50]%		[0-5]%		[20-30]%	100%
Slovakia		[10-20]%	[10-20]%					[80-90]%			100%

Source: Parties' estimates

Table 55: Historical market shares – 2010 (by value)

	Baxter	Gambro	Combined	Med-comp	Arrow (Teleflex)	Covidien (Tyco/Quintan)	Bard/Vascath	FMC	B. Braun	Others	Total
Austria	[10-20]%	[30-40]%	[40-50]%	[0-5]%	[10-20]%	[20-30]%		[0-5]%		[5-10]%	100%
Belgium-Luxembourg	[20-30]%	[60-70]%	[80-90]%	[0-5]%	[0-5]%			[0-5]%		[5-10]%	100%
Denmark	[10-20]%	[20-30]%	[30-40]%	[20-30]%		[10-20]%	[20-30]%	[0-5]%		[5-10]%	100%
Germany	[0-5]%	[40-50]%	[40-50]%	[0-5]%	[10-20]%	[5-10]%		[0-5]%		[30-40]%	100%
Greece	[40-50]%	[50-60]%	[90-100]%					[0-5]%		[0-5]%	100%
Ireland	[60-70]%	[30-40]%	[90-100]%								100%
Netherlands	[10-20]%	[20-30]%	[40-50]%	[10-20]%	[20-30]%		[5-10]%			[10-20]%	100%
Norway	[10-20]%	[20-30]%	[30-40]%	[10-20]%		[10-20]%	[5-10]%	[0-5]%	[5-10]%	[20-30]%	100%
Spain	[30-40]%	[20-30]%	[50-60]%	[0-5]%	[10-20]%	[10-20]%		[0-5]%		[10-20]%	100%
Sweden	[5-10]%	[20-30]%	[30-40]%	[20-30]%		[20-30]%	[20-30]%	[0-5]%			100%
United Kingdom	[30-40]%	[10-20]%	[50-60]%	[5-10]%	[10-20]%		[10-20]%			[10-20]%	100%
Czech Republic	[60-70]%	[10-20]%	[70-80]%					[20-30]%	[5-10]%		100%
France	[5-10]%	[10-20]%	[10-20]%	[50-60]%	[5-10]%	[5-10]%	[0-5]%			[5-10]%	100%
Italy	[10-20]%	[10-20]%	[20-30]%	[20-30]%	[10-20]%	[10-20]%	[5-10]%			[10-20]%	100%
Poland	[10-20]%	[30-40]%	[50-60]%		[5-10]%	[30-40]%		[0-5]%		[5-10]%	100%
Slovakia		[20-30]%	[20-30]%					[80-90]%			100%

Source: Parties' estimates

c. Results of the market investigation

454. A large number of respondents to the Commission's requests for information raised concerns with respect to the market power of the merged entity in CRRT both at EEA-level and at national level.¹⁷⁷ Some customers raise concerns of that the Transaction will lead to higher prices, less competition, fewer products or decreased product development.¹⁷⁸ Moreover, a majority of competitors expressing a view believe that the merged entity is less likely to face significant competition from other suppliers of CRRT products.¹⁷⁹ Almost all of those competitors who expressed a view state that the proposed merger would have a negative impact on competition in the CRRT markets and most have expressed that they consider that the Transaction would lead to a significant increase in market power for the merged entity.¹⁸⁰

¹⁷⁷ Notably, competitors as well as customers or distributors in Austria, France, Germany, Greece, Ireland, Italy, the Netherlands, Spain, Sweden, and the United Kingdom. See responses to question 37 of Q1 - Questionnaire to Competitors; responses to question 44 of Q3 - Questionnaire to CRRT Customers; and responses to question 26 to Q4 – Questionnaire to Distributors.

¹⁷⁸ See responses to questions 47, 48 and 49 of Q3 - Questionnaire to CRRT Customers.

¹⁷⁹ See responses to question 37 of Q1 - Questionnaire to Competitors.

¹⁸⁰ See responses to question 72.2 of Q1 - Questionnaire to Competitors.

455. Moreover, CRRT customers consider that, in order to be able to extract the best value for money in a tender, at least three, preferably four or even more bidders would be needed.¹⁸¹ Moreover, as discussed in more detail in paragraph 495 below, the market investigation has shown that a number of customers prefer to engage in dual or multi-sourcing for reasons relating to ensuring competitive prices or security of supply.

d. The Commission's assessment

456. The larger the market share, the more likely a firm is to possess market power. And the larger the addition of market share, the more likely it is that a merger will lead to a significant increase in market power.¹⁸²

457. Although market shares and additions of market shares only provide first indications of market power and increases in market power, the Commission considers that the magnitude of the merged entity's market shares both at EEA-level and at national level, in Group 1 countries (and in particular in countries where the combined market share exceeds [50-60]%) are important factors in the assessment of this case. The following sections IV.B. 2 to IV.B. 5 will also analyse a number of other factors, which together with the Commission's assessment of the market shares of the merging parties, lead to a finding of serious doubts in relation to CRRT.

CRRT systems

(i) Group 1 countries

458. As regards the CRRT system market, Fresenius is the most important competitor, but there are also other suppliers like Bellco, B Braun, Dirinco, Kimal, Toray, Medcomp or Arrow. However, as explained in paragraph 439 above, not all of these competitors supply the whole range of products on the market. Medcomp and Arrow are supplying only other disposables, whereas Kimal supplies only dialysers, bloodlines and vascular access products. In addition to the Parties, only Fresenius, B. Braun and Bellco offer a full range of products ("system providers"). While Dirinco supplies entire CRRT systems, it only produces fluids itself but sells, amongst others, [...] monitors and other [...] products ([...]). It cannot, therefore, be regarded as a system provider that is independent of the Parties. Moreover, it is active only in the Netherlands and Belgium and therefore, it is not an alternative competitor in other national markets. The market shares of non-system providers are reflected in the category of "other competitors" in the tables reproduced in paragraph 449 above. On a CRRT system market, these "other" competitors cannot be regarded as close competitors of the Parties on the CRRT system market as they are not able to supply full CRRT systems.

459. In Ireland and the United Kingdom, the Transaction would lead to a [...]. In many other countries (notably Austria, Belgium/ Luxembourg, Denmark, France, Germany, Greece, the Netherlands¹⁸³, Norway, Spain and Sweden), the Parties have a combined

¹⁸¹ See responses to question 27 of Q3 - Questionnaire to CRRT Customers.

¹⁸² Paragraph 27 of the Horizontal Merger Guidelines.

¹⁸³ In the Netherlands, the merged entity's largest competitor is Dirinco ([30-40]%) but, as explained in paragraph 458, it is not a close competitor as Dirinco is not a system provider and competes by selling, amongst others, [...] products.

market share exceeding (or just under) [50-60]% with essentially one system provider – Fresenius - continuing to compete post-Transaction with the merged entity.

460. While market shares of the Parties remain large, in the Czech Republic and Italy, two more competitors (B. Braun and Bellco) compete with the merged entity in addition to Fresenius. In Italy, where the merged entity will have a combined market share of [50-60]%, there would be three main competitors, namely Bellco with [10-20]% market share and Fresenius with only [10-20]%. Also in the Czech Republic, customers can source not only from the merged entity ([40-50]% in 2012) but also Fresenius ([20-30]%), B. Braun ([5-10%]) market share, and, since 2011, Bellco ([0-5]%).
461. In Poland, the Parties' combined market share is [40-50]% and Fresenius accounts for [30-40]% of that market and B. Braun [10-20]%.

(ii) Non-Group 1 countries

462. As regards the CRRT system market in Romania, a Group 3 market, the Parties' market shares remained under [30-40]% in the past six years (except in 2011 when it was [30-40]%). Fresenius is the leading supplier by far with a market share ranging between [40-50]% in 2012 and [60-70]% in 2008. As regards Slovakia, the market shares appear to fluctuate from year to year¹⁸⁴. The Parties' combined share in 2012 amounted to [20-30]% (with an increment from Gambro of [5-10]%). Moreover, no specific concerns have been raised by customers in the course of the market investigation as regards these markets. Therefore, the Transaction is unlikely to raise serious doubts as to its compatibility with the internal market in respect of these possible markets.

CRRT monitors and sets

(i) Group 1 countries

463. In the possible market for CRRT monitors and sets, besides the merged entity, only Fresenius would be present on most of the Group 1 markets (except in the Czech Republic and Italy discussed further below). In Ireland and the United Kingdom, the Transaction would even lead to a [...] situation. Moreover, Fresenius would have a much smaller market presence in almost all of those Group 1 markets in which essentially two companies would continue to compete post-Transaction. The only exception is the German market in which Fresenius has been stronger than the merged entity in 2012. With Fresenius being the only credible alternative in all of those countries, the proposed transaction would severely limit customers' possibility to extract the best price and conditions in their procurement.
464. As regards the Czech Republic and Italy, contrary to the other Group 1 countries, at least one other CRRT system provider such as B. Braun or Bellco has a sizeable presence in those markets exceeding a market share of [10-20]%. In the Czech Republic, Gambro is a recent entrant as it has had [0-5]% in 2011 and 2010. The Transaction would therefore lead to a relatively limited increment of [0-5]%. Furthermore, B. Braun and, since 2011, Bellco are both present in the Czech Republic

¹⁸⁴ The Parties submit that this is due to the very limited size of the Slovakian CRRT segment where relatively small changes in purchases by few customers may radically change the market shares of suppliers.

and have gained share. As regards Italy, Bellco would continue to be the number two in its home market with a share of [20-30]% in 2012. B. Braun and other providers are also present there.

(ii) Non-Group 1 countries

465. As regards the Romanian market for CRRT monitors and sets, a Group 3 market, the merged entity would have a combined share of [20-30]% in 2012. However, Fresenius would continue to be the leading competitor by far with a share of [60-70]% in 2012. In Slovakia, where the Parties' combined market shares in 2012 were [20-30]% (with an increment of [0-5]% from Gambro), B. Braun has increased its market share to [20-30]% since its expansion into this market in 2011. Moreover, no specific concerns have been raised by customers in the course of the market investigation as regards these markets. Therefore, the Transaction is unlikely to raise serious doubts as to its compatibility with the internal market in respect of these possible markets.

CRRT fluids

(i) Group 1 countries

466. As regards the possible CRRT fluids market, the situation is similar to the one in the monitor and sets market. Fresenius would be essentially the only competitor to the merged entity in all Group 1 countries with the exception of Poland and Slovakia (discussed further below). The merged entity will have [...] in Ireland and the United Kingdom also in the fluids market. Moreover, Fresenius's position on these Group 1 country markets is comparatively weak. Only in Austria and Germany, Fresenius is a stronger player albeit not as strong as the merged entity. The other players on this market such as B Braun have an insignificant presence on the market. With Fresenius being the only credible alternative in all of those countries, the proposed transaction would severely limit customers' possibility to extract the best price and conditions in their procurement.
467. As regards Slovakia, the market shares fluctuate a lot from year to year. The Parties submit that this is due to the very limited size of the Slovakian CRRT segment where relatively small changes in purchases by few customers may radically change the market shares of suppliers. The Parties' combined share in 2010 amounted to [20-30]% (with an increment of [5-10]% by Gambro) and [70-80]% in 2011 (with an increment of [5-10]% by Gambro) and [50-60]% in 2012 but with a minimal increment of [0-5]% (representing revenues of EUR [...]). While since 2010 Baxter has constantly increased its presence on this market reaching [50-60]% in 2012, Gambro's market share fluctuated a lot but did not exceed [5-10]% in the past 5 years. Moreover, B. Braun has entered the market in 2011 and would be a second strong competitor (with [10-20]% in 2012) in addition to Fresenius.
468. As regards Poland, although the merged entity has increased its presence on this market from one year to another since 2008, it may nevertheless continue to be constrained by two competitors Fresenius and B. Braun which have a significant presence with market shares of [20-30]% and [20-30]% in 2012, respectively.

CRRT other disposables

(i) Group 1 countries

469. In the possible market for CRRT other disposables, contrary to other CRRT markets, the market shares of the merged entity will be generally lower although still exceeding [50-60]% in five countries (Belgium/Luxembourg, Denmark, Ireland, Spain, and the United Kingdom). In Ireland and the United Kingdom, the merged entity would have a [...] position. In Belgium/Luxembourg, the merged entity has a very large market share of [80-90]% in 2012. Also in Spain, the merged entity has a high market share of [60-70]% ([80-90]% in 2011). While there are other competitors present on this market, they are not very strong (the largest competitor – Arrow - had [10-20]% of this market). As for Denmark, both Bard/Vascath and Medcomp have market shares larger than [10-20]% each and Covidien, with [5-10]%, is a third credible competitor in 2012. However, the Parties' market share was [90-100]% in 2011.
470. Generally, Fresenius has a limited presence on this product market. There are, however, other companies such as Medcomp, Arrow, Covidien, and Brand/Vascath (all specialised in vascular access products) and B. Braun (with a strong presence in Norway) that are present on this market and may constrain the merged entity in the remaining Group 1 countries (Austria, Germany, Greece, the Netherlands, Norway and Sweden).

(ii) Non-Group 1 countries

471. As regards the possible markets for other disposables in the Czech Republic, France, Italy, Poland and Slovakia, which are Group 3 markets, the Parties' combined market shares were below [30-40]% in 2012. Medcomp had a by far larger market share in France and Slovakia and a similar market share in Italy in 2012. In the Czech Republic, Arrow seized [60-70]% of this market in 2012. Moreover, other competitors such as Fresenius in Slovakia and Arrow and Covidien in France and Italy have a sizeable market presence and will continue to compete in those markets. In Poland, the existence of other two main players in this market (Medcomp and Covidien) and of other competitors with smaller market shares (like Arrow and Fresenius) may constrain the merged entity. Moreover, no specific concerns have been raised by customers in the course of the market investigation as regards these markets.¹⁸⁵ Therefore, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in respect of these possible markets in the Czech Republic, France, Italy, Poland and Slovakia.

2. Closeness of competition – Merging firms are close competitors

a. The View of the Notifying Party

472. The Notifying Party submits that Baxter and Gambro are not perceived by customers as close competitors in CRRT.
473. First, the Notifying Party submits that Fresenius is Gambro's closest competitor in CRRT. The Parties consider Fresenius as very price aggressive with an increasing market share in light of the ever increasing cost constraints in the healthcare sector.

¹⁸⁵ Where respondents expressed concerns in France and Italy, these were not specifically related to the segment / market of other disposables.

474. By contrast and in particular due to [*Details on Baxter's products*], Baxter's market share in CRRT has declined. While Gambro's products are generally regarded as state-of-the-art CRRT equipment, [*Details on Baxter's products*].
475. Second, according to Baxter, this fact is also reflected in the Parties' shares of sales at CRRT components level. Larger differences in customer demand for the Parties' products indicate that their products are not viewed as close substitutes. For instance, Baxter's presence is particularly small in CRRT monitors ([5-10]%), whereas Gambro's shares amounts to [60-70]% at EEA level. As for CRRT fluids - the only CRRT component that Baxter manufactures itself - Gambro's share is still [...] times as large as Baxter's at EEA level.
476. Third, Gambro's business model in CRRT is to sell monitors and captive disposables (bloodlines and filters). Fresenius and Bellco operate the same model. By contrast, Baxter sells some disposables, including dialysers, also separately from its CRRT monitor. Also, its bloodlines and dialysers are not compatible with Gambro monitors. As such, there would be no head-to-head competition between Gambro and Baxter's CRRT sets.

b. Results of the market investigation

477. First, the majority of customers and distributors across the EEA that responded to the Commission's requests for information indicated Gambro as the closest competitor of Baxter at system level, closely followed by Fresenius.¹⁸⁶ At component level, the majority of distributors also refer to Gambro as the closest competitor to Baxter, whereas a similar number of customers refer to Fresenius or Gambro as the closest competitor of Baxter.¹⁸⁷ Other competitors such as Bellco and B. Braun are hardly ever mentioned and when they are, this is limited to a few customers in Italy and France (Bellco) and in the Czech Republic and (in one case) the Netherlands (B. Braun).
478. Second, while the majority of customers and distributors identify Fresenius as Gambro's closest competitor both at system and component level, a large minority also refers to Baxter, well ahead of other competitors (such as Bellco and B. Braun).¹⁸⁸
479. Third, competitors identify both Fresenius and Baxter as close competitors to Gambro both for CRRT system as a whole and for the various components constituting such a system.¹⁸⁹ Moreover, competitors named Gambro as the closest competitor of Baxter.¹⁹⁰ On average, competitors rank Gambro, Baxter and Fresenius closest to each other on parameters such as the range of products offered and the local presence across EEA countries. In addition, B. Braun is ranked similarly to Baxter on its capacity to

¹⁸⁶ See responses to question 42.1 of Q1 - Questionnaire to Competitors and responses to question 24.1 of Q4 – Questionnaire to Distributors.

¹⁸⁷ See responses to questions 42.2-42.5 of Q1 - Questionnaire to Competitors and responses to questions 24.2-24.5 of Q4 – Questionnaire to Distributors.

¹⁸⁸ See responses to questions 43.1-43.5 of Q1 - Questionnaire to Competitors, and responses to questions 25.1-25.5 of Q4 – Questionnaire to Distributors.

¹⁸⁹ See responses to question 36 of Q1 - Questionnaire to Competitors.

¹⁹⁰ See responses to question 35 of Q1 - Questionnaire to Competitors.

offer innovative products and its assistance to customers, whereas B. Braun scores slightly better than Baxter on quality (with Gambro and Fresenius leading in these categories).¹⁹¹ Other competitors such as Bellco and (as far as vascular access products are concerned) Toray scored significantly lower on all of those parameters.¹⁹²

c. The Commission's assessment

480. At the request of the Commission the Parties collected bidding data covering both HD and CRRT markets. Whereas information from the tenders inviting offers of HD products allowed for a rather solid bidding analysis, the information collected by the Parties on tenders including CRRT products is far less comprehensive. Notably, the Parties submitted certain information regarding CRRT products sold in tenders for eight Member States. Only for the United Kingdom was a separate data base for CRRT provided. For the rest of the Member States, information on the Parties' bids for HD and CRRT were provided together in one data base.
481. The data did not allow for a meaningful and complete quantitative analysis to conclude on the level of the competitive constraints imposed by one Party on the other. This is either because only a small proportion of sales in a certain country are made through tenders or because information on competitors was not available.
482. Having said this, as a general observation valid across all datasets, in the vast majority of cases wherever certain information on the Parties' rivals was available (either as competitors present in tenders or as winners), only Gambro (also with its brand, Hospel), Fresenius and Baxter (or its distributors where known) appear in the datasets.
483. Contrary to the Notifying Party's claim, both the responses to the market investigation and the general observations derived from the very limited bidding data indicate that together with Fresenius, Baxter and Gambro are close competitors in CRRT. The market investigation confirms that this is true both at system and component level. Substitutability with the product offering of other firms appears to be limited in particular given the range of products offered by the merging parties and Fresenius as well as their widespread local presence across EEA countries.
484. As to the question which company competes the closest with Gambro (or, in countries where Baxter is market leader, which company competes the closest with Baxter), the precise response would depend on which EEA country is being considered. There are strong indications that in certain markets the Parties are each other's closest competitor.
485. *United Kingdom and Ireland.* Taking CRRT system market shares over the past three years as an indicator, it can be noted that Fresenius is absent from the CRRT markets in Ireland and almost so in the United Kingdom. In the United Kingdom bidding data set, the limited information on competitors showed that the only competitors invited to tenders were Gambro, Fresenius and Baxter. [...] tenders lost by Gambro were won by

¹⁹¹ See responses to question 34 of Q1 - Questionnaire to Competitors. Note that the questionnaire also asked respondents to rank competitors on price but that the results are ignored here given that the question could be, and was, understood in differing ways by respondents, thus making a clear evaluation impossible.

¹⁹² So did Dirinco, Medcomp and Arrow (Teleflex) but those companies manufacture only fluids (Dirinco) or vascular access products (Medcomp and Arrow).

Baxter whereas [...] tenders lost by Baxter were won by Gambro (where data was available). The few responses to the relevant question in the market investigation (one customer and one distributor in each of Ireland and the United Kingdom) were inconclusive.¹⁹³

486. *Denmark, Greece, Norway, Spain and Sweden.* According to its market shares, Fresenius has a weaker position than Baxter in a number of countries including Denmark, Greece, Norway, Spain and Sweden. Tender data in those countries (where available) do not allow any conclusions as to whether Baxter or Fresenius compete closest with Gambro.¹⁹⁴ The market investigation results in Spain are mixed, whereas responding Swedish customers appear to perceive Fresenius as a closer competitor to Gambro than Baxter, but a majority perceives Gambro as a closer competitor to Baxter than Fresenius. For Denmark, Greece, and Norway, there are too few responses in order to allow for meaningful country-specific conclusions.
487. *France, Italy, the Netherlands and Belgium/Luxembourg.* In these countries, Baxter and Fresenius' market shares are of similar magnitude. Available tender data in those countries does not, however, allow any conclusions as to whether Baxter or Fresenius competes the closest with Gambro.¹⁹⁵ The market investigation is also inconclusive on this point as Italian customers and distributors responding to the Commission's requests for information indicate Bellco, Fresenius and Baxter as closest competitors to Gambro, whereas the outcome in the Netherlands is mixed. In Belgium/Luxembourg, Fresenius appears to have gained strength in the past three years, almost doubling its market share from [5-10]% to [10-20]% whereas Baxter's share diminished from [5-10]% to [5-10]%. However, a majority of customers and distributors from Belgium still rank Gambro and Baxter as closest competitors to each other.¹⁹⁶ In France, there were too few responses to this particular question.¹⁹⁷
488. *Austria, Germany, Poland, Czech Republic.* Out of the Group 1 countries, market shares at CRRT system level would suggest that Fresenius is likely to compete closer with Gambro than Baxter in Austria, Germany and Poland. Moreover, in the Czech Republic, Fresenius appears to compete closest with Baxter, whereas Gambro is a

¹⁹³ For all references in the following paragraphs to the market investigation, see responses to questions 42-43 of Q1 - Questionnaire to Competitors and responses to questions 24-25 of Q4 – Questionnaire to Distributors.

¹⁹⁴ In Denmark (and Finland), the Parties' bidding data mention only a few CRRT tenders and the only suppliers names mentioned were Gambro, Fresenius and Baxter. In Sweden, Gambro appeared very strong, winning [...] tenders mentioned in the dataset. For Spain (and France), Gambro has another brand (Hospal) for selling CRRT products. In these two countries it seems that some independent distributors participate directly in tenders as their names are mentioned in the data sets as competitors. However, bidding data does not allow for an identification of the suppliers whose products are sold by these distributors.

¹⁹⁵ In the Netherlands, the dataset submitted by Gambro (Baxter's data does not contain any information on CRRT) shows that Fresenius and Dirinco (...) are the only competitors present in tenders. For Italy, there is very little information on competitors. No dataset has been submitted for Belgium/Luxembourg.

¹⁹⁶ See responses to questions 42 and 43 of Q3 - Questionnaire to CRRT Customers and responses to questions 24 and 25 of Q4 – Questionnaire to Distributors. There are no responses of CRRT customers or distributors from Luxembourg.

¹⁹⁷ Only two CRRT customers and no distributor from France expressed a view on this question.

weaker competitor. This result of an analysis of market shares tends to be supported by customers and distributors from the relevant EEA countries identifying Fresenius as the closest competitor to Baxter and Gambro. Having said this, given that the Parties did not provide any bidding data for CRRT in these countries, it is unclear to what extent Baxter currently is a significant competitive constraint in Austria, Germany and Poland, and to what extent Gambro exercises such constraint in the Czech Republic.

489. As to the Notifying Party's argument that Baxter would sell some disposables, including dialysers, also separately from its CRRT monitor and therefore pursues a different business model than Gambro selling only sets dedicated to its monitors, the Commission notes that it is not evident that the sale of some components separately (in addition to sales of sets) would constitute a significant difference that would disqualify Baxter from being a close competitor of Gambro. However, even if this difference were to be assumed to be a significant criterion, the Commission notes several points. Firstly, the economic relevance of the "additional business model" is limited. Like Gambro, Baxter also sells CRRT sets (called "Aquaset") that are only compatible with its own monitor. In 2012, [...] of Baxter's sales of all CRRT dialysers and bloodlines in the EEA (EUR [...] million out of EUR [...] million) were sold in sets. Second, while Baxter indeed sells bloodlines (called "Aqualine") separately from CRRT sets, they are, however, not compatible with third party monitors,¹⁹⁸ hence there is no significant difference in business model with respect to this component. Third, while Baxter does sell dialysers (called "Aquamax") that are compatible with the monitors of other main CRRT suppliers in the EEA (except Gambro), Fresenius, B. Braun and Bellco also do so, which means that the latter would not be any closer a competitor to Gambro than Baxter on the particular criterion of "business model".
490. A similar observation can be made for the Notifying Party's argument that since Baxter's bloodlines and dialysers would be incompatible with Gambro monitors, there would be no head-to-head competition between Gambro and Baxter. First, no competitor in the EEA produces bloodlines and dialysers that are compatible with Gambro's monitors (as these are technically or legally shielded from doing so). Second, as concluded in paragraph 39 above, the market investigation revealed that the relevant product markets are either the overall CRRT system market or the market encompassing CRRT monitors, bloodlines and dialysers/ sets. Therefore, Baxter and Gambro compete head-to-head on these relevant product markets in terms of winning contracts / tenders, and not on selling an individual component such as dialysers for a competitor's monitor.

d. Conclusion

491. The Commission concludes that Baxter and Gambro are likely to be close competitors in the market for CRRT systems and its components in all Group 1 countries. Moreover, there are indications that both companies are the closest competitors in a number of national markets.

¹⁹⁸ According to Annex 6.12 to the Form CO, entitled "Compatibility Of Disposables, Fluids, And Technical Services With CRRT Monitors."

3. *Possibilities to switch suppliers - customers have limited possibilities of switching suppliers*

a. The View of the Notifying Party

492. The Notifying Party submits that hospitals (especially larger ones) in Austria, Belgium/ Luxembourg, France, Italy, the Netherlands, Sweden, and, to a lesser extent, Germany generally source from two or more CRRT suppliers, to avoid over-reliance on a single CRRT supplier and make staff comfortable to use several devices. Moreover, roughly half of the customers in the Czech Republic, Norway and Spain would dual- or multi-source. Single-sourcing would be predominant in Denmark, Ireland, Poland and the United Kingdom.
493. Dual or multi-sourcing may mean two different things. For one, a customer could source CRRT monitors from two or more suppliers and also source disposables and fluids from these suppliers. Second, customers could purchase monitors from one supplier and certain disposables (such as fluids or vascular access products) from another supplier.
494. The Notifying Party further submits that customers can easily switch suppliers and do so frequently.

b. Results of the market investigation

495. The results of the market investigation as regards the prevalence of dual- and multi-sourcing are mixed. A majority of customers expressing a view do not multisource while a large minority does multisource from between two to four suppliers.¹⁹⁹ Reasons given for their multi-sourcing policy include competition for better price, medical evaluations concerning therapies or functionalities, and security of supply. Reasons not to multisource relate to payment per treatment contracts and the limited number of CRRT treatments in a given hospital.
496. As regards switching, the market investigation revealed that customers would generally try to switch supplier in case of a price increase.²⁰⁰ However, immediate switching is not possible due to the time required to train hospital staff on new monitors, to engage in tender/ contracting procedures and to evaluate different products and offers.²⁰¹ CRRT customers replying to the market investigation indicated that the time to switch suppliers (including the evaluation of a new supplier and training staff in CRRT) could be anywhere between one month and one year.²⁰² Moreover, switching components is not possible individually for those components that are technically bundled to the monitor (that is, bloodlines and dialysers). Some customer replies indicate, however, that switching may be more immediate for certain components such as CRRT fluids.
497. The market investigation also provided evidence that in practice, convincing a CRRT customer to switch supplier may be more difficult than in HD. As pointed out by one

¹⁹⁹ See responses to question 34 of Q3 - Questionnaire to CRRT Customers.

²⁰⁰ See responses to question 45 of Q3 - Questionnaire to CRRT Customers.

²⁰¹ See responses to question 35 of Q3 - Questionnaire to CRRT Customers.

²⁰² See responses to question 35 of Q3 - Questionnaire to CRRT Customers.

recent entrant, the US company NxStage, "to convince a hospital to switch to a new CRRT machine is very hard since this would change all procedures and routines in the hospital. The nurses need to be trained in order to perform the treatment with a new machine."²⁰³ However, nurses working in intensive care units only use CRRT monitors once in a while, in addition to many other machines and tasks related to the necessary treatment in such hospital units.²⁰⁴

498. Moreover, the market investigation showed that a large majority of CRRT customers has not switched supplier for CRRT systems or for any given CRRT component in the last three years, thereby indicating that this is not a frequent event.²⁰⁵ For those that did switch in the past three years and gave details, many customers procured new CRRT systems. As an Italian customer points out:

*"Really it was not a switching; we purchased (Pay per treatment) a new monitor by another manufacturer [...] to test a new CRRT monitor with the possibility to do a new Technique (CPFA) for the treatment of patients with septic shock as well as standard CRRT. In the meantime we continued to use 6 monitors and other products by [another manufacturer]."*²⁰⁶

499. A number of other customers also procured new monitors. A French customer [...].²⁰⁷
500. As regards CRRT fluids, the market investigation indicated that in practice, the vast majority of customers buy all disposables from the same supplier, even in situations where contractually, fluids could be purchased from different suppliers.²⁰⁸ Second, a large majority of customers prefer to source all main categories of CRRT products from the same provider.²⁰⁹ Asked to report concrete switching events in the past three years, only one customer (from Ireland) indicated that it switched its fluid supplier.²¹⁰
501. As regards other RRT-specific disposables used in CRRT, the market investigation did not reveal specific results. Customers appear to buy all disposables from the same supplier, although they are not technically linked to a particular monitor and could therefore, in principle, be sourced from any supplier (unless a PPT contract is in place that would prevent a customer from doing so).²¹¹

²⁰³ See agreed minutes of conference call with NxStage on 24 May 2013.

²⁰⁴ See agreed minutes of conference call with Fresenius on 14 May 2013. This is a very different situation from HD treatment centres or clinics, where nurses are typically only dealing with HD dialysis treatment and HD equipment and consumables are the major cost item. Therefore, it is easier to convince a HD customer to switch HD monitors or systems (see paragraph 79).

²⁰⁵ See responses to question 38 of Q3 - Questionnaire to CRRT Customers.

²⁰⁶ Reply by [...] to question 38.1.1 of Q3 - Questionnaire to CRRT Customers.

²⁰⁷ See responses to question 38.1.1 of Q3 - Questionnaire to CRRT Customers.

²⁰⁸ See replies to questions no 17 to Q3 – Questionnaire to customers (CRRT) and minutes of the phone call with Fresenius on 14.05.2013, paragraphs 2 and 31.

²⁰⁹ See replies to question no 31 to Q3 – Questionnaire to customers (CRRT).

²¹⁰ See reply of [...] to question no 31 to Q3 – Questionnaire to customers (CRRT).

²¹¹ See replies to question no. 17 to Q3 – Questionnaire to customers (CRRT).

c. The Commission's assessment

502. The market investigation shows that certain barriers to switching exist, notably related to the effort and cost for retraining staff on a new monitor, testing new products and adapting to new processes of operation and maintenance related to a monitor. For customers, switching from one supplier to another as a result of a price increase in the market for CRRT monitors and sets (or in the overall CRRT system market) is therefore far from being immediate and straightforward as it requires time, adaptations and costs. Unlike in the HD market(s), bloodlines and dialysers (CRRT sets) are generally technically linked to the CRRT monitor,²¹² so that a customer wishing to switch any of those components would necessarily also need to switch the CRRT monitor. In this situation, a customer would not only face the barriers to switching identified in this paragraph, but such decision would also constitute a long-term investment decision by the customer given the lifetime of machines of seven years or more. These factors therefore seem to act as major deterrents in situations where customers do not have a need to purchase a new CRRT monitor as their currently available monitors would still be sufficient to meet the demand by a hospital's intensive care unit(s).
503. Moreover, a cost-benefit analysis provides fewer incentives for CRRT customers to switch monitors / systems than is the case for HD customers. First, re-training on a new CRRT monitor of all or a great part of intensive care nurses is crucial even though CRRT is not frequently administered by them. According to Baxter, only an estimated [...] % of patients in the intensive care unit require CRRT treatment. This is why intensive care nurses only occasionally administer this therapy. However, when a patient suffers from acute kidney injury, s/he will require immediate and intensive supportive treatment until their kidney function recovers.²¹³ Therefore, in any of the several daily shifts in intensive care units, nurses must be trained and familiar with the CRRT monitor (even if s/he does not use it frequently). In addition, these nurses must be trained to operate all other (non-dialysis) machines placed in the intensive care unit such as external pacemakers, equipment for the constant monitoring of bodily functions etc.²¹⁴ Since the available time for nurses to be retrained on any of those machines used in intensive care units (dialysis or non-dialysis) is limited, this fact would also restrict the switching to new CRRT monitors.
504. Second, the benefits of switching are less important from the perspective of an intensive care unit than from the perspective of a HD clinic or centre. This is because CRRT monitors and consumables are only one of many cost items in intensive care units.²¹⁵ Also, the number of monitors in CRRT is much lower than in HD. According to Baxter, a (HD) dialysis unit has approximately [...] HD machines on average in the EEA, whereas the average number of CRRT machines in an intensive care unit is approximately [...].

²¹² See replies to question 15 to Q3 – Questionnaire to CRRT customers and paragraph 36 of this decision.

²¹³ According to Baxter, the mortality rate of patients suffering from AKI and requiring RRT is high and may exceed 50%.

²¹⁴ See Form CO, paragraph 2231.

²¹⁵ According to Baxter, CRRT equipment may sometimes be tendered together with other equipment used in intensive care units, but not usually in combination with other RRT products.

505. In Ireland and the United Kingdom, customers would no longer be able to switch to an alternative source of supply given that there is no other competitor present in those markets post-Transaction.

d. Conclusion

506. For the above reasons, the Commission concludes that customers have limited possibilities of switching suppliers. In particular on the CRRT systems market and on the market for CRRT monitors and sets, customers face a considerable level of switching costs and time especially if compared to the benefits of switching supplier that appear to be more limited for intensive care units than for (HD) customers. Therefore, CRRT customers are likely vulnerable to price increases, in particular if they are not willing or able to invest into a new monitor to add to their existing inventory of CRRT monitor(s). Moreover, as explained in detail in section IV.B.1, in all possible product markets, there are few alternative suppliers left post-Transaction to which customers could switch. In many Group 1 markets, there would be only Fresenius left to compete.

4. **Entry and expansion – Significant barriers to entry and expansion**

a. The View of the Notifying Party

507. The Notifying Party submits that there are no barriers to enter the CRRT markets.

508. As regards recent entrants into CRRT, Asahi Kasei Medical would have a relatively new CRRT monitor with which it would have recently entered the German market through distributor agreements. The Parties expect Asahi to continue expanding its CRRT business in the EEA in the near future.

509. Moreover, the Notifying Party submits that there are no country-specific barriers to expansion that suppliers of CRRT products would face. In countries where only Fresenius would be active, those suppliers that already offer CRRT products in other EEA states (such as [...] or [...]) and that would already supply other medical devices (for instance in HD) would also represent a constraint against the Parties raising prices post-Transaction, as they could easily expand their CRRT offering into this country.²¹⁶ The Notifying Party submits that investment into the direct sales force would be modest. Otherwise, expansion could take place from neighbouring countries in which a supplier has a presence. For instance, [...] and [...] (currently a distributor of CRRT catheters and CRRT fluids) could easily expand their CRRT activities from the [...] to [...] given the minimal presence that would be needed on the ground for such a move (many aspects, such as customer service, being easily manageable at a distance).²¹⁷

²¹⁶ The Parties submit that an example would be [...] in [...]: [...] would have a solid presence and track record in [...] in respect of HD and in other medical areas. It would therefore have the infrastructure necessary to expand easily and quickly so as to also sell CRRT products in [...] were it to perceive opportunities to do so.

²¹⁷ The Parties also submit [...] as another example. [...] would have expanded in the HD market from the United Kingdom into Ireland availing of support from its [...] team to facilitate rapid and successful expansion. There would be no product-specific barriers that would prevent [...] from adopting a similar approach for CRRT. [...] would also actively look into the United Kingdom CRRT market(s). Moreover, the Notifying Party submits that [...] is likely to expand its activities into CRRT both in Ireland and the United Kingdom in the near future. As noted in paragraph 449, the Parties would have a [...] on the CRRT system market in Ireland and [...] in the United Kingdom post-Transaction.

Alternatively, expansion could be facilitated through the engagement of a local distributor of which there would be generally a number of suitable ones in each Group 1 country.

510. Finally, CRRT suppliers of some components could expand their offering to other CRRT components. B. Braun would be an example for such portfolio extension as it would have entered the CRRT market at EEA level by offering CRRT fluids and subsequently expanded its offering by adding a CRRT monitor and disposables.²¹⁸

b. Results of the market investigation

511. First, respondents to the Commission's market investigation consider that R&D, IP rights, brand loyalty of customers, economy of scale, the need for, and length of, regulatory approvals of products, and the need for a local and qualified sales force all represent significant barriers to new entry.²¹⁹ There is some variation according to the relevant component segment/market. As regards monitors, most competitors and distributors consistently note that barriers for all of the aforementioned parameters are high. Brand loyalty appears to be slightly less high a barrier for other disposables or fluids (although results are inconclusive as to the latter). Results for the need for a local presence to sell components such as bloodlines, dialysers, and other disposables are more varied as well but barriers to entry appear to be significant²²⁰.
512. Furthermore, the market investigation confirmed that regulatory approval appears to be most demanding for fluids as marketing authorisation under pharmaceutical legislation is needed for CRRT replacement fluids (not dialysates) rather than obtaining a CE mark under the medical device directive. Depending on a company's starting point for sterile fluid production, the process for pharmaceutical approval can take around two years or even longer.²²¹
513. Second, as for recent (in the last three years) product entry into the market for any CRRT product, most competitors and distributors are not aware of any company newly entering the market.²²² Some respondents point to NxStage's System One device that would be marketed for HHD therapy as well as CRRT. However, NxStage itself only refers to itself as entering the EEA market for HHD,²²³ and a Dutch distributor selling the NxStage monitor notes that in any event, the monitor is not yet accepted on

²¹⁸ Neither Gambro nor Baxter would have any concrete intelligence as regards a specific timeline for B. Braun's entry into the CRRT market at EEA level. However, Gambro believes that B. Braun entered the CRRT market in several countries in the EEA through the offering of CRRT fluids and subsequently expanded its offering into other product segments.

²¹⁹ See responses to question 51 of Q1 - Questionnaire to Competitors and responses to question 41 of Q4 – Questionnaire to Distributors.

²²⁰ Respondents were asked whether each parameter constitutes a low, medium, or high barrier to entry. Replies indicate "medium" on average.

²²¹ See responses to question 54 of Q1 - Questionnaire to Competitors and responses to question 43 of Q4 – Questionnaire to Distributors.

²²² See responses to question 58 of Q1 - Questionnaire to Competitors and responses to question 46 of Q4 – Questionnaire to Distributors.

²²³ See response by NxStage to questions 56.1 and 58.1 of Q1 - Questionnaire to Competitors.

the market.²²⁴ As regards the Italian company Bellco, it entered the CRRT market more than three years ago.

514. With respect to expected new entry into CRRT, a majority of competitors and distributors expressing a view do not expect new entry.²²⁵ A minority of competitors such as B. Braun and Nikkiso responded that new product entry into CRRT could come from Chinese or Asian suppliers but did not specify this any further, or whether this would likely concern individual CRRT components or CRRT system entry.
515. Third, as to the barriers to geographic expansion by existing CRRT competitors into a new EEA country, some competitors suggest that creating a direct local sales organisation would take quite long.²²⁶ Nipro estimates that *"from planning until first commercial success it would take up to three years. There are all the administrative hurdles of registering a new company as well as hiring local experienced staff (small pool of candidates). The main delay would be to gain the initial customers and gain a foot on the ground. Another significant delay would be a tender driven market. These offer an interrupted sales cycle that only offers limited number of sales opportunities."* Another CRRT competitor believes geographic expansion through the creation of an own sales force would take even longer than three years.
516. Moreover, finding, contracting and training a suitable local distributor by a CRRT supplier would take from one to three years, depending on the country.²²⁷ For instance, B. Braun responded that it takes *"2-3 years to screen/analyze the market and potential cooperation partners, negotiate the set-up, train the people, apply for local authorizations, etc."*. Covidien estimated 12-24 months. Moreover, the vast majority of responding distributors state that they would not be able to start selling/ distributing CRRT products in another EEA country than the one(s) in which they are currently present. Moreover, an Irish distributor replied that not only the logistical setting up and establishing a profile of credibility (and quality of the products) acts a barrier to entry but also the age profile of the monitors installed in the market. If monitors are still quite "young" – as they are in the Irish market – the relative lack of demand for new monitors acts as a barrier to entry to the whole CRRT market.²²⁸
517. Fourth, as regards the strategy of portfolio extension, the market investigation revealed that such a strategy is unlikely to work, at least with respect to customers preferring to source all components from one supplier. NxStage, a company active in CRRT in the United States and having recently entered the HHD segment in some EEA countries, points out that *"[a] common model is that in the [CRRT] tender companies are required to offer a broad range of products. If a company is not able to offer for example fluids, it will not be able to participate in the tender and this is considered an*

²²⁴ See response by [...] to question 46 of Q4 – Questionnaire to Distributors.

²²⁵ See responses to question 59 of Q1 - Questionnaire to Competitors and responses to question 47 of Q4 – Questionnaire to Distributors.

²²⁶ See for instance the response by Nipro Europe to question 61 of Q1 - Questionnaire to Competitors.

²²⁷ See responses to question 61 of Q1 - Questionnaire to Competitors and responses to question 49 of Q4 – Questionnaire to Distributors.

²²⁸ See reply by [...] to question 48 of Q4 – Questionnaire to Distributors.

important disadvantage, especially that tenders for PPT contracts are on long term."²²⁹

c. The Commission's assessment

518. In light of the market investigation, the Commission considers that barriers to new (product) entry into the CRRT market(s) appear to be significant.
519. As regards suppliers that already offer CRRT products in other EEA countries, it appears, firstly, that successful expansion into other countries may take considerable time exceeding the threshold of two years that is typically considered as sufficiently timely entry.²³⁰ There are considerable challenges to build up a sales organisation or, alternatively, find, contract and train a suitable distributor with prior experience in the RRT sector. Second, the more or less sporadic sales opportunities (for instance through tenders) in a given country would appear to be capable of depriving a new entrant from getting rapid traction in a market, casting doubt upon the sufficient scope and magnitude of entry.
520. The market investigation also confirmed that geographic entry/ expansion into a new EEA country can generally not take place through using the (direct or indirect) sales force and/or technical assistance staff present in a neighbouring country due to the need for a local presence.
521. The Commission has also indications that credible entry is unlikely to happen if a competitor (or its distributor) cannot offer the full range of CRRT components to the extent that the national CRRT markets are systems market in which monitors drive the sales of consumables. As pointed out in paragraph 38 above, there is a strong customer preference for sourcing all CRRT components from one supplier as a package, which appears to make entry more difficult for suppliers who do not have a broad range of CRRT products.

d. Conclusion

522. In the light of the above, the Commission has serious doubts as to the likelihood, timeliness or sufficiency of potential entry into the CRRT markets of concern.

5. ***Countervailing buyer power***

a. The View of the Notifying Party

523. The Notifying Party submits that customers across the EEA are sophisticated, strong, and can exercise countervailing buyer power and price pressure. Customers are hospitals, both public and private. These customers would increasingly team up in purchasing organisations or consortia to condense and enhance their purchasing power and thus obtain better prices from their CRRT suppliers.

²²⁹ See agreed minutes of the conference call with NxStage on 24.5.2013.

²³⁰ See paragraph 74 of the Horizontal Merger Guidelines.

b. Results of the market investigation

524. The market investigation revealed that a majority of competitors believe that CRRT customers can exercise buyer power.²³¹
525. Furthermore, it appears that while the grouping of demand differs from one country to another, the majority of responding CRRT customers does not group purchases of CRRT products.²³²

c. The Commission's assessment

526. The Commission observes that while the value of customers' CRRT contracts vary significantly from one customer to another,²³³ the commercial significance of the Parties' customers, even large ones, to Baxter or Gambro respectively appears to be limited. Whereas a few top customers represent a larger share of Baxter's total sales in a given national market (this is less so for Gambro), most are more modest.²³⁴ Out of all top CRRT customers in the EEA provided by Gambro, the median value of the share of a customer out of Gambro's sales in the respective national market is [0-5]% whereas the average value is [5-10]%.²³⁵ Out of all top CRRT customers in the EEA provided by Baxter, the median value is [5-10]% whereas the average value is [5-10]%.²³⁶
527. Moreover, even if a few customers (such as regional consortia or even large hospitals) were to enjoy buyer power, they could not protect smaller customers against hypothetical price increases arising from the Transaction. However, as stated in the Horizontal Merger Guidelines, "*[c]ountervailing buyer power cannot be found to sufficiently off-set potential adverse effects of a merger if it only ensures that a particular segment of customers with particular bargaining strength is shielded from significantly higher prices or deteriorated conditions after the merger.*"²³⁷
528. Finally, the Commission notes that, even if (some) customers had so far been able to exercise a degree of buyer power, the ability to continue doing so by switching to alternative suppliers would be highly restricted post-Transaction, given that there remain few alternative sources as noted in the conclusion to the section on the possibilities to switch suppliers in paragraph 506 above. This is even more so for those customers who currently dual-source or multi-source CRRT products.

d. Conclusion

529. For the above reasons, the Commission does not consider that there is sufficient buyer power to offset the adverse effects of the Transaction.

²³¹ See responses to question 65 of Q1 - Questionnaire to Competitors.

²³² See replies to question 6 of Q3 – Questionnaire to CRRT Customers.

²³³ See Annex CRRT 8.6.1 and Annex CRRT 8.6.2 to the Form CO.

²³⁴ See Annex CRRT 8.6.1 and Annex CRRT 8.6.2 to the Form CO.

²³⁵ See Annex CRRT 8.6.2 to the Form CO.

²³⁶ See Annex CRRT 8.6.1. to the Form CO.

²³⁷ Paragraph 67.

6. Conclusion on serious doubts in the CRRT market(s)

530. For the above reasons, the Transaction raises serious doubts with respect to its compatibility with the internal market with respect to CRRT systems at EEA level and in the following Group 1 countries: Austria, Belgium/Luxembourg, Denmark, France, Greece, Ireland, the Netherlands, Norway, Spain, Sweden and the United Kingdom. The existence or not of serious doubts in the Czech Republic, Germany, Italy and Poland can be left open for the purposes of the present decision as the remedy submitted by Baxter has a worldwide scope and would also address any competitive concerns in these countries.
531. If the relevant product market were to be component markets (CRRT monitors and sets; fluids; other disposables), the Transaction raises serious doubts with respect to its compatibility with the internal market in all of these possible component markets at EEA level.
532. With respect to the possible national markets, the Transaction raises serious doubts in the possible market for CRRT monitors and sets in Austria, Belgium/Luxembourg, Denmark, France, Greece, Ireland, the Netherlands, Norway, Poland, Spain, Sweden and the United Kingdom. The existence or not of serious doubts in the Czech Republic, Germany and Italy can be left open for the purposes of the present decision as the remedy submitted by Baxter has a worldwide scope and would also address any competitive concerns in these countries.
533. As for the possible market for CRRT fluids, the Transaction raises serious doubts in Austria, Belgium/Luxembourg, Denmark, Germany, Greece, Ireland, Italy, Norway, Romania, Spain, Sweden and the United Kingdom. The existence or not of serious doubts in Poland and Slovakia can be left open for the purposes of the present decision as the remedy submitted by Baxter has a worldwide scope and would also address any competitive concerns in these countries.
534. As for the possible market for CRRT other disposables, the Transaction raises serious doubts in Belgium/Luxembourg, Denmark, Ireland, Spain and the United Kingdom. The existence or not of serious doubts in Austria, Germany, Greece, the Netherlands, Norway, and Sweden can be left open for the purposes of the present decision as the remedy submitted by Baxter has a worldwide scope and would also address any competitive concerns in these countries.

C. Horizontal overlaps in relation to adjacent treatments, products and services

1. Water treatment systems

535. The Notifying Party submits that the Transaction does not raise concerns on the market of water treatment systems whether on a national or EEA-wide basis as Baxter's activities are [...]. This is partly because unlike Gambro, Baxter does not [...]. In such situations, Baxter [*Details on Baxter's water treatment system activities*] and provides it to the customer together with its HD products. Baxter's activities in water treatment are largely focused on single-patient water treatment systems. In contrast, Gambro as a manufacturer of water treatment systems, also supplies large-scale systems for HD treatment units.

Table 56: Market shares in the EEA for water treatment systems (in value)

Competitor	Share of sales		
	2010	2011	2012
Baxter	[0-5]%	[0-5]%	[0-5]%
Gambro	[30-40]%	[40-50]%	[30-40]%
Combined	[30-40]%	[40-50]%	[40-50]%
Culligan	[5-10]%	[0-5]%	[0-5]%
DWA	[10-20]%	[10-20]%	[10-20]%
Fresenius	[10-20]%	[10-20]%	[10-20]%
Lauer	[10-20]%	[10-20]%	[10-20]%
Purite	[0-5]%	[0-5]%	[0-5]%
Others	[10-20]%	[10-20]%	[5-10]%
Total	100%	100%	100%

Source: Parties' estimates

536. In 2012, Baxter's EEA sales of water treatment systems amounted to approximately EUR [...]. As such, the increment to Gambro's market share of [30-40]% brought about by the Transaction is negligible at [0-5]%. There are several competitors on the water treatment system market, in particular Fresenius ([10-20]%), but also DWA ([10-20]%), Lauer ([10-20]%), Culligan ([0-5]%) and Purite ([0-5]%). RRT suppliers that do not manufacture water systems are able to team up with suppliers of water treatment solutions, e.g., Bellco with DWA²³⁸, Nipro with Phoenix²³⁹ and B. Braun with Lauer²⁴⁰.

537. Given Baxter's limited sales of water treatment systems, the increment in market share resulting from the Transaction is also relatively modest if national markets are considered. In 2012, Baxter recorded sales in seven Member States: Denmark, Finland, Ireland, the Netherlands, Spain, Sweden and the United Kingdom as shown in the following table.

Table 57: Market shares for water treatment systems (in value)

	Baxter	Gambro	Comb.	DWA	FMC	Culligan	Lauer	Purite	Elga	Ovivo	PWS	Other	Total
Denmark	[0-5]%	[60-70]%	[60-70]%	[5-10]%	[20-30]%							[0-5]%	100%
Finland	[0-5]%	[80-90]%	[80-90]%			[10-20]%							100%
Ireland	[10-20]%	[10-20]%	[20-30]%					[40-50]%	[20-30]%				100%
Netherlands	[0-5]%	[30-40]%	[30-40]%	[0-5]%	[0-5]%		[0-5]%			[40-50]%	[10-20]%	[0-5]%	100%
Spain	[0-5]%	[30-40]%	[30-40]%	[0-5]%	[20-30]%	[0-5]%	[5-10]%					[20-30]%	100%
Sweden	[5-10]%	[60-70]%	[70-80]%	[0-5]%	[5-10]%		[10-20]%						100%
United Kingdom	[0-5]%	[40-50]%	[40-50]%	[0-5]%	[0-5]%		[0-5]%	[30-40]%	[10-20]%				100%

Source: Parties' estimates

238 See www.bellco.net/products-and-therapies/chronic-line/10-en_c-3-19/default.aspx

239 See www.nipro-europe.com/products/product-range/renal-care/water-treatment-systems/

240 See www.B.Braun.de/cps/rde/xchg/B.Braun-de/hs.xsl/news_15616.html

538. With the exception of Ireland, the increment in market share is less than [5-10]% in all the aforementioned Member States meaning that the Transaction is unlikely to result in a significant change to the market structure.
539. In Denmark, Baxter's sales in 2012 amounted to EUR [...] which corresponds to a market share of [0-5]%. The majority of its revenues relate to rental revenue of single-patient water treatment systems including [...] new systems placed in 2012. Baxter [*Details on Baxter's sales*]. In contrast, the majority of Gambro's turnover was derived from the sale of large central water treatment systems, water rooms and technical services while only a minority ([10-20]%) related to the sale of single-patient water treatment systems and disposables. This indicates that the Parties are not close competitors in Denmark as regards the supply of water treatment systems. In addition, the merged entity will continue to face competition from other suppliers such as FMC ([20-30]%) and DWA ([5-10]%).
540. In Finland, although the merged entity would have strong position on the market with a share of [80-90]%, the increment resulting from the Transaction is limited at [0-5]%. In addition, the Parties are not particularly close competitors as the [...] of Gambro's revenues ([...]) relate to the provision of large water treatment systems and technical services whereas Baxter's focus is the supply of single-patient water treatment systems of which it sold [...] in 2012.
541. In Ireland, although the increment arising from the Transaction is not negligible at [10-20]%, the merged entity's market share would only amount to [20-30]% and it would continue to face competition from other suppliers such as Purite, the market leader with [40-50]% market share and Elga ([20-30]%).
542. In the Netherlands, the merged entity's market share would be [30-40]% with an increment of [0-5]% from Baxter. In 2012, however, Baxter's sales in the Netherlands were limited to [*Details on Baxter's sales*]. Baxter assumed the ongoing obligation to provide such services when it took over Nikkiso's business from Cablon in 2011. Baxter itself, however, [*Details on Baxter's sales*]. Even if the Parties were to be considered as competing on the market for the supply of water treatment systems in the Netherlands, they would continue to face competition post-Transaction from a number of other suppliers such as Ovivo ([40-50]%), PWA ([10-20%]) and Lauer ([0-5]%).
543. In Spain, the merged entity's market share would be [30-40]% with an increment of [0-5]% from Baxter. Baxter's sales were limited to the supply of single-patient water treatment systems, an area where Gambro only obtained [0-5]% of its turnover. This illustrates that the Parties are not close competitors on the Spanish market for the supply of water treatment systems. In any event, the merged entity will continue to face competition from a number of other suppliers including FMC ([20-30%]), Lauer ([5-10]%) and DWA ([0-5]%).
544. In Sweden, the merged entity's market share would be [70-80]% with an increment of [5-10]% from Baxter. Given the limited increment added by Baxter, its removal as an independent reseller of HD water treatment systems is not expected to have a significant impact on competition. In any event, the merged entity will continue to face competition from other suppliers post-Transaction such as Lauer ([10-20]%), FMC ([5-10]%) and DWA ([0-5]%).

545. In the United Kingdom, the merged entity's market share would be [40-50]% with an increment of [0-5]% from Baxter. Given the limited increment added by Baxter, its removal as an independent reseller of HD water treatment systems is not expected to have a significant impact on competition. In any event, the merged entity will continue to face competition from other suppliers post-Transaction such as Purite ([30-40]%), Elga ([10-20]%) and FMC ([0-5]%).
546. The market investigation confirmed that the proposed concentration between Baxter and Gambro does not raise competitive concerns on the water treatment systems market. The large majority of customers do not expect significant effects either in the EEA or in any country specifically.²⁴¹
547. In view of the above, the proposed transaction does not raise serious doubts as to its compatibility with the internal market with regard to water treatment systems either at a national or EEA-wide level.

2. Therapeutic plasma exchange

548. The Parties submit that TPE is an ancillary business activity for which no data is publicly available. As such, the Parties do not systematically keep track of their market shares or their competitors' activities. That said, they estimate that after the Transaction, the merged entity would have a market share in the EEA of [20-30]% with an increment of [0-5]% coming from Baxter's sales. In view of the merged entity's market position, the modest increment in market share and the presence of other competitors including Fresenius, Asahi, Bellco and Haemonetics, the Transaction is not expected to raise concerns at the level of the EEA.
549. If national markets are considered, the Parties' activities would overlap in nine Member States where Baxter has TPE sales (Austria, the Czech Republic, France, Germany, Ireland, Italy, Poland, Spain and the United Kingdom). As noted above, given the relatively limited revenues derived from their TPE sales in comparison to their overall activities, the Parties do not systematically track their shares or their competitors' activities in TPE. At the Commission's request, however, they have provided additional information regarding their respective positions in three Member States (France, Germany and the United Kingdom) which together account for [70-80]% of their TPE sales.²⁴² In France, the Parties' estimate Gambro's market share to be in the region of [20-30]% and the increment from Baxter to be [0-5]% meaning that the Transaction is not likely to raise concerns. A similar conclusion can also be drawn with respect to Germany where the merged entity would have a market share of [10-20]% with an increment of less than [0-5]% and the United Kingdom where the figures are [10-20]% and less than [10-20]% respectively²⁴³.

²⁴¹ See replies to question no 62.3 to Q2 – Questionnaire to customers (HD) and to question no 50.3 to Q3 – Questionnaire to customers (CRRT).

²⁴² The market share ranges provided are primarily based on Gambro's estimates of the total number of TPE treatments provided in each of these Member States. According to the Parties, this proxy, in combination with Gambro's own revenues, allows for a rough estimate of the total market size (based on an estimate of the total number of treatments) and of Baxter's shares.

²⁴³ For all other Member States where the Parties have overlapping sales but where they are unable to estimate the total market size, their combined sales are relatively limited (always below EUR [...]) and the increment even smaller (between less than EUR [...] and lightly above EUR [...]).

550. In the market investigation, whilst the majority of respondents either did not express an opinion regarding the effects of the Transaction on the TPE market or confirmed that it would have no impact, a limited number of respondents considered that it could lead to higher prices. However, as the sale of the TPE filters sourced by Baxter from [...] forms part of Baxter's CRRT business that will be divested, the overlap resulting from the Transaction will be removed. It is therefore concluded that the Transaction does not raise serious doubts as to its compatibility with the internal market with regard to the market for TPE either on a national or EEA-wide basis.

D. Conglomerate effects

551. The Guidelines on the assessment of non-horizontal mergers under the Council Regulation on the control of concentrations between undertakings ("the Non-Horizontal Merger Guidelines")²⁴⁴, state that the combination of products in related markets may confer on the merged entity the ability and incentive to leverage a strong market position from one market to another by means of tying or bundling or other exclusionary practices. In assessing the likelihood of such a scenario, the Commission examines, first, whether the merged firm would have the ability to foreclose its rivals, second, whether it would have the economic incentive to do so and third, whether a foreclosure strategy would have a significant detrimental effect on competition²⁴⁵.

552. In assessing the ability of the merged firm to foreclose its rivals, it must have a significant degree of market power in one of the markets concerned²⁴⁶. In the present case, Baxter, though not Gambro, is active in the supply of PD equipment where it has a market share of [70-80]% at EEA-level. The Commission therefore examined whether the merged entity would be able to leverage its strong position in PD to the HD and/or CRRT on the one hand or between HD and CRRT on the other hand by means of tying or bundling or other exclusionary practices.

1. The View of the Notifying Party

553. The Notifying Party submits that Transaction will not confer on the new entity the ability or the incentive to leverage Baxter's market position in PD into HD or CRRT. As regards the ability to foreclose, the Notifying Party argues that sourcing pattern in the EEA exclude the possibility of commercial bundling or tying as customers generally source PD in different tenders to CRRT or HD products. Occasionally tenders may include both PD and HD, however they are part of separate lots and suppliers have to compete for each of them. CRRT, as a therapy administered in intensive care units, is generally part of separate tenders.

554. In addition, according to the Notifying Party, price is one important selection criterion among other criterion such as quality, performance, and physicians' preferences. Hospitals organise tenders in a manner that best suits their need, therefore they would be able to adapt the procurement process in a way to obtain the best possible offer. As to competitors, according to the Notifying Party, Fresenius has a similar product portfolio and would be able to respond to multi-product discounts offers that may be

²⁴⁴ OJ C 265, 18.10.2008, p. 6.

²⁴⁵ Non-Horizontal Merger Guidelines, paragraph 93 and 94.

²⁴⁶ Non-Horizontal Merger Guidelines, paragraph 99.

proposed by the new entity. Lastly, the Notifying Party explains that both Baxter and Gambro could already have offered packages of PD and HD or CRRT but have not done so in the past²⁴⁷.

2. Assessment

555. The market investigation has indicated that the merged entity would not have the ability to leverage its position in PD in order to foreclose rivals in HD. In this respect, a clear majority of HD customers confirmed that if the merged entity were to attempt such a strategy, they would be willing and able to switch to alternative suppliers of HD products.^{248, 249}
556. In a similar fashion, the market investigation has indicated that the merged entity would not have the ability to leverage its position in PD in order to foreclose rivals in CRRT as the products in each category are typically purchased by different customers and / or through distinct procurement processes.²⁵⁰ This element would also militate against the merged entity's ability to leverage its position in HD to CRRT (or vice versa, notwithstanding the fact that the Transaction will not add to the merged entity's market position in CRRT in light of the divestment of Baxter's CRRT business described below in Section V).
557. In addition, the tendering data submitted by the Notifying Party, showed when a customer buys PD, HD and CRRT that tenders are organised separately or at least the products are grouped in different lots. Therefore, this would significantly reduce the possibility for the merged entity to quote a price for products in one lot on the condition of obtaining a contract for another lot. Customers have also confirmed the Notifying Party's argument that they would adapt their purchasing strategy in a way to avoid bundled offers.²⁵¹
558. Finally, the market investigation has confirmed that technical tying in the markets at issue can be excluded as PD, HD and CRRT are different products with limited therapeutic complementarity.²⁵²

3. Conclusion

559. Taking into account the elements outlined above which clearly demonstrate the merged entity's limited ability to engage in a foreclosure strategy, there is no need in the present case to assess whether it would have the incentive to do so and the ultimate effect on competition. In conclusion, it is therefore unlikely that the Transaction will lead to conglomerate effects.

²⁴⁷ Gambro was historically present in PD, HD and CRRT but sold its PD business to Fresenius in 2010 after a decision to focus on extracorporeal RRT.

²⁴⁸ See replies to questions no 56, 57 and 58 to Q2 – Questionnaire to customers (HD).

²⁴⁹ See replies to questions no 57.1, 58.1 to Q2 – Questionnaire to customers (HD).

²⁵⁰ See replies to questions no 13 and 17 to Q2 – Questionnaire to customers (HD).

²⁵¹ See replies to question no 46 to Q3 – Questionnaire to customers (CRRT).

²⁵² See replies to questions no 14, 15 and 16 to Q2 – Questionnaire to customers (HD). See replies to questions no 11 and 12 to Q3 – Questionnaire customers (CRRT).

V. PROPOSED REMEDIES

A. Initial Commitments submitted on 1 July 2013

560. In order to address the serious doubts identified by the Commission in relation to the CRRT market and to render the concentration compatible with the internal market, the Parties have modified the notified concentration by entering into the commitments annexed to this Decision.
561. The business to be divested ("Divestment Business") comprises Baxter's worldwide CRRT business. This business is not included in a single business subsidiary but spread over several entities within the Baxter group, which are also involved in other renal replacement therapies. The remedy package includes production assets, supply agreements, employees, intellectual property ("IP") rights, product and marketing authorizations, and customer contracts and records.
562. In the initial set of commitments submitted on 1 July 2013, the Notifying Party committed itself to:
- build a new CRRT fluid production line, based on its proprietary design, at either: (a) an existing [...] CRRT fluid facility in [...] that would be divested (option 1); or (b) at an existing or new facility of the purchaser's choosing in Europe or elsewhere (option 2); or (c) at [...] existing fluid factory either in [...] or [...] (option 3). During the transitional period of [...] that could potentially be required for the new line to become fully operational, Baxter would supply the purchaser with CRRT fluids on a cost-plus basis;
 - transfer an irrevocable, perpetual, royalty free license of IP rights (including know-how) regarding CRRT [...];
 - supply the film required for manufacturing Accusol fluid bags;
 - conclude an engineering support services agreement for ongoing support on a cost-plus basis of the Baxter-proprietary ClearFlex production line operated by the Purchaser;
 - transfer approximately [...] employees worldwide, including (a) technical support and maintenance personnel, (b) R&D/regulatory personnel, and (c) marketing and sales staff.
 - transfer to the purchaser its current supply agreements with manufacturers of monitors, bloodlines, dialysers and catheters.
563. The Commission market tested the proposed commitments. The feedback received from respondents to the market test as to the suitability of the remedy to remove the serious doubts identified by the Commission was broadly positive but a number of respondents, however, raised certain issues relating to the proposed commitments.
564. Firstly, a number of respondents indicated that the viability of the commitments depended strongly on the identity and characteristics of the purchaser of the

Divestment Business²⁵³. The respondents underlined that expertise in the field, ability to innovate, as well as an efficient logistical organisation and a good, locally based sales network are important for the viability of the business.

565. Second, some respondents voiced concerns regarding the impact of the location of the fluid production line on the viability or the independence of the Divestment Business. In the case of option 1, a majority of distributors and competitors considered that a fluid producer with production facilities located outside Europe would find it difficult to compete on the EEA market due to the high cost of transporting five-litre bags of fluid into the EEA.²⁵⁴ Other drawbacks highlighted by respondents included the need for additional registrations, increased delivery time and the disincentive for customers to switch to a non-EEA manufacturer in light of the high value placed by customers on security of supply²⁵⁵. In the case of option 3, a majority of competitors stressed that the physical segregation of Baxter's on-going activities from the Purchaser's production line would be very difficult to effect and operate in practice and would jeopardise the independence of the Divestment Business.²⁵⁶
566. Third, a number of respondents expressed concern as to whether the personnel to be transferred were sufficient both in terms of number and function²⁵⁷.
567. Finally, as regards the supply agreements for CRRT components not manufactured by Baxter, several respondents with experience in the CRRT field highlighted the risk to the viability of the Divestment Business posed by not having upfront the consent of the suppliers to have their agreement with Baxter transferred to the purchaser²⁵⁸.

B. Final Commitments submitted on 12 July 2013

568. In light of the issues raised by respondents to the Commission's market test, the Notifying Party made modifications to the proposed commitments and submitted a revised version on 12 July 2013 (attached to this Decision).

²⁵³ See responses to question no 4 of market test questionnaire Q1 - Questionnaire to CRRT customers, See responses to question no 1 of market test questionnaire Q2 - Questionnaire to competitors, See responses to question no 1 of market test questionnaire Q3 - Questionnaire to distributors.

²⁵⁴ See responses to question no 6 of market test questionnaire Q1- Questionnaire to CRRT customers, See responses to question no 6 of market test questionnaire Q2 - Questionnaire to competitors, See responses to question no 6 of market test questionnaire Q3 - Questionnaire to distributors.

²⁵⁵ See references in footnote 254 and responses to question no 4.2 of market test questionnaire Q2 - Questionnaire to competitors.

²⁵⁶ See responses to question no 9 of market test questionnaire Q2 - Questionnaire to competitors.

²⁵⁷ See responses to question no 7.1 of market test questionnaire Q1 - Questionnaire to CRRT customers, See responses to question no 11 of market test questionnaire Q2 - Questionnaire to competitors, See responses to question no 8 of market test questionnaire Q3 - Questionnaire to distributors.

²⁵⁸ See responses to question no 1 of market test questionnaire Q3* - Questionnaire to competitors, in particular Dirinco's and Nipro's responses. See also Fresenius' response to question no 1 of market test questionnaire Q2 - Questionnaire to competitors and Medites Pharma's response to question no 18 of market test questionnaire Q2 - Questionnaire to competitors: "Purchases generally takes place as a whole, i.e. monitors, bloodlines, solutions."

* *should read: Q2*

569. As noted above in paragraph 561, the Divestment Business is not a stand-alone legal entity. It is currently integrated into Baxter's renal therapy products business which also comprises PD and HD activities where the Commission did not find serious doubts. As a consequence a carve-out of the Divestment Business will need to be achieved prior to its sale to a suitable purchaser. In addition, the Divestment Business is currently supplied by a number of third party manufacturers with which the purchaser will have to conclude appropriate arrangements.
570. In such carve-out operations, it is of utmost importance for the viability of the transferred business that it has access to all inputs and other resources necessary to carry out its operation in full independence. The Commission can only accept commitments which require the carve-out of a business if it can be certain that, when the business is transferred to the purchaser, the risks for the viability and the competitiveness caused by the carve-out will be reduced to a minimum. In such cases, only the proposal of an up-front buyer will enable the Commission to conclude with the requisite degree of certainty that the business will be effectively divested to a suitable purchaser²⁵⁹.
571. To this end, the commitments now include an up-front buyer clause and specific purchaser criteria. Under the up-front buyer clause²⁶⁰, the Notifying Party cannot close the proposed concentration with Gambro before it has completed the sale of the Divestment Business to a suitable Purchaser. In particular, it is now specified that the purchaser must have experience in renal replacement therapy and have an existing local presence for sales, marketing and technical support either directly or indirectly via distributors in several EEA countries.²⁶¹
572. Second, as regards the CRRT fluid production line, the revised commitments now only provide for an obligation of the Notifying Party to build the production line at an existing or a new facility of the purchaser's choosing in the EEA or Switzerland. This production line will mirror the capacity of that of the production line on which Accusol is produced by Baxter in [...]. On this basis, the Divestment Business will have sufficient CRRT fluid capacity to meet its demands. The Notifying Party also commits, at the option of the purchaser, to procure and/or install all the additional infrastructure needed for the production process (such as mixing, sterilisation and packaging) unless the manufacturing location identified by that purchaser is already equipped with such infrastructure or is planned to be equipped with such infrastructure within a number of years. The Notifying Party commits to help the Purchaser set up additional infrastructure (mixing, sterilization, and packaging) as needed. Therefore, the commitments now address the concerns regarding viability and independence raised by respondents to the market investigation in relation to the provision of CRRT fluid production assets.
573. Third, as regards the number and function of employees transferred, the total staff to be transferred now amounts to [...] employees instead of [...] as initially proposed and are distributed as follows between the different functions: [...] sales and marketing,

²⁵⁹ Commission notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004, OJ 267, 22.10.2008, p. 1, paragraph 53.

²⁶⁰ Clause 1 of the Commitments dated 12 July 2013.

²⁶¹ Clause 14 of the Commitments dated 12 July 2013.

[...] technical support and maintenance, [...] R&D and [...] regulatory employees. Another modification consists in including technical and maintenance employees as part of the divested business. Baxter initially proposed as options to the purchaser's choice to transfer these employees (now included in the divested package) or to provide technical support and maintenance services.

574. Fourth, as regards the supply agreements between Baxter and third parties for CRRT components, the commitments now provide that the consent of the [...] third party suppliers must have been procured by the Notifying Party by the date it proposes a purchaser to the Commission.²⁶²
575. The Divestment Business according to the terms of the commitments submitted by the Notifying Party on 12 July 2013 now includes:
- a. the following main tangible assets:
 - i. a Baxter-proprietary Renal ClearFlex production line for Accusol with a capacity mirroring that of the production line on which Accusol is currently produced in [...], to be set up in an existing or new manufacturing location in the EEA or Switzerland identified by the purchaser.
 - ii. all CRRT products, parts, supplies, materials and other inventories to the extent used or held for the Divestment Business as well as the monitors placed with any customers or other user of the monitors owned by Baxter.
 - b. the following main intangible assets:
 - i. the transfer of all IP rights that are held by Baxter and of certain copyrights, used exclusively with respect to the development, manufacture and/or sale of CRRT products worldwide, and know-how. Including, patents that Baxter holds or is in the process of obtaining, targeted specifically at CRRT;
 - ii. irrevocable, perpetual, and royalty-free license for patents that were originally designed by Baxter for [...], but are formulated broad enough so that they also cover Accusol [...], for use in the CRRT field;
 - iii. a copyright license related to its CRRT business;
 - iv. production know-how for the manufacture of certain CRRT [...] and know-how for the production of CRRT [...];
 - v. documentation relating to the [...];
 - c. relevant licenses, permits and authorizations;

²⁶² See clause 15 of the Commitments dated 12 July 2013. Clause 15A provides for an alternative solution in the event that the consents are not procured by that date. Further to this clause, the Notifying Party may request an extension of the First Divestiture period to procure the relevant consents. The Notifying Party may also, in the event that one or more consents is not forthcoming, request that Baxter procures instead a supply agreement (or agreements depending on the number of outstanding consents) so as to meet the demands of the Divestment Business for the product with another supplier acceptable to the purchaser, on similar terms and conditions to those on which the divestment business is currently supplied for the same product, in line with good industry practice and in a manner which does not affect the viability and competitiveness of the divestment business after closing.

- d. supply agreements with third parties for CRRT components not manufactured by Baxter;
- e. customer contracts, list and records regarding CRRT;
- f. Key personnel, as well as personnel currently working in the Divestment Business, including (i) technical support and maintenance personnel, (ii) R&D/regulatory personnel, and (iii) marketing and sales staff. At the option of the Purchaser, sufficient technical and operation personnel for the CRRT fluid production line (based on Baxter's current operations in [...]). The R&D employees currently working in Baxter's [...], which form part of the Divestment Business, will be able to continue to work there (albeit ring-fenced from Baxter's R&D activities) for a transitional period of [...]. The R&D employees currently working in [...] which form part of the Divestment Business will also have access to the [...] during this transitional period.
- g. A contract manufacturing agreement by which the Notifying Party would supply for Accusol and Monosol fluids and lactate to the Divestment Business for a transitional period;
- h. certain transitional services by the Notifying Party to the Divestment Business pursuant to a transition services agreement as well as arrangements for the supply of certain products and services, including: an arrangement for the supply of the film required for the manufacture of Accusol bags and an arrangement for the supply of spare parts to the Divestment Business for the CRRT production line.

576. In addition, the Notifying Party has entered into related commitments regarding the separation of the divested business from the retained businesses and the preservation of the viability, marketability and competitiveness of the Divestment Business, including: the appointment of a monitoring trustee and if necessary, a divestiture trustee.

VI. ASSESSMENT OF THE PROPOSED REMEDIES

577. Under Article 6(1)(b) of the Merger Regulation, when a concentration raises serious doubts that it may lead to a significant impediment to effective competition, the Parties may undertake to modify the concentration so as to remove the serious doubts regarding its compatibility with the internal market.

578. As set out in the Commission Notice on Remedies, the commitments have to eliminate the competition concerns entirely and have to be comprehensive and effective from all points of view and must be capable of being implemented effectively within a short period of time as the conditions of competition on the market will not be maintained until the commitments have been fulfilled. In assessing whether or not the remedy will restore effective competition, the Commission considers the type, scale and scope of the remedies by reference to the structure and the particular characteristics of the market in which the competition concerns arise.

579. Divestiture commitments are the best way to eliminate competition concerns resulting from horizontal overlaps. The divested activities must consist of a viable business that, if operated by a suitable purchaser, can compete effectively with the merged entity on a lasting basis and that is divested as a going concern. Although normally the divestiture of an existing viable standalone business is required, the Commission taking into account the principle of proportionality, may also consider the divestiture of businesses which have existing strong links or are partially integrated with

businesses retained by the parties and therefore need to be 'carved out' in those respects. However, the Commission is only able to accept such commitments if it can be certain that, at least at the time when the business is transferred to the purchaser, a viable business on a standalone basis will be divested and the risks for the viability and competitiveness caused by the carve-out will thereby be reduced to a minimum.

580. The business must include all the assets which contribute to its current operation or which are necessary to ensure its viability and competitiveness and all personnel which are currently employed or which are necessary to ensure the business' viability and competitiveness. Personnel and assets which are currently shared between the business to be divested and other businesses of the parties, but which contribute to the operation of the business or which are necessary to ensure its viability and competitiveness, must also be included. Otherwise, the viability and competitiveness of the business to be divested would be endangered. Therefore, the divested business must contain the personnel providing essential functions for the business such as, for instance, group R&D staff — at least in a sufficient proportion to meet the on-going needs of the divested business.
581. The Commission considers that the remedies submitted by the parties on 12 July 2013 are sufficient to remove the serious doubts regarding the compatibility of the Transaction with the internal market. In particular, the Commission considers that the scope of the Divestment Business, which will completely remove the overlap in CRRT resulting from the concentration, is such as to provide the purchaser with all the necessary resources to successfully run the CRRT business and effectively compete in the CRRT market. The setting up of a fluid production line at a facility of the purchaser's choice in the EEA or Switzerland and the IP rights included in the divestment will enable the purchaser to takeover Baxter's current position in CRRT fluid production. The transitional contract manufacturing of CRRT fluids and the technical assistance which will cover the interim period will enable the purchaser to be able to be present in the market as of the date of transfer of the Divestment Business. In addition, the number and qualifications of the employees to be transferred appear to be sufficient for running the CRRT business.
582. The viability and competitiveness of the Divestment Business is further provided for by the upfront transfer of third party supply contracts to the purchaser. Furthermore, the specific criteria for suitability of the purchaser and the requirement for an upfront buyer in this case further reduce risks to the viability of the divestment business in this carve-out remedy.
583. In light of the above, the Commission concludes that the commitments dated 12 July 2013 entered into by the Notifying regarding the CRRT market are sufficient to remove the serious doubts as to the compatibility of the transaction with the internal market in relation to the CRRT market.

VII. CONDITIONS AND OBLIGATIONS

584. Under the first sentence of the second subparagraph of Article 6(2) of the Merger Regulation, the Commission may attach to its decision conditions and obligations intended to ensure that the undertakings concerned comply with the commitments they have entered into vis-à-vis the Commission with a view to rendering the concentration compatible with the internal market.
585. The fulfilment of the measure that gives rise to the structural change of the market is a condition, whereas the implementing steps which are necessary to achieve this result are generally obligations on the parties. Where a condition is not fulfilled, the Commission's decision declaring the concentration compatible with the internal market no longer stands. Where the undertakings concerned commit a breach of an obligation, the Commission may revoke the clearance decision in accordance with the Merger Regulation. The undertakings concerned may also be subject to fines and periodic penalty payments under Articles 14(2) and 15(1) of the Merger Regulation.
586. In accordance with the basic distinction between conditions and obligations described above, the decision in this case is conditioned on the full compliance with the requirements set out in Section B of the commitments submitted by the Notifying Party on 12 July 2013 which constitute conditions, whereas the other sections of the commitments constitute obligations on the Notifying Party.
587. The full text of the commitments is annexed to this decision and forms an integral part thereof.

VIII. CONCLUSION

588. For the above reasons, the Commission has decided not to oppose the notified operation as modified by the commitments and to declare it compatible with the internal market and with the functioning of the EEA Agreement. This decision is adopted in application of Article 6(1)(b) in conjunction with Article 6(2) of the Merger Regulation.

*For the Commission
(signed)
Joaquín ALMUNIA
Vice-President*

BY HAND AND BY E-MAIL

European Commission
DG Competition
Merger Registry
Place Madou / Madouplein 1
1210 Saint-Josse-ten-Noode / Sint-Joost-ten-Node
Belgique / België

Case M.6851 – Baxter International / Gambro

AMENDED COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Article 6(2) of Council Regulation (EC) No. 139/2004 (the “Merger Regulation”), Baxter International Inc. (“Baxter”) hereby provides the following Commitments (the “Commitments”) in order to enable the European Commission (the “Commission”) to declare the acquisition of Gambro AB by Baxter compatible with the internal market and the EEA Agreement by its decision pursuant to Article 6(1)(b) of the Merger Regulation (the “Decision”).

The Commitments shall take effect upon the date of adoption of the Decision.

This text shall be interpreted in the light of the Decision to the extent that the Commitments are attached as conditions and obligations, in the general framework of Union law, in particular in the light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004.

Section A. Definitions

For the purpose of the Commitments, the following terms shall have the following meaning:

Affiliated Undertakings: undertakings controlled by Baxter, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in the light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004.

Baxter: Baxter International Inc. incorporated under the laws of the State of Delaware, with registered office at One Baxter Parkway, Deerfield, Illinois 60015, U.S.A.

Closing: the transfer of the legal title of the Divestment Business to the Purchaser.

Divestment Business: Baxter’s CRRT business as defined in Section B and the Schedule that Baxter commits to divest.

Divestiture Trustee: one or more natural or legal person(s), independent from the Parties, who is approved by the Commission and appointed by Baxter and who has received from Baxter the exclusive Trustee Mandate to sell the Divestment Business to a Purchaser at no minimum price.

Effective Date: the date of adoption of the Decision.

First Divestiture Period: the period of [...] from the Effective Date.

Hold Separate Manager: the person appointed by Baxter for the Divestment Business to manage the day-to-day business under the supervision of the Monitoring Trustee.

Key Personnel: all personnel necessary to maintain the viability and competitiveness of the Divestment Business, as listed in Annex 1.

Monitoring Trustee: one or more natural or legal person(s), independent from the Parties, who is approved by the Commission and appointed by Baxter, and who has the duty to monitor Baxter's compliance with the conditions and obligations attached to the Decision.

Parties: Baxter and Gambro AB.

Personnel: all personnel currently employed in the Divestment Business listed in the Schedule, including Key Personnel.

Purchaser: the entity approved by the Commission as acquirer of the Divestment Business in accordance with the criteria set out in Section D.

Trustee(s): the Monitoring Trustee and the Divestiture Trustee.

Trustee Divestiture Period: the period of [...] from the end of the First Divestiture Period.

Section B. The Divestment Business

Commitment to divest

1. In order to restore effective competition, Baxter commits to divest, or procure the divestiture of the Divestment Business by the end of the Trustee Divestiture Period as a going concern to a purchaser and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 15. To carry out the divestiture, Baxter commits to find a purchaser and to enter into a final binding sale and purchase agreement for the sale of the Divestment Business within the First Divestiture Period. If Baxter has not entered into such an agreement at the end of the First Divestiture Period, Baxter shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business in accordance with the procedure described in paragraph 24 in the Trustee Divestiture Period. The proposed concentration shall not be implemented unless and until Baxter or the Divestiture Trustee has entered into a final binding sale and purchase agreement for the sale of the Divestment Business and the Commission has approved the purchaser and the terms of sale in accordance with paragraph 15.

2. Baxter shall be deemed to have complied with this commitment if, by the end of the Trustee Divestiture Period, Baxter has entered into a final binding sale and purchase agreement, if the Commission approves the Purchaser and the terms in accordance with the procedure described in paragraph 15 and if the Closing of the sale of the Divestment Business takes place within a period not exceeding 3 months after the approval of the Purchaser and the terms of sale by the Commission.
3. In order to maintain the structural effect of the Commitments, Baxter shall, for a period of 10 years after the Effective Date, not acquire direct or indirect influence over the whole or part of the Divestment Business, unless the Commission has previously found that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business is no longer necessary to render the proposed concentration compatible with the internal market.

Structure and definition of the Divestment Business

4. The Divestment Business consists of Baxter's worldwide CRRT business as further defined in the Schedule. The present legal and functional structure of the Divestment Business as operated to date is described in Annex 2. The Divestment Business, described in more detail in the Schedule, includes
 - (a) all tangible assets, including placed CRRT monitors owned by Baxter identified in Annex 3, which contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business, and a Baxter-proprietary ClearFlex production line for Accusol to be set up in an existing or new manufacturing location in the EEA or Switzerland identified by the Purchaser;
 - (b) all intangible assets (including intellectual property rights, notably trademarks, patents, licensed patents, licensed copyrights, and licensed know-how), which contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business;
 - (c) all licenses, permits and authorizations issued by any governmental organization for the benefit of the Divestment Business, including CE marks and medicinal product authorizations;
 - (d) all contracts (including supply agreements with Nikkiso and other contract manufacturers, distribution agreements and agreements with customers), commitments and customer orders of the Divestment Business; all customer, credit and other records of the Divestment Business (items referred to under (a)-(d) hereinafter collectively referred to as "Assets");
 - (e) the Personnel; and

- (f) transitional contract manufacturing of CRRT fluids and technical assistance for a period of up to [...] after Closing and on a cost-plus basis,²⁶³ as detailed in the Schedule, unless otherwise agreed with the Purchaser. The contract manufacturing can be extended for a further period of [...] at the request of the Purchaser based on a report of the Monitoring Trustee. Baxter is further prepared to supply film for the manufacture of Accusol bags as well as spare parts for the ClearFlex Production line.

Section C. Related commitments

Preservation of Viability, Marketability and Competitiveness

- 5. From the Effective Date until Closing, Baxter shall preserve the economic viability, marketability and competitiveness of the Divestment Business, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of the Divestment Business. In particular Baxter undertakes:
 - (a) not to carry out any act upon its own authority that might have a significant adverse impact on the value, management or competitiveness of the Divestment Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Business;
 - (b) to make available sufficient resources for the development of the Divestment Business, on the basis and continuation of the existing business plans;
 - (c) to take all reasonable steps, including appropriate incentive schemes (based on industry practice), to encourage all Key Personnel to remain with the Divestment Business.

Hold-separate obligations of Parties

- 6. Baxter commits, from the Effective Date until Closing, to keep the Divestment Business separate from the businesses it is retaining and to ensure that Key Personnel of the Divestment Business – including the Hold Separate Manager – have no involvement in any business retained and vice versa. Baxter shall also ensure that the Personnel do not report to any individual outside the Divestment Business.
- 7. Until Closing, Baxter shall assist the Monitoring Trustee in ensuring that the Divestment Business is managed as a distinct and saleable entity separate from the businesses retained by Baxter. Baxter shall appoint a Hold Separate Manager who shall be responsible for the management of the Divestment Business, under the supervision of the Monitoring Trustee. The Hold Separate Manager shall manage the Divestment Business independently and in

²⁶³ The reasonable cost-plus basis to be agreed with the Purchaser will be based on fully allocated costs as measured by Baxter's existing cost accounting system as well as a mark-up to be negotiated with the Purchaser.

the best interest of the business with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by the Parties.

8. [Intentionally left blank.]

Ring-fencing

9. Baxter shall implement all necessary measures to ensure that it does not after the Effective Date obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestment Business. In particular, the participation of the Divestment Business in a central information technology network shall be severed to the extent possible, without compromising the viability of the Divestment Business. Baxter may obtain information relating to the Divestment Business which is reasonably necessary for the divestiture of the Divestment Business or whose disclosure to Baxter is required by law.

Non-solicitation clause

10. Baxter undertakes, subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit, the Key Personnel transferred with the Divestment Business for a period of [...] after Closing.

Due Diligence

11. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Business, Baxter shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process:

- (a) provide to potential purchasers sufficient information as regards the Divestment Business;
- (b) provide to potential purchasers sufficient information relating to the Personnel and allow them reasonable access to the Personnel.

Reporting

12. Baxter shall submit written reports in English on potential purchasers of the Divestment Business and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than 10 days after the end of every month following the Effective Date (or otherwise at the Commission's request).

13. Baxter shall inform the Commission and the Monitoring Trustee on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of an information memorandum to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

Section D. The Purchaser

14. In order to ensure the immediate restoration of effective competition, the Purchaser, in order to be approved by the Commission, must:

- (a) be independent of and unconnected to the Parties;
- (b) have the financial resources, proven expertise and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors;
- (c) be an industry Purchaser (as opposed to a financial investor) and have experience in renal replacement therapy;
- (d) have an existing local presence for sales, marketing and technical support, either directly or indirectly via distributors, in several EEA countries of concern²⁶⁴;
- (e) neither be likely to create, in the light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed, and must, in particular, reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business (the before-mentioned criteria for the Purchaser hereafter the “**Purchaser Requirements**”).

15. The final binding sale and purchase agreement shall be conditional on the Commission’s approval. When Baxter has reached an agreement with a purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), to the Commission and the Monitoring Trustee. Baxter must be able to demonstrate to the Commission (i) that the purchaser meets the Purchaser Requirements, (ii) that the Divestment Business is being sold in a manner consistent with the Commitments, and (iii) that the [...] parties with which Baxter has supply agreements to be transferred to the Purchaser ([...]²⁶⁵) have given their consent to the transfer. For the approval, the Commission shall verify that the purchaser fulfils the Purchaser Requirements and that the Divestment Business is being sold in a manner consistent with the Commitments. The Commission may approve the sale of the Divestment Business without one or more Assets or parts of the Personnel, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed purchaser.

15A. The Commission may consider a request from Baxter under paragraph 34(i) during the First Divestiture Period where Baxter has reached an agreement with a purchaser but one or more of the third parties with which Baxter has supply agreements, as specified in

²⁶⁴ These countries are Austria, Belgium, the Czech Republic, Denmark, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Poland, Slovakia, Spain, Sweden, and the United Kingdom.

²⁶⁵ See the first two bullets of para. 2(d) of the Schedule.

paragraph 2(d) of the Schedule, has yet to give its consent to the transfer of the agreement to the purchaser. In such a case, Baxter shall demonstrate that any outstanding third party consents are likely to be secured within the extended time period. Such request from Baxter must be accompanied by a report of the Monitoring Trustee. If Baxter demonstrates that the third party (or third parties as the case may be) in question have refused to give its consent (or their consent as the case may be), the Commission may consider accepting a request from Baxter that Baxter procures instead a supply agreement (or agreements as the case may be) so as to meet the demands of the Divestment Business for the said product (or products as the case may be) with another supplier (or suppliers as the case may be) acceptable to the Purchaser and on similar terms and conditions to those on which the Divestment Business is currently supplied for the same product, in line with good industry practice and in a manner which does not affect the viability and competitiveness of the Divestment Business after Closing. Such request from Baxter must be accompanied by a report of the Monitoring Trustee.

Section E. Trustee

I. Appointment Procedure

16. Baxter shall appoint a Monitoring Trustee to carry out the functions specified in the Commitments for a Monitoring Trustee. If Baxter has not entered into a binding sales and purchase agreement one month before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by Baxter at that time or thereafter, Baxter shall appoint a Divestiture Trustee to carry out the functions specified in the Commitments for a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Extended Divestment Period.
17. The Trustee shall be independent of the Parties, possess the necessary qualifications to carry out its mandate, for example as an investment bank or consultant or auditor, and shall neither have nor become exposed to a conflict of interest. The Trustee shall be remunerated by Baxter in a way that does not impede the independent and effective fulfillment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestment Business, the fee shall also be linked to a divestiture within the Trustee Divestiture Period.

Proposal by Baxter

18. No later than one week after the Effective Date, Baxter shall submit a list of one or more persons whom Baxter proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one month before the end of the First Divestiture Period, Baxter shall submit a list of one or more persons whom Baxter proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the proposed Trustee fulfils the requirements set out in paragraph 17 and shall include:
 - (a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;

- (b) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks;
- (c) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

Approval or rejection by the Commission

19. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfill its obligations. If only one name is approved, Baxter shall appoint or cause to be appointed, the individual or institution concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, Baxter shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New proposal by Baxter

20. If all the proposed Trustees are rejected by the Commission, Baxter shall submit the names of at least two more individuals or institutions within one week of being informed of the rejection, in accordance with the requirements and the procedure set out in paragraphs 16 and 19.

Trustee nominated by the Commission

21. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom Baxter shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

II. Functions of the Trustee

22. The Trustee shall assume its specified duties in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or Baxter, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and obligations of the Monitoring Trustee

23. The Monitoring Trustee shall:

- (i) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision.
- (ii) oversee the on-going management of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by Baxter with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:

- (a) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Business, and the keeping separate of the Divestment Business from the business retained by the Parties, in accordance with paragraphs 5 and 6 of the Commitments;
 - (b) supervise the management of the Divestment Business as a distinct and saleable entity, in accordance with paragraph 7 of the Commitments;
 - (c) (i) in consultation with Baxter, determine all necessary measures to ensure that Baxter does not after the Effective Date obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestment Business, in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business, and (ii) decide whether such information may be disclosed to Baxter as the disclosure is reasonably necessary to allow Baxter to carry out the divestiture or as the disclosure is required by law;
 - (d) monitor the splitting of assets and the allocation of Personnel between the Divestment Business and Baxter or Affiliated Undertakings;
 - (e) monitor the appropriateness of supply agreements between Baxter and the Purchaser and their terms;
 - (f) mediate any disagreements between Baxter and the Purchaser relating to the execution of the Commitments if mediation is agreed to by the Purchaser; and submit a report to the Commission on such issues and on the outcome of the mediation to the Commission;
- (iii) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision;
 - (iv) propose to Baxter such measures as the Monitoring Trustee considers necessary to ensure Baxter's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Business, the holding separate of the Divestment Business and the non-disclosure of competitively sensitive information;
 - (v) review and assess potential purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process, (a) potential purchasers receive sufficient information relating to the Divestment Business and the Personnel in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process, and (b) potential purchasers are granted reasonable access to the Personnel;
 - (vi) provide to the Commission, sending Baxter a non-confidential copy at the same time, a written report within 15 days after the end of every month. The report shall cover the operation and management of the Divestment Business so that the Commission can assess whether the business is held in a manner consistent with the Commitments

and the progress of the divestiture process as well as potential purchasers. In addition to these reports, the Monitoring Trustee shall promptly report in writing to the Commission, sending Baxter a non-confidential copy at the same time, if it concludes on reasonable grounds that Baxter is failing to comply with these Commitments;

- (vii) within one week after receipt of the documented proposal referred to in paragraph 15, submit to the Commission a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Business after the Sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the Sale of the Divestment Business without one or more Assets or not all of the Personnel affects the viability of the Divestment Business after the sale, taking account of the proposed purchaser.

Duties and obligations of the Divestiture Trustee

- 24. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell at no minimum price the Divestment Business to a purchaser, provided that the Commission has approved both the purchaser and the final binding sale and purchase agreement in accordance with the procedure laid down in paragraph 15. The Divestiture Trustee shall include in the sale and purchase agreement such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall protect the legitimate financial interests of Baxter, subject to Baxter's unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.
- 25. In the Trustee Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to Baxter.

III. Duties and obligations of Baxter

- 26. Baxter shall provide and shall cause its advisors to provide the Trustee with all such cooperation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of Baxter's or the Divestment Business' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and Baxter and the Divestment Business shall provide the Trustee upon request with copies of any document. Baxter and the Divestment Business shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.
- 27. Baxter shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment

Business. This shall include all administrative support functions relating to the Divestment Business which are currently carried out at headquarters level. Baxter shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. Baxter shall inform the Monitoring Trustee on possible purchasers, submit a list of potential purchasers, and keep the Monitoring Trustee informed of all developments in the divestiture process.

28. Baxter shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale, the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, Baxter shall cause the documents required for effecting the sale and the Closing to be duly executed.
29. Baxter shall indemnify the Trustee and its employees and agents (each an “*Indemnified Party*”) and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to Baxter for any liabilities arising out of the performance of the Trustee’s duties under the Commitments, except to the extent that such liabilities result from the willful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.
30. At the expense of Baxter, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to Baxter’s approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should Baxter refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard Baxter. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 29 shall apply mutatis mutandis. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served Baxter during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

IV. Replacement, discharge and reappointment of the Trustee

31. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a conflict of interest:
 - (a) the Commission may, after hearing the Trustee, require Baxter to replace the Trustee; or
 - (b) Baxter, with the prior approval of the Commission, may replace the Trustee.
32. If the Trustee is removed according to paragraph 31, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 16-21.

33. Beside the removal according to paragraph 31, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

Section F. The Review Clause

34. The Commission may, where appropriate, in response to a request from Baxter showing good cause and accompanied by a report from the Monitoring Trustee:

- (i) Grant an extension of the time periods foreseen in the Commitments, or
- (ii) Waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments.

Where Baxter seeks an extension of a time period, it shall submit a request to the Commission no later than one month before the expiry of that period, showing good cause. Only in exceptional circumstances shall Baxter be entitled to request an extension within the last month of any period.

.....
duly authorized for and on behalf of

Baxter International Inc.

SCHEDULE

1. The Divestment Business as operated to date has the following legal and functional structure: The Divestment Business is integrated in various local Baxter affiliates as set out in **Annex 2**.
2. Following paragraph 4 of these Commitments, the Divestment Business includes:

(a) the following main tangible assets:

- a Baxter-proprietary Renal ClearFlex production line for Accusol with a capacity mirroring that of the production line on which Accusol is currently produced in [...], to be set up in an existing or new manufacturing location in the EEA or Switzerland identified by the Purchaser. Baxter would help the Purchaser set up additional infrastructure as needed (mixing, sterilization, packaging).

The Baxter-proprietary Renal ClearFlex production line for Accusol is a form-fill-seal production unit with integrated pouching equipment, which produces the Accusol product in its final format. This production line produces [...], and its annual capacity is approximately [...], which would correspond to [...].

At the option of the Purchaser, Baxter commits to procure and/or install all the additional infrastructure needed for the production process (such as mixing, sterilization and packaging) unless the manufacturing location identified by the Purchaser is already equipped with such infrastructure or is planned to be equipped with such infrastructure within the next [...];

- all CRRT products, parts, supplies, materials and other inventories to the extent used or held for the Divestment Business as well as the monitors placed with any customers or other user of the monitors owned by Baxter as illustrated in **Annex 3**.
- (b) the following main intangible assets: all IP rights that are held by Baxter and, except in the case of the patents referred to in the third bullet below and of certain copyrights, used exclusively with respect to the development, manufacture and/or sale of CRRT products worldwide, and know-how, including:
- the trademarks [...];
 - patents that Baxter acquired [...], and patents that Baxter holds or is in the process of obtaining, targeted specifically at CRRT, described in more detail in **Annex 4**;
 - an irrevocable, perpetual, and royalty-free license for patents that were originally designed by Baxter for [...], but are formulated broad enough so that they also cover Accusol [...], for use in the CRRT field as described in more detail in **Annex 5**;

- a copyright license related to its CRRT business, covering, *inter alia*, information booklets and website content;
 - production know-how for the manufacture of [...] as well as know-how associated with obtaining the relevant production approvals. The relevant know-how is embodied in design history files, technical files, drawings, product specifications, manufacturing process descriptions, validation documentation, packaging specifications, and quality control standards. The know-how license will be limited to the CRRT field;
 - know-how for the production of CRRT [...]. The know-how license for the production granted by Baxter in this context will be limited to the CRRT field;
 - documentation relating to the [...];
- (c) the following main licenses, permits and authorizations:
- transfer of, or if not legally possible, access to, as appropriate, all current and pending CE marks relating to the Divestment Business held by Baxter as described in **Annex 6**, including all relevant dossiers relating to the current or pending CE marks relating to the Divestment Business available to Baxter, and where necessary, reasonable assistance to the Purchaser to make any necessary regulatory filings and obtain necessary authorizations;
 - transfer of, or, if not legally possible, access to, as appropriate, all licenses, permits, and authorizations issued by any governmental organization and held by Baxter that are necessary to manufacture and/or sell the products belonging to the Divestment Business, including any relevant dossiers relating to current or pending authorizations available to Baxter and, where necessary, reasonable assistance related to the transfer to the Purchaser of such licenses, permits, and authorizations concerning the Divestment Business, and providing reasonable assistance to the Purchaser to make any necessary regulatory filings and obtain any necessary authorizations;
- (d) the following main contracts, agreements, leases, commitments and understandings:
- Baxter will use its best efforts to transfer the supply agreement with Nikkiso or to enable the Purchaser to conclude an agreement with Nikkiso to purchase from Nikkiso the Aquarius monitor (and ancillary products (*e.g.*, spare parts));
 - Baxter will use its best efforts to transfer the supply agreements or to enable the Purchaser to conclude agreements with [...] to purchase dialyzers, with [...] to purchase bloodlines and ancillary products (*e.g.*, drainage bags, adaptors, syringes *etc.*), and with [...], to purchase catheters;

- Baxter will use its best efforts to transfer distribution agreements or the CRRT part of such agreements to the Purchaser. In the event that such arrangements cannot be made, Baxter is prepared to conclude back-to-back distribution agreements with the Purchaser to distribute products for the Purchaser on a reasonable cost-plus basis;²⁶⁶
- (e) the following customer, credit and other records: Baxter’s existing contracts with customers worldwide relating to the products belonging to the Divestment Business with the consent of the customers, and Baxter’s CRRT customer list and customer records as they relate to CRRT products. In case a customer would not agree to a transfer, a back-to-back arrangement on a reasonable cost-plus basis to be agreed with the Purchaser will have to be entered into under which the Purchaser supplies Baxter to fulfill its remaining obligations;²⁶⁷
- (f) personnel currently working in the Divestment Business, including (i) technical support and maintenance personnel, (ii) R&D/regulatory personnel, and (iii) marketing and sales staff as listed in **Annex 1**. As of July 9, 2013, these include approximately [...] employees at global level, [...] employees at EMEA level, [...] employees in the Asian region, [...] employees in the EU and Switzerland, [...] employee in Saudi Arabia, [...] employees in Australia/New Zealand and [...] employees in Latin America;
- at the option of the Purchaser, sufficient technical and operation personnel for the ClearFlex production line (based on Baxter’s current operations at [...]);
- The [...] R&D employees currently working in Baxter’s [...] will be able to continue to work there (albeit ring-fenced from Baxter’s R&D activities) for a transitional period of [...]. The [...] R&D employees currently working in [...] will also have access to [...] during this period.
- (g) the following Key Personnel: as listed in **Annex 1**;
- (h) the arrangements for the supply with the following products or services by Baxter or Affiliated Undertakings for a transitional period in order to maintain the economic viability and competitiveness of the Divestment Business:
- Baxter is prepared to conclude a transitional contract manufacturing agreement for Accusol and Monosol fluids and lactate with the Purchaser for a period of up to [...] after Closing on a reasonable cost-plus basis to be agreed with the Purchaser, and in accordance with good industry practice.²⁶⁸ The contract manufacturing can be extended for a further

²⁶⁶ “Cost-plus” here refers to a pass-through of the product price plus the cost of any resources required for management of the relationship, shipping costs, and the like.

²⁶⁷ See footnote 266.

²⁶⁸ See footnote 263.

period of [...] at the request of the Purchaser based on a report of the Monitoring Trustee;

- Baxter is prepared to provide certain transitional services to the Purchaser pursuant to a transition services agreement against a reasonable compensation for a period of up to [...]. At the Purchaser's option, such services would cover (i) HR functions (*e.g.*, HR support, payroll, pensions administration); (ii) finance functions (*e.g.*, banking, supplier payments, credit roll, VAT, treasury, tax, internal audit, and statutory accounting); (iii) IT (*e.g.*, email, business management software, helpdesk, server hosting, telecoms *etc.*); (iv) sales and customer support functions (*e.g.*, customer service support, order desk for spare parts, customer support services helpdesk, stock management *etc.*); and (v) other administrative functions (*e.g.*, insurance, legal and export compliance, travel services *etc.*);
- (i) an arrangement for the supply with the following products and services by Baxter or Affiliated Undertakings:
- Baxter is prepared to conclude a supply agreement for the film required for the manufacture of Accusol bags on a reasonable cost-plus basis to be agreed with the Purchaser, and in accordance with good industry practice;²⁶⁹
 - Baxter is prepared to conclude a transitional engineering support and training services agreement for ongoing support of the Baxter-proprietary ClearFlex production line operated by the Purchaser. Baxter is prepared to provide such engineering support and training until such time as the Purchaser has established its own engineering support for the ClearFlex production line;
 - Baxter is prepared to supply spare parts to the Purchaser for the ClearFlex Production line;
 - Baxter will provide the transitional engineering support and training services and supply spare parts for the ClearFlex Production line at terms equivalent to those given by Baxter to its Affiliated Undertakings.
- (j) Baxter is prepared to put in place firewalls between its sales and marketing personnel, on the one hand, and the engineering support services and fluids and sheeting production, on the other.

3. The Divestment Business shall not include:

- any R&D facilities;
- Baxter's CRRT business unit's global director, a marketing person, who is based in the U.S. and who is scheduled to stay with Baxter.

²⁶⁹ See footnote 263.

Overview Of Baxter Employees To Be Transferred

[...]

Entities Active In Baxter's CRRT Business

[...]

Placed CRRT Monitors Owned By Baxter

[...]

Patents To Be Assigned

[...]

Patents To Be Licensed

[...]

Marketing Authorizations In Baxter's CRRT Business

[...]