Acquisition of Gambro AB (via Indap Holding AB) by Baxter International Inc.

Notice Seeking Clearance pursuant to Section 66 Commerce Act 1986 by Baxter International Inc.

13 March 2013

EXECUTIVE SUMMARY

(A) Baxter International Inc. (**Baxter**) seeks the NZCC's clearance pursuant to Section 66 Commerce Act 1986 for the purchase of Gambro AB's (**Gambro**) New Zealand business as part of a global acquisition of Gambro AB. Similar approvals are being sought with the relevant authorities in Brazil, Canada, China, European Union, South Korea, Turkey, the Ukraine and Australia. In the US early termination of the waiting period has already been granted.

(B) The two global groups (Baxter and Gambro) have largely complementary businesses. Baxter is primarily a supplier of a range of plasma-based proteins for various purposes, products for regenerative medicine, vaccines, and a range of intravenous (IV) solutions, administration sets, premix drugs and various other products that are not produced by Gambro.

(C) Baxter is also a significant supplier of peritoneal dialysis (**PD**) products for treating chronic kidney patients and Gambro does not supply PD products.

(D) A small proportion of Baxter's business concerns the supply as a distributor of the other two main kidney treatments predominantly manufactured by others: haemodialysis (**HD**) and continuous renal replacement technologies (**CRRT**). Manufacturing and distributing HD, and to a lesser extent, CRRT are the focuses of Gambro's business and, at least in respect of distribution, the two firms are competitors.

(E) **[ ]**

(F) There are other competitors for CRRT and HD products such as Fresenius Medical Care (**Fresenius**) (the largest RRT supplier in the world and the New Zealand market leader in HD) and a range of entrants who already participate in the ANZ market place or are in the process of entering the industry (such as NxStage and B. Braun). Not all of these new entrants have yet shown in the sales share figures which give only a 'rear vision mirror' view of those suppliers who were successful at the last round of tenders or, in some instances, provided a machine pursuant to a pricing agreement. For these reasons, Baxter is of the view that the acquisition of Gambro in full would not substantially lessen competition.

(G) **[**

(H) **]**

(I) In relation to HD, it is also unlikely that there would be any significant change. At present Nikkiso supplies HD machines to Baxter **[ ]**

(J) For these reasons, the effect of the transaction in the areas of overlap can be illustrated using the following 2011 sales shares in New Zealand for machines (which is a leading indicator of sale of related products used with the machines):

	HD New Zealand (pre-transaction)	HD New Zealand (post-transaction)	CRRT New Zealand (pre-transaction)	CRRT New Zealand (post-transaction)
Fresenius	**[**	**]**		**]**

Gambro	[			]
Baxter				]
[				]
Total				

(K) In summary, therefore, the transaction will not substantially lessen competition in any relevant market because:

(1) for the vast majority of Baxter's business, Gambro is not a competitor;

(2) to the extent that there is overlap between the parties (i.e. for HD and CRRT therapies), there are existing competitors and potential entrants; and

(3) **[ ]**

(L) Even so, the transaction will not alter the market position in any material way because:

(1) **[ ];** and

(2) **[ ]**

(M) The body of this Submission provides a detailed explanation of the medical, commercial and competition aspects of the industry and this transaction. Baxter would be pleased to assist the NZCC in relation to any further questions it may have in relation to the transaction.

PART 1: TRANSACTION DETAILS

The person giving notice

1.	Provide the name of the acquirer (person giving notice), and the name and position of the individual responsible for the notice. Please include the: • registered office address, postal address and physical address of the acquirer; • telephone and fax numbers and website of the acquirer; and • email address, telephone number and position of the contact person.

1.1	This notice is given by Baxter International, Inc (**Baxter**).	
	Registered office:	One Deerfield Parkway, Deerfield, Illinois 60015, United States of America
	Postal Address:	As above.
	Physical Address:	As above.
	Telephone:	+1 224 948 1812
	Fax:	+1 847 948 2450
	Website:	www.baxter.com
1.2	All correspondence and notices in respect of this application should be directed in the first instance to:	
	Nicholas J. Taylor, Partner, and Paul Smith, Associate, Jones Day (Sydney)	
	Email:	njtaylor@jonesday.com and pasmith@jonesday.com
	Telephone:	(+61) 2 8272 0715 and (+61) 2 8272 0521

Other merger party

2.	Provide the name of the other merger parties, and the name/position of the relevant individual within the relevant merger parties. For each merger party, please include the: • registered office address, postal address and physical address; • telephone and fax number and website; and • email address, telephone number and position of the contact person.

2.1	The other merger party is Gambro AB (**Gambro**).	
	Registered office:	P.O Box 10101, SE-220 10 LUND, Sweden
	Postal Address:	P.O. Box 10101, SE-220 10 LUND, Sweden
	Physical Address:	Magistratsvagen 16, 226 43, Sweden
	Telephone:	+46 46 16 90 00
	Fax:	+46 46 16 96 96
	Website:	www.gambro.com
2.2	All correspondence and notices in respect of this application should be directed in the first instance to:	
	Fiona Crosbie, Partner, Allens (Sydney)	
	Email:	Fiona.Crosbie@allens.com.au
	Telephone:	(+61) 2 9230 4383
	and/or	
	Jonas Koponen, Partner and Marcus Pollard, Solicitor, Linklaters LLP (Brussels)	
	Email: jonas.koponen@linklaters.com and marcus.pollard@linklaters.com	
	Telephone:	(+32) 2 505 0227 and (+32) 2 501 9145

The acquisition

3. With respect to the merger parties, list the relevant companies and the person or persons controlling these directly or indirectly. Please use organisational charts or diagrams to show the structure of the ownership and control of the acquirer and participant(s) to the acquisition.

   When answering question 3, bear in mind that the Commission is only seeking information that is relevant to the proposal. The Commission does not require exhaustive details of the persons interconnected to, or associated with, the merger parties unless those interconnections or associations are relevant to the Commission's consideration of the competition implications of the proposal.

   If relevant, identify and explain any other links, formal or informal, between the merger parties, including interconnected bodies corporate and other persons identified in question 3 above and its/their existing competitors in each market.

   For further information on interconnected persons and associated persons, please refer to Part 2 of the Mergers and Acquisitions Guidelines.

Acquirer

3.1 Baxter is a global medical products and services company that is incorporated in the United States of America and listed on the New York Stock Exchange and the SIX Swiss Stock Exchange. No shareholder holds shares in Baxter that confer control over Baxter. Baxter Healthcare Limited (104549) is the New Zealand operating subsidiary of Baxter.

3.2 Baxter develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide. Baxter had 2011 sales of USD 13.9 billion (approximately NZD 16.5 billion) and has approximately 48,500 employees.

3.3 Baxter's Australian operations commenced in 1963 and now comprise a manufacturing plant in Toongabbie, Western Sydney (which employs approximately 400 people), distribution and warehousing depots in New South Wales, Queensland, Victoria, South Australia, Western Australia and Tasmania, and aseptic compounding facilities in New South Wales, Queensland, Victoria, Western Australia and South Australia. New Zealand operations commenced in 1980 and include a head office in Auckland; warehouse and distribution centres in Auckland and Christchurch; and aseptic compounding pharmacies in Auckland and Christchurch.

3.4 Baxter had 2012 sales in New Zealand of approximately NZD127 million and has approximately 141 employees in New Zealand.

3.5 Baxter's business primarily includes two parts:

(A) BioScience (global 2011 revenue: USD6.1 billion (approximately AUD6.3 billion))

Baxter is a manufacturer of recombinant and plasma-based proteins to treat haemophilia and other bleeding disorders; plasma-based therapies to treat immune deficiencies, alpha 1-antitrypsin deficiency, burns and shock, and other chronic and acute blood-related conditions; products for regenerative medicine, such as biosurgery products; and vaccines.

(B) Medical Products (global 2011 revenue: USD7.8 billion (approximately AUD8 billion))

Baxter's Medical Products business manufactures products used in the delivery of fluids and drugs to patients. These include intravenous (IV) solutions and administration sets, premixed drugs and drug-reconstitution systems, IV nutrition products, infusion pumps and inhalation anesthetics. The business also provides products and services related to pharmacy compounding, drug formulation and packaging technologies. In addition, Baxter's Medical Products business provides renal home-based therapies, such as peritoneal dialysis, and offers other products and services for people with chronic and acute kidney disease including the supply of renal devices.

3.6 Baxter's ANZ business also includes pharmacy services, which provide Therapeutic Goods Act (**TGA**) regulated aseptic compounding services, for hospital pharmacies throughout Australia and New Zealand. Products include chemotherapy, antibiotics, analgesics for pain relief and intravenous nutrition.

3.7 Annexure A contains a structure chart showing how Baxter Healthcare Limited fits within the Baxter corporate group.

Target

3.8 Gambro AB (**Gambro**) was founded in Lund, Sweden, in 1964 and has approximately 7,500 employees, 13 production facilities in 9 countries, sales in more than 100 countries and global 2012 revenues of approximately **[ ]**.

3.9 Gambro is wholly owned by Indap Holding AB, which is indirectly held by private equity funds managed by EQT Partners AB and the investment company, Investor AB.

3.10 Gambro develops, manufactures and supplies products and therapies for chronic and acute kidney dialysis, liver dialysis, myeloma kidney therapy, related water systems and other extracorporeal therapies for chronic and acute patients.

Gambro is not active in peritoneal dialysis since it divested that business to Fresenius in 2010. [1]

3.11 Gambro distributes products in New Zealand **[ ]**. Gambro employees perform the sales and marketing functions. **[ ]** Gambro's 2012 revenue in New Zealand was approximately **[ ]**.

3.12 Annexure B contains a structure chart for the Gambro organization.

4. Provide details on what is to be acquired.

Acquisition

4.1 As a result of the acquisition of Indap Holding AB by Baxter (**Proposed Transaction**), Baxter will acquire the entire share capital of Indap Holding AB and Gambro will thus become a wholly-owned subsidiary of Baxter. Completion of the Proposed Transaction is subject to customary conditions precedent, including necessary approvals from relevant competition authorities. All the conditions precedent except clearances from relevant competition authorities must be obtained by April 4, 2013 and clearances from relevant competition authorities must be obtained by June 4, 2013, otherwise either Party can terminate the Share Purchase Agreement.

4.2 Although both companies supply products to address kidney disease, the majority of Baxter's business is complementary to Gambro's. Within the field of kidney treatments, Baxter's business is primarily focused on the manufacture and sale of peritoneal dialysis (**PD**) products used to treat patients suffering from chronic kidney disease (**CKD**). Since divesting its PD business in 2010, Gambro does not sell and has never sold any PD products in New Zealand or elsewhere.[2] Gambro focuses on the manufacture and sale of hemodialysis (**HD**) products, which are marketed for use in CKD. Baxter does not manufacture any HD equipment, but distributes a modest amount of such products in New Zealand that are made by other manufacturers, such as Nikkiso and Nipro (both are Japanese manufacturers)[3].

4.3 The primary area of competitive overlap between Gambro and Baxter is in relation to continuous renal replacement therapy (**CRRT**) products, which are designed to treat acute kidney injury (**AKI**). Gambro is a manufacturer (overseas) and distributor (in New Zealand and overseas) of these products. Baxter is a manufacturer and distributor of CRRT fluids in Australia, a distributor

[1] The rationale for the divestiture of the PD business in 2010 to Fresenius Medical Care was **[ ]**.

[2] Other than minor sales pursuant to short-term transition agreements with FMC.

[3] See discussion below.

of CRRT fluids in New Zealand and a distributor in New Zealand and overseas of other CRRT products manufactured by other manufacturers. At present in New Zealand, Gambro is the largest supplier of CRRT. **[ ]**

4.4 The remainder of this Submission will deal only with PD, HD and CRRT products used to treat CKD and AKI. There are a number of other products that are also available for purchase from both Baxter and Gambro.[4] In these areas, the sales revenue is either *de minimis* or the products supplied are used both in connection with renal therapy and a wide range of other medical procedures and therefore they are sold by a very wide range of suppliers. In Baxter's view these minor product lines do not warrant a separate consideration by the NZCC but if market inquiries identify any other products for which the NZCC would like specific information, Baxter would supply that information.

4.5 **[ ]**

5. Fully explain the commercial rationale for the proposed merger. Specify whether this is part of an international merger.

5.1 Both parties develop, manufacture and supply products used in the treatment of chronic and acute renal failure, but their businesses are largely used in different therapies (Baxter being a PD focused company which is relatively larger in the US and Gambro being more focused on HD and larger in Europe). The Proposed Transaction will improve Baxter's ability to provide dialysis products to customers globally, enable Baxter to save costs by gaining scale, enhance Baxter's ability to expand its product offering in some jurisdictions, and

[4] This includes catheters and needles to establish vascular access, water treatment systems used to produce pure pre-treated water, which is used by HD machines in all dialysis units to manufacture dialysate and replacement fluids from concentrates. Other niche area treatments involve liver dialysis, therapeutic plasma exchange, multiple myeloma treatment, hemoperfusion, and ultrafiltration/aquapheresis. While these other treatments are related and sometimes use the same or similar equipment as HD or CRRT, they are not part of the standard HD or CRRT treatments and also require additional specific equipment. In Australia, these products account for approximately **[ ]** of Gambro's overall revenue and a smaller proportion for Baxter.

accelerate innovation, thus improving the quality of patients' lives.

6. Provide copies of the final or the most recent versions of any documents bringing about the proposed merger (e.g. contracts, sales and purchase agreements, or offer documents if it is a public bid).

6.1 A copy of the Share Purchase Agreement appears at Annexure C.

7. If any other jurisdiction's competition agency has been (or will be) notified of the proposed merger, please list each competition agency notified (or to be notified) and the date of the notification.

Please indicate whether you would be willing to provide the Commission with a waiver allowing it to exchange confidential information with competition agencies in other jurisdictions in respect of the proposed merger.

For further information on international mergers and waivers, please refer to the Mergers and Acquisitions Clearance Process Guidelines.

7.1 The following jurisdictions' competition agencies have been or are intended to be notified of the Proposed Transaction:

(A) Australia – filing was made with the ACCC on 20 February 2013;

(B) EU – draft Form CFO was submitted with the European Commission on 11 March 2013;

(C) USA – early termination of the waiting period was granted by the FTC on 4 February 2013;

(D) China – filing was made with the Antimonopoly Bureau on 28 December 2012;

(E) Brazil – filing was made on 15 February 2013;

(F) South Korea – filing was made with the KFTC on 19 February 2013;

(G) Canada – filing was made with the CCB on 8 February 2013;

(H) Turkey;

(l) Ukraine.

7.2 Baxter has provided the Commission with a waiver to allow it to exchange confidential information with those competition agencies in other jurisdictions in respect of the Proposed Transaction for whom the Commission has requested waivers.

PART 2: THE INDUSTRY

Goods or services supplied by the merger parties

8. Describe the relevant goods or services supplied by the merger parties (it is sufficient to refer in general terms to activities in which there will be no aggregation).

8.1 See Response to Question 1 and Question 9 below.

Industries affected by acquisition

9. Describe the industry or industries affected by the proposed acquisition. Where relevant, describe how sales are made, the supply chain(s) of any product(s) or service(s) involved, and the manufacturing process. If relevant, provide a glossary of terms and acronyms.

Kidney Disease and Treatments

9.1 The kidneys perform a wide range of vital functions in the human body, including removing waste products and foreign chemicals from the blood, balancing water and electrolyte (salt) concentration, regulating blood pressure and acid-base balance, and producing hormones to support, *inter alia*, red blood cell production and bone strength. Renal Replacement Therapy (**RRT**), a generic term that refers to dialysis, which is an artificial process that performs the key functions of healthy kidneys where a patient suffers kidney deterioration or failure.

9.2 Kidney failure can be the result of a chronic disease (usually occurring gradually over time and resulting in permanent failure – "chronic kidney disease" (CKD)) or of a rapid loss of kidney function (occurring suddenly and being potentially reversible – "acute kidney injury", (AKI)). In either form of failure, the filtering of the blood by the kidneys is either slowed or stopped, causing waste products and other toxic substances to build up in the blood.

9.3 There are various therapeutic modalities available to treat both CKD and AKI. The therapeutic modality best suited for an individual patient will depend on a number of factors including patient's clinical conditions (for example, the stage of the patient's illness, the presence or absence of other diseases or the patient's degree of independence) as well as factors such as resources available at the

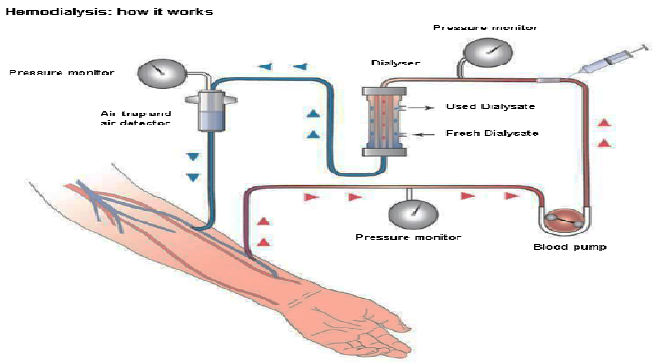
hospital in question, individual preference or expertise of the prescribing physician and familiarity of doctors and staff with particular therapies.[5]

RRT Methods Overview

9.4 All renal replacement therapies – whether for AKI or CKD patients – pursue the same objective: to remove waste substances from the blood and to correct fluid abnormalities associated with renal failure. With the exception of PD, RRT essentially "cleans" the blood by making use of a semi-permeable membrane and takes place outside the patient's body in an extracorporeal circuit.

9.5 *Extracorporeal methods:* are where blood is pumped by a machine (referred to as a monitor) through a dialyser (chronic), or filter (acute), containing a synthetic semi-permeable membrane used to remove the waste substances and toxins, with the 'cleaned' blood then returned to the patient. Blood is removed from the patient either through: (a) a plastic tube (called a central venous catheter) inserted into a large vein in the neck (acute or chronic therapies) or groin (acute therapy); or (b) through a fistula (a surgically created join between a vein and an artery in the arm) and accessed using a fistula needle.

9.6 In extracorporeal methods, the filtering process which takes place outside the body is regulated by the monitor. The blood is drawn intravenously, passes through a membrane device (referred to as a dialyser or filter) and is returned to the body through tubing into a blood vessel. In HD, the dialysate is pumped out to a disposal tank while the cleaned blood is returned to the body. The blood is circulated and diffused numerous times during dialysis and each circulation removes more waste and excess fluids.



Source: European Kidney Patients' Federation[6]

[5] Further discussed at Section 6.

9.7 Principal methods of extracorporeal RRT can be distinguished as follows:

(A) Haemodialysis (**HD**) where the primary mode of clearance of molecules is diffusion (i.e., the movement of solutes from fluid with a high to a low concentration across a semi-permeable dialyser membrane). Dialysate solution flows counter-current to the blood flow in the outer compartment of the dialyser/filter.

(B) Haemofiltration (**HF**), where the primary mode of clearance of molecules is convection (ie. the use of a pressure gradient to remove waste substances). As a result of the pressure gradient arising from additional solution being added to the blood before it enters the filter, water moves across the semi-permeable membrane rapidly "dragging" the unwanted waste substances along with it. Salts and water lost from the blood during this process are replaced with a "substitution fluid" that is infused into the cleaned blood, which is then returned to the patient.[7]

(C) Haemodiafiltration (**HDF**) is a combination of convection and diffusion to move molecules and water across a semi-permeable membrane. The blood is pumped through the blood compartment of the dialyser. Dialysate solution flows counter current to the blood flow in the dialysate compartment of the dialyser. The lost water must be replaced by substitution fluid.[8]

9.8 Acute Kidney Injury (**AKI**)

(A) AKI is a rapid loss of renal function due to damage to the kidneys. AKI occurs in different grades of severity and in its most severe form requires RRT to sustain life while the kidneys recover. AKI usually occurs as a result of a sudden reduction in the blood supply to the kidneys often in the context of a systemic problem affecting other organs following trauma, sepsis or haemorrhage or as the result of problems affecting the kidneys alone (e.g. an inflammatory problem or obstruction). AKI is a relatively common complication in critically ill patients and occurs frequently due to exposure to nephrotoxins, infection, surgery, trauma or hemorrhage. An estimated 5-15% of patients in the intensive care unit (**ICU**) require RRT. Patients suffering from AKI require immediate and intensive supportive treatment until their kidneys recover function. The mortality rate of patients suffering from AKI and requiring RRT is high and may exceed 50%.

(continued…)

[6] European Kidney Patients' Federation. See, www.ceapir.org/wb/media/Renal%20Survey%20Result/Renal%20care%20report%20final.pdf.

[7] HF is one modality of CRRT.

[8] HDF is a modality used by both HD and CRRT.

(B) The principal treatment options for patients suffering from AKI and requiring RRT include continuous renal replacement therapy (**CRRT**) and sustained low efficiency daily dialysis (**SLEDD**).[9]

(C) CRRT is a treatment exclusively used for critically ill patients requiring RRT. It uses the same fundamental principles of diffusion and/or convection to remove toxins and excess water from the blood and the balance the blood's electrolyte (salt) composition. CRRT is however continuous treatment, i.e. it is administered for 24 hours a day over several days and acts in a much slower and more controlled fashion than HD performed on ESRD patients.

(D) CRRT is perfomed in ICUs looked after by intensive care specialists and using equipment specifically designed for this purpose:

(1) a dedicated CRRT monitor[10] (see Gambro's CRRT monitor "Prismaflex" and Baxter's CRRT monitor "Aquarius" below);

Source: Gambro[11]

Source: Baxter[12]

(2) disposables including filters and tubing, which can be provided together as a "set" or as separate items. Ancillary products such as catheters, bags and spikes are also available. Other hardware

[9] The term SLEDD is used by Baxter to cover the treatment option described as intermittent hemodialysis (**IHD**) that is sometimes referred to separately in other jurisdictions. Gambro and other suppliers such as Fresenius prefer to distinguish SLEDD and IHD from each other as IHD is not generally performed by ICU staff.

[10] A large number of different modalities of CRRT can be performed using the same monitor and disposables by simply choosing a different technical setting: CVVHF (continuous venovenous hemofiltration), CVVHD (continuous venovenous hemodialysis), CVVHDF (continuous venovenous hemodiafiltration), SCUF (slow continuous ultrafiltration). The venovenous modalities are most frequently used and adjusted to the patient's condition.

[11] See, www.gambro.com/en/uk/Products/Acute-Care/Acute-Monitors/Prismaflex/.

[12] See, www.baxter.nl/healthcare_professionals/products/aquarius.html.

options can be purchased separately for the Prismaflex machine such as blood warmers; and

(3) fluid solutions that are delivered in ready-to-use bags. CRRT solutions have a specific formulation and will be used in large volumes over the course of a day's therapy. CRRT solutions are not substitutable with solutions used for HD or SLEDD.

(E) The supply of CRRT monitors may often also include the provision of nurse training and technical services, such as installation, maintenance, repair, product adjustments, installation of new components and software upgrades. Monitor suppliers typically offer this type of service for their own products. Third parties are also active in the provision of these technical services, typically for a variety of monitors from different suppliers. In addition, customers may perform the requisite services with their own technical staff

(F) As noted in paragraph 4.8(B) above, another modality of dialysis therapy used in the ICU is "sustained/slow extended daily dialysis" ("SLEDD"[13]). This uses a conventional HD machine[14] for the treatment of AKI (for instance, in New Zealand Baxter understands that the Middlemore ICU uses SLEDD exclusively not CRRT). SLEDD runs for prolonged periods (typically 8 to 10 hours), with low blood pump speed and lower dialysate flow compared to standard HD. Treatments are intermittent but usually daily.

(G) In hospital ICUs, patients with acute kidney injury may be treated with any of these types of dialysis, depending on individual patient condition and available hospital infrastructure.

9.9 Chronic Kidney Disease (**CKD**)

(A) CKD occurs when the kidneys gradually lose their function over a period of months or years. Common causes for CKD include diabetes mellitus, arterial hypertension and glomerulonephritis. In December 2010, there were 2,378 patients receiving dialysis treatment.[15]

(B) There are various stages of CKD. In many patients, CKD progresses to what is known as end-stage renal disease (**ESRD**), when the damage done to the kidneys is irreversible and dialysis (or a kidney transplant) is required to replace the lost function of the kidneys.

[13] Also known as sustained low-efficiency daily dialysis or extended daily dialysis (EDD).

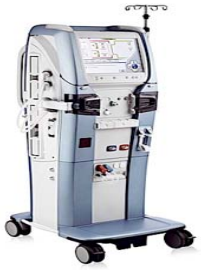
[14] Or CRRT monitor.

[15] Australian and New Zealand Dialysis & Transplant Registry 2011 Annual Report, available at: http://www.anzdata.org.au/v1/annual_reports_download.html. Baxter is not aware of equivalent statistics for acute patients.

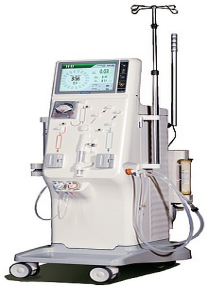
(C) The primary treatment options for CKD patients are HD and PD. The decision as to what type of dialysis therapy to use for a CKD patient is generally determined by the treating physician (usually a nephrologist) along with the patient depending upon, *inter alia,* individual patient condition and available hospital or treatment center resources.

(D) A typical HD treatment lasts approximately 4 hours and is usually performed on average three times a week. The equipment required to perform HD (and HDF) comprises:

(1) a monitor (machine) to choose the required settings for the treatment and to supervise the treatment (mostly the same monitors can be used for HD and HDF (if using HDF an additional pump is required);



Source: Gambro[16]



Source: Nikkiso[17]

(2) a dialyser that contains a membrane is used to clean the blood;

Source: Gambro;[18] Fresenius.[19]

(3) bicarbonate powers, concentrates and purified water are used to

[16] See, www.gambro.com/en/uk/Products/Hemodialysis/Monitors/Artis/.

[17] See, www.nikkiso-europe.eu/pr_details.html?&no_cache=1&L=1&tx_ttnews[backPid]=289&tx_ttnews[tt_news]=31016&cHash=535d47d03e49450cf24a7b9842f422fe.

[18] See, www.gambro.com/en/uk/Products/Hemodialysis/Dialysers/Polyflux-H-series/.

[19] See, www.Freseniusna-dialysers.com/hemoflow.html

prepare dialysate and, in some cases (HDF), replacement fluid,

Source: Gambro;[20] B. Braun.[21]

(4) tubing is used to connect the patient's bloodstream (via a fistula needle or catheter) to the machine; and

Source: Gambro;[22] B.Braun.[23]

(5) other ancillary products such as catheters (used until a fistula is ready to use) and needles, to establish vascular access. Dialysers, tubing and other ancillary products are often referred to

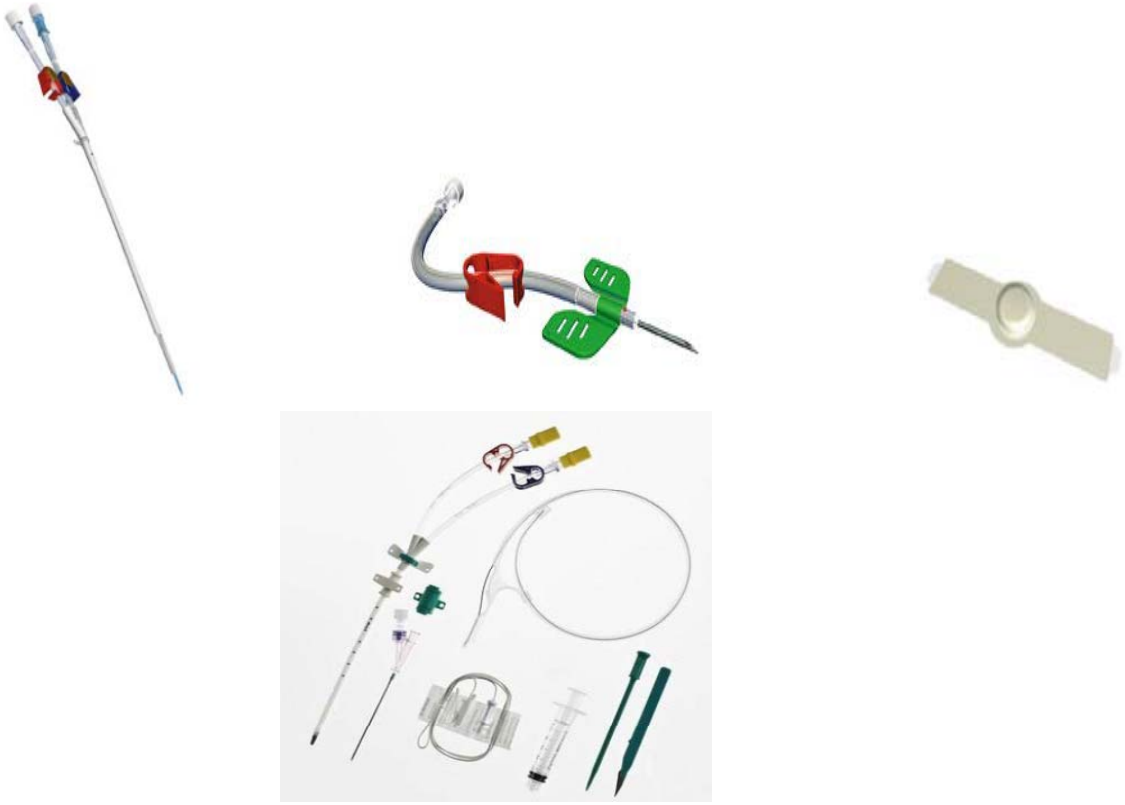
[20] See, www.gambro.com/en/uk/Products/Hemodialysis/Concentrates/BiCart/; www.gambro.com/en/Germany/Produkte/Haemodialyse/Konzentrate/SelectBag_One/.

[21] See, www.bbraun.de/cps/rde/xchg/bbraun-de/hs.xsl/products.html?id=00020741570000000451&prid=PRID00003984

[22] See, www.gambro.com/en/uk/Products/Hemodialysis/Bloodlines/Artiset/?tab=documentTab#tabList.

[23] See, www.bbraun.de/cps/rde/xchg/bbraun-de/hs.xsl/products.html?id=00020741570000000455 &prid=PRID00005283

together as disposables/consumables.



Source: Gambro,[24] B. Braun.[25]

(E) As with CRRT, the supply of HD monitors often also includes the provision of nurse training and technical services, such as installation, maintenance, repair, product adjustments, installation of new components, and software upgrades. Monitor suppliers typically offer this type of service for their own products. Third parties are also active in the provision of technical services, typically for a variety of monitors from different suppliers. In addition, customers may perform the requisite services with their own technical staff.

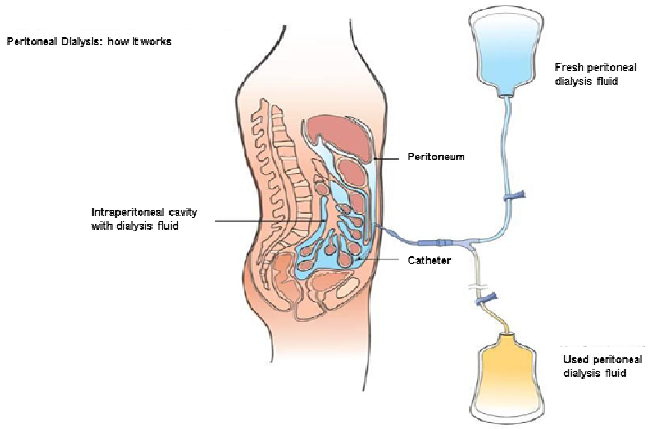
(F) HD treatments are usually performed at specialized hospitals, dialysis centers or in the patients home (referred to as Home Hemodialysis (**HHD**)). Monitors used in HHD are either the same or essentially the same as used for in-centre HD, with only minor modifications (such as an adjustable screen that faces the patient rather than the nurse or pre-configured treatment settings for safe and simple use). HHD may

[24] See, www.gambro.com/en/uk/Products/Vascular-Access/.

[25] See, www.bbraun.de/cps/rde/xchg/bbraun-de/hs.xsl/products.html?id=000207415700000004 54&prid=PRID00004008.

increase in the future, in particular because of improved clinical outcomes with more frequent, high dose and longer sessions at home, improved patient functional status and potential cost savings compared to "in-centre" treatments.

(G) PD cleans the blood without removing it from the body. Dialysate, made up mostly of salts, water and sugar (glucose), is injected into the peritoneal space in the abdomen through a two-way catheter. The membrane that lines the abdomen (the peritoneum) acts as a natural filter, allowing waste and fluid to pass from the blood into the dialysate, which is then pumped out of the abdomen. Typically, PD exchanges roughly two litres of dialysate while the person is active, three to six times a day. The patient connects a bag of dialysate fluid to a catheter in the abdomen. After the dialysate filters for 4 to 6 hours, the patient exchanges it for fresh fluid.



Source: European Kidney Patients' Federation[26]

(H) In one form of PD called Continuous Ambulatory PD (**CAPD**) (shown in the diagram above), patients generally complete four manual bag exchanges of fluid every day. Automated PD (**APD**) is another form of PD in which the exchanges are performed by a small pumping machine at night while the patient is asleep.

(I) The equipment required to perform PD consists of:

(1) a catheter to insert fluid in the peritoneum,

(2) dialysate fluid in bags,

(3) a bag warmer to bring the fluid to body temperature, and

[26] European Kidney Patients' Federation. See, www.ceapir.org/wb/media/Renal%20Survey%20Result/Renal%20care%20report%20final.pdf.

(4) a small pumping machine in the case of automated PD.

Source: Baxter[27]

Source: Baxter[28]

(J) PD was used to treat 36% of all dialysis patients in New Zealand in 2010.[29]

Overview of the Parties' RRT activities in New Zealand: CRRT

9.10 As discussed above, Baxter Australia manufactures its own CRRT fluids in Sydney and imports these to New Zealand, other than two solutions that are manufactured by Baxter in Castlebar, Ireland and imported. The other CRRT products supplied by Baxter in New Zealand are manufactured by third parties and imported as follows:

(A) the Aquarius machine, which is manufactured by Nikkiso Europe and imported from Germany;

(B) tubing, which is manufactured by Hemotronic and imported from Italy;

(C) filters, which are manufactured by Bellco and imported from Italy;

(D) waste bags, spikes and adaptors, which are manufactured by Hemotronic and imported from Italy; and

(E) catheters, which are manufactured by MedComp and imported from the USA.

9.11 In contrast, Gambro manufactures its own CRRT machine (the Prismaflex), fluids and disposables and imports these for sale in New Zealand.

Overview of the Parties' RRT activities in New Zealand: HD

9.12 The HD products supplied by Baxter in Australia are manufactured by third parties as follows:

[27] See, www.baxter.com/downloads/patients_and_caregivers/therapies/renal/bplpc.pdf.

[28] See, www.baxter.com/patients_and_caregivers/therapies/renal/home_dialysis/peritoneal_dialysis.html.

[29] Australian and New Zealand Dialysis & Transplant Registry 2011 Annual Report

(A) machines and tubing are manufactured by Nikkiso Japan in Tokyo;

(B) dialysers are manufactured by Nipro in Japan (are Baxter labeled); and

(C) concentrates are manufactured by Fresenius Medical Care (**Fresenius**) in Australia.

9.13 Baxter currently has no HD machine or consumables footprint in New Zealand.

9.14 Gambro manufactures its own HD products and imports these to New Zealand**.**

Overview of the Parties' RRT activities in New Zealand: PD

9.15 Baxter manufactures the majority of its own PD products (machines, disposables and fluids) and supplies these in New Zealand. Gambro divested its PD business to Fresenius in 2010 and is not active in the PD space**.**

Industry trends

10. Describe the current industry trends and developments including the role of imports and exports, emerging technologies, and/or changes in supply and demand dynamics.

10.1 See Section 9 above regarding a possible trend towards HHD. As discussed in the competitors section below, there are a significant number of international manufacturers and suppliers of CRRT and HD products that are active globally and have already commenced supply (whether directly or through distribution channels) in ANZ.

10.2 The industry is dynamic and permits new competitors with innovative technologies to make significant inroads in the market, as with NxStage and TeckMed described in the competitors section below. An example of this relates to the delivery of CRRT to critically ill neonates and children, which is currently performed by adapting adult systems to the much smaller paediatric and neonatal population. This is a clinical and technological challenge, particularly for children weighing less than 10 kg. The CA.R.PE.DI.E.M. (Cardio-Renal Pediatric Dialysis Emergency Machine) has been developed as part of a project conducted by the Department of Nephrology and International Renal Research Institute of the San Bortolo Hospital in Vicenza, to provide neonates and infants with a reliable dialysis machine that is specifically designed for this age group. The actual apparatus was built in Mirandola, Italy with the collaboration of two Italian industrial companies (Bellco and Medica). The machine has received

European Union certification and once the other development steps are achieved is likely to have a significant impact on the renal industry.[30]

Recent mergers

11. Please highlight any relevant mergers that have occurred in this industry over the past three years. Include:

- any acquisition of assets of a business or shares which the merger parties (or any interconnected or associated businesses) have undertaken in the last three years.

11.1 As discussed elsewhere in this Submission, Baxter acquired Edwards in 2009 and Gambro divested its PD business to Fresenius in 2010.

11.2 Baxter acquired from HHD, LLC the assets associated with DEKA Research & Development & Development Corp.'s ("DEKA") development of a next-generation home hemodialysis monitor in 2011.

PART 3: MARKET DEFINITION

Horizontal Aggregation

12. For each area of aggregation of market shares, please define the relevant market(s) for the:

- product(s) or service(s);
- functional level;
- geographic area; and
- customer dimension and timeframe (if relevant).

12.1 The two key considerations when establishing the relevant market(s) are the product dimension and the geographic dimension and each is dealt with in turn below.

Product market, services and customer dimension

[30] Ronco, C., Garzotto, F. & Ricci, Z. (2012). CA.R.PE.DI.E.M. (Cardio-Renal Pediatric Dialysis Emergency Machine): evolution of continuous renal replacement therapies in infants. A personal journey. Retrieved from: http://www.bellco.net/public/allegati/PDF/Abstract_articoli/Carpediem_evolution.pdf.

12.2 Under Australian and New Zealand law, the relevant product market has been described as follows[31]:

> *Within the bounds of a market there is substitution--substitution between one product and another, and between one source of supply and another, in response to changing prices. So a market is the field of actual and potential transactions between buyers and sellers amongst whom there can be strong substitution, at least in the long run, if given a sufficient price incentive. Let us suppose that the price of one supplier goes up. Then on the demand side buyers may switch their patronage from this firm's product to another, or from this geographic source of supply to another. As well, on the supply side, sellers can adjust their production plans, substituting one product for another in their output mix, or substituting one geographic source of supply for another. Whether such substitution is feasible or likely depends ultimately on customer attitudes, technology, distance, and cost and price incentives.*
>
> *It is the possibilities of such substitution which set the limits upon a firm's ability to "give less and charge more". Accordingly, in determining the outer boundaries of the market we ask a quite simple but fundamental question: If the firm were to "give less and charge more" would there be, to put the matter colloquially, much of a reaction? And if so, from whom? In the language of economics the question is this: From which products and which activities could we expect a relatively high demand or supply response to price change, i.e. a relatively high cross-elasticity of demand or cross-elasticity of supply?*

12.3 From a practical perspective, the first consideration is usually a technical one: to what extent is it technically possible to switch between two available products? Where it is technically possible to switch, the second consideration is an economic one: if the supplier of a particular product were to raise the price of that product, would a sufficient number of buyers and sellers switch their purchasing or production choices to make the price increase unprofitable?

12.4 Considering first the choices that patients might make instead of renal replacement therapies, educational material provided by Baxter to patients[32] acknowledges that some patients with chronic kidney failure choose to opt for what is known as “conservative management” (which means choosing to manage only the symptoms of kidney disease with the almost inevitable consequence that the body will cease to function in a relatively short period of time). The material also explains that some patients seek, and are lucky enough to obtain, a suitable kidney transplant – usually after years of renal therapy. Due to these characteristics, neither conservative management nor kidney transplantation are close economic substitutes for renal replacement therapies and neither of them are likely to fall within the same market or markets in which renal therapies are supplied. Patients with acute kidney failure have no effective option other than renal replacement therapy and are often too unwell to participate in the clinical decision making process (in contrast to CKD).

[31] ACCC v Liquorland (Australia) Pty Ltd (2006) ATPR 42-123 at p440

[32] Provided with this submission.

12.5 Within the universe of products sold for use in renal replacement therapies, a number of distinctions can be observed:

(A) The products are used for specific modes of therapy that differ by technique, location and equipment type: PD, HD and CRRT;

(B) The products may be used in hospitals, clinics or within the home[33] ;

(C) Patient characteristics can vary in ways that can influence the choice of treatment:

(i) kidney disease is *chronic* and kidney injury *acute*;

(ii) other medical characteristics of the patient can be relevant (for example whether or not a particular patient has other ongoing medical conditions); and

(iii) non-medical characteristics of the patient, in a chronic setting can be relevant (for example if they have a significant fear of needles or they live a long way from the nearest medical facility treating kidney patients and therefore prefer a home based therapy).

(D) Each treatment uses several items which can be procured separately or together. PD, HD and CRRT each use a machine, CAPD uses a bag warmer, all treatments involve consumables (which principally comprise a tubing set, dialyser, concentrate, bicarbonate powers for HD and a tubing set, filter, waste bags, spikes and fluids for CRRT). Access to the patient's bloodstream is required before a therapy can commence and catheters (acute and chronic) or fistula needles are used.

12.6 The above distinctions do not necessarily delineate separate markets for competition law purposes. Rather, the primary question that determines whether a separate market exists on the basis of any of the above distinctions is whether or not there is sufficient supply and/or demand side substitution between the distinct groups for any of them to constitute separate markets. There does not need to be complete substitution between the different categories to fall within the one market. Rather, a single market exists if there is enough substitution to make a price rise by a hypothetical monopolist supplying only one of the distinct categories unprofitable.

12.7 Distinguishing between CKD and AKI may not be particularly helpful in approaching product market definition as the same type of equipment (HD) can be used to treat either condition, albeit using slightly different methods. The underlying medical problem – kidney failure – is the same in chronic and acute patients, and – except for PD – the same fundamental principles of diffusion and/or convection to remove toxins and excess water from the blood and to balance the blood's electrolyte (salt) composition are used no matter whether a patient is suffering from CKD or AKI

[33] CRRT is conducted in ICUs and CRRT products are not used in the home.

12.8 Although HD machines are mostly used for chronic patients, the same equipment that is used to treat chronic HD patients – HD monitors, dialysers, fluids and ancillary products such as catheters – are used for SLEDD, which refers to modalities of HD in an acute setting. Although it should be noted that some suppliers such as Gambro do not promote or otherwise support the use of HD monitors for AKI patients. The AKI treatments using HD simply differ in terms of duration and frequency from the CKD treatments using HD, if at all.

12.9 Some suppliers of RRT equipment – other than Baxter or Gambro – have even begun explicitly to promote HD treatment systems as crossing the divide between CKD and AKI. For example, Fresenius explicitly stresses that its Genius HD monitor can be used for the management of AKI and CKD patients alike and in a variety of clinical environments, including in the ICU[34] (although Baxter is not aware whether the Genius monitor is available in ANZ at this stage). Its tank is filled with a large fixed volume of ultrapure water, and the machine can then easily be moved to where it is intended to be used. The Genius machine can deliver HD therapy over 4 hours (the standard duration for the treatment of CKD patients) or over 8 hours or more (i.e., a duration commonly used in SLEDD). It is user-friendly and treatment can, with minimal guidance from a specialised dialysis nurse, be monitored by ICU nurses as well. Similarly, the U.S. company NxStage offers an HD monitor that was originally intended primarily for home HD use and in Australia and New Zealand is only promoted for that purpose, but in other countries "*is indicated for the treatment of acute and chronic renal failure or fluid overload using hemodialysis with or without ultrafiltration, in an acute or chronic care facility*"[35] (emphasis added). Against this background, it makes more sense to focus on the different forms of treatment (CRRT, HD, PD), notably since the substitutability between them is limited.

Demand Side Substitution

12.10 The discussion below focuses on the extent of demand side substitution between different forms of treatment (CRRT, HD, PD).

(A) CRRT vs. HD

[34] "*GENIUS® 90-Therapie-System für die akute und chronische Hämodialyse […] Das neue GENIUS®90-Therapie-System ermöglicht die sichere und effiziente Durchführung nachfolgender Therapieverfahren in der chronischen Zentrumsdialyse oder im Intensivbereich: Intermittierende Hämodialyse (HD); Langsame verlängerte tägliche Dialyse (SLEDD); Langsame kontinuierliche Ultrafiltration (SCUF) […] Neben der Behandlung von Patienten mit chronischem Nierenversagen können mit dem GENIUS®-Therapie-System auch Patienten mit akutem Nierenversagen (ANV) behandelt werden*", see, http://www.Fresenius-deutschland.com/files/GENIUS90_FolderD.pdf.

Own translation: "*GENIUS® 90 therapy system for acute and chronic hemodialysis [...] The new GENIUS®90 therapy system allows the safe and efficient administration of the following therapies for chronic in-center dialysis or for the acute care setting: intermittent hemodialysis (HD); slow extended daily dialysis (SLEDD); slow continuous ultrafiltration (SCUF) [...] The GENIUS® 90 therapy system cannot only be used to treat patients suffering from chronic renal failure, but also for patients suffering from acute renal failure (ARF).*"

[35] See, www.nxstage.com/homehemodialysis/products/the-system-one-cycler.

(1) CRRT is a more recently developed therapy, which is primarily used for acute patients in the ICU. The therapeutic advantages of CRRT are that it removes fluid on a continuous basis, which results in greater haemodynamic stability (i.e., better maintenance of blood pressure) and better control of fluid balance, and that large fluctuations and fluid shifts are avoided. Advantages of HD (used in the form of SLEDD for AKI patients) is the daily restricted treatment period, which allows time for diagnostic and therapeutic interventions between sessions.

(2) *Different decision-makers with different preferences*. The physician that decides on the treatment of acute kidney failure often differs for CRRT or SLEDD. The question as to who takes the decision can depend on the location of the patient when the kidney condition is diagnosed. If the patient is in a general (renal/surgical) ward and not critically ill, the nephrologist will be the key decision-maker and the patient will most likely be treated with IHD/SLEDD. If AKI occurs in a critically ill patient in the emergency room or ICU, the intensivist will decide to initiate RRT. These patients will more often than not be treated with CRRT. CRRT is only administered in an intensive care setting under the direction of an intensivist. Once the patient's condition is stable they are discharged from the ICU and if there renal function has not returned and they require further RRT, IHD may well be administered.

(3) *Different medical indications*. The KDIGO[36] clinical guidelines for acute kidney injury[37] suggest that CRRT rather than IHD or SLEDD should be administered to haemodynamically unstable patients[38] and for patients with increased intracranial pressure or brain edema. Such patients represent approximately 50% of AKI patients. Other patients could be treated with either CRRT or IHD/SLEDD, depending on the equipment available at the hospital or the ward where the patient is treated.

(4) *Different products*. HD treatment systems and CRRT treatment systems both consist of monitors, disposables (including dialysers/filters, tubing and certain ancillary products, e.g., vascular access, see above), and fluids and essentially perform a similar function, i.e., cleaning the blood and removing excess fluids. However, monitors cannot be used to perform both HD and

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36 Kidney Disease: Improving Global Outcomes, a global non-profit organization.

37 See, http://www.kdigo.org/clinical_practice_guidelines/AKI.php.

38 Hemodynamic instability refers to a reduced blood pressure (hypotension), which may require the use of supportive medication (vasopressors). In essence, hemodynamic instability can be seen as the collapse of the cardiovascular system. This collapse is manifested clinically by a significant drop in blood pressure.

CRRT. HD fluids (solutions and concentrates) differ from the replacement fluid used in CRRT (both in terms of composition and in form of delivery (CRRT: fluids in ready-to-use bags; HD: concentrates in bottles or bags)). CRRT filters are normally not interchangeable with HD dialysers in practice. However, an adaptor can be procured but this can be inconvenient and there is the cost of the adaptor. CRRT tubing tends to be specifically designed for a particular monitor or integrated with the filter systems (as in the case of Gambro's CRRT systems) and cannot be used with HD equipment or competitors' CRRT systems.

(5) *Cost differences*. It is very difficult to make cost comparisons in New Zealand because the total cost of a treatment is a function of price of the items purchased for each therapy, the quantities used and different cost of other items used along with the therapies such as medicines. However, in the parties' experience, clinical considerations are more important than cost differences.

(6) *Separate tenders.* Dialysis equipment in New Zealand is almost exclusively procured by DHB's through tenders. In the Parties' experience, CRRT and HD equipment is typically procured in separate tenders. The installed equipment base at a given customer also influences the purchasing pattern. Some tenders are only for upgrading an existing system. In that case, products of the other treatment method are not an alternative. A summary of the tenders in which the Parties participated since 1 January 2010 are attached as Annexures D and E.

(B) CRRT vs. PD

(1) In New Zealand, CRRT is only used to treat AKI (or in some cases ESRD patients admitted to an ICU) and PD is only used for CKD.[39] There is therefore no demand-side substitutability.

(C) HD vs. PD

(1) Both HD and PD are used to treat CKD patients including those suffering from ESRD. Overall, HD and PD are equivalent in terms of patient survival.

(2) The choice between HD and PD is based on the clinical status and needs of the patient, but also on factors such as total cost and the resources available, the individual preference or expertise of the prescribing physician, and the familiarity of doctors and staff with a particular therapy. There is a broad range of factors that have to be taken into account by healthcare professionals to

[39] The Parties estimate that PD is only used in 2-3% of AKI cases, for example where no vascular access can be established or anti-coagulation is not possible, or in small children.

assess individually for every patient which modality is the most suitable.[40]

(3) *Limited suitability for certain patients*. Not all ESRD patients are suitable candidates for both types of therapy. Around 10% of ESRD patients are not suitable for HD therapy and around 15% of ESRD patients are not suitable for PD therapy. Patients who cannot use HD include, for example, those with (i) lack of vessels for vascular access, (ii) severe angina,[41] and (iii) severe heart failure and low blood pressure. Patients who cannot use PD include those with (i) colostomy, [42] (ii) ileostomy, [43] (iii) ileal conduit,[44] and (iv) intra-abdominal adhesions[45]. Other challenges for HD (but which do not wholly preclude its use) are, for example, (i) long distance from the HD unit, (ii) severe vascular disease,[46] and (iii) active diabetic retinopathy,[47] while for PD, a patient's lack of suitable housing and cognitive dysfunction can be challenges. Beyond medical suitability, some patients prefer to be treated with HD at a dialysis center with the treatment performed by a nurse. Other relevant factors are mobility (PD is typically a home dialysis program, whereas HD normally requires the patient to travel to a dialysis center three times per week),[48] housing, family or social support,[49] work,[50] and co-existent vascular disease[51] or respiratory disease.[52]

[40] For a comprehensive overview, see, Levy/Morgan/Brown, Oxford Handbook of Dialysis (2009), p. 48 *et seq*.

[41] Angina (angina pectoris) is chest pain that occurs when the heart is not getting enough blood, typically as a result of arteriosclerotic vascular disease (when plaque builds up inside the coronary arteries).

[42] An artificial opening that connects the end of the colon (large intestine) to the surface of the abdomen.

[43] An artificial opening that connects the end or loop of the ileum (small intestine) to the surface of theabdomen.

[44] Creation of a urine reservoir from a segment of small intestine, which connects to the surface of the abdomen.

[45] Bands of fibrous scar tissue that form between structures in the abdominal cavity, *e.g.*, related to prior abdominal surgery.

[46] Diseases that affect the circulatory system.

[47] Damage to blood vessels inside the eye as a complication of diabetes.

[48] If hospital transport is needed for HD, this greatly increases hours spent away from home. PD is not suitable for patients with limited mobility, unless they have support to help carry out PD. With respect to travel, HD requires arrangements with the local HD unit, while PD patients can carry on independently and PD fluid can be delivered to most parts of the world.

[49] PD patients benefit from support at home, in particular if they need assistance. Support is also important for compliance with dietary restrictions, and transport to hospital for HD sessions.

[50] Many patients working full-time opt for PD or HD at home or overnight in the hospital.

(4) *Different products*. As outlined above, an HD treatment system essentially consists of a monitor, disposables (including a dialyser, tubing, and certain ancillary products, *e.g.*, vascular access) and fluids.[53] For APD a machine is used but it is not interchangeable for HD machines. In CAPD, fluids are the principal products, and no monitors or dialysers are used but a bag warmer can be used. The fluids are supplied in the form of ready-to-use solution bags, come in sets (solution bag and drain bag) and with lines attached or – alternatively – with short lines and a connector that fits to the PD cycler. None of the products used in PD – PD solutions, disposables (like transfer sets, clamps, bag warmers) and, in the case of APD, a cycler machine – have any use in HD or CRRT.

(5) *Different delivery infrastructure*. PD principally takes place at the patient's home – with hospital staff involvement limited e.g. requiring generally only 1 or 2 nurses. In contrast, HD is more resource intensive for hospital renal units or dialysis clinics – requiring a larger number of medical staff to enable continual shifts throughout the week to enable a larger patient pool to visit the renal unit for their HD throughout the week.

(6) *Different clinical preferences.* In the Parties' experience, within the medical community there are distinct preferences by nephrologists and renal nurses as to the use of PD or HD. For example, during their clinical training, they may have had greater exposure and frequency of use of PD or HD – which is likely to influence their practice and suggested course of treatment for a CKD patient.

(7) *Cost differences*. Cost comparisons are difficult to make in New Zealand for the same reasons as they are between CRRT and HD. Although clinical considerations are also important, hospitals are more likely to consider cost savings when choosing between PD and HD than they are when choosing between CRRT and PD..

Supply Side Substitution

12.11 The discussion below focuses on the extent of supply side substitution between different forms of treatment (CRRT, HD, PD).

(A) CRRT vs. HD

(continued…)

[51] For patients with ischemic heart disease (reduced blood supply to the heart muscle), HD might result in hypotensive episodes causing angina or myocardial infarction. Arterial access for HD might be difficult to establish in patients with arterial disease.

[52] Patients with severe respiratory problems may tolerate excess fluid in PD less well.

[53] In addition, pure and pre-treated water is required to prepare the fluid.

Tubing is imported into New Zealand from manufacturers overseas. The same production facilities can be used to produce tubing for use in CRRT and HD. The same production lines can produce CRRT fluids and HD concentrates although HD concentrate production by Baxter ceased two years ago. Both types of fluid may be put in the bags made at the same facility but HD concentrates typically are packaged in bottles.

(B) CRRT vs. PD

Machines and tubing are imported into New Zealand from manufacturers overseas. The same production lines cannot be used to produce CRRT and PD machines but the same production facilities can be used to produce tubing for use in CRRT and PD. The same production lines can produce CRRT fluids and PD fluids. Both types of fluid may be put in the bags made at the same facility.

(C) HD vs. PD

Baxter's own APD machine and tubing are imported into New Zealand by Baxter (Gambro does not have a PD business). CAPD does not require a machine but uses bag warmers that Baxter also imports from Nikkiso. Baxter imports third party HD machines and tubing from manufactures overseas and Gambro imports its own HD products into New Zealand. The same production lines cannot be used to produce APD and HD machines but the same production facilities can be used to produce tubing for use in PD and HD. The same production lines can produce PD fluids and HD fluids although HD production by Baxter ceased two years ago. Both types of fluid may be put in the bags made at the same facility but HD concentrate may also be packaged in bottles.

12.12 Obtaining data as to the proportion of patients for which substitution between brands is technically and economically feasible is a difficult task. Baxter will endeavour to compile such data and provide it to the NZCC if it is available.

Conclusion as between therapy types

12.13 For the reasons set out above, this Submission focuses on the areas in which there is an over-lap between Baxter and Gambro, those being each of (i) HD and (ii) CRRT, and demonstrates that there will not be any significant lessening of competition for the supply of either of them.

No separate components markets.

12.14 The equipment used to perform CRRT and HD treatments comprises various components, which can be grouped into the segments (i) monitors, (ii) disposables, and (iii) fluids. In PD, a distinction can be made between cycler machines (for APD only), bag warmers (CAPD only), disposables/accessories, and fluids. The components are briefly described below.

12.15 From a demand side perspective, monitors, tubing, filters, dialyzers, fluids and

concentrates cannot be substituted between use for PD, HD and CRRT respectively. However, within each of these therapies the situation is more complex. Certain consumable items are, and others are not, substitutable between brands of monitor within a therapy. The relevant demand side substitution possibilities are set out below:

Compatibility of dialyzers and bloodlines with CRRT monitors:

GENERAL PRODUCT COMPATIBILITY CRRT	
Compatibility of CRRT monitors with other suppliers' sub-components	
Bloodlines and dialyzer sets	-[54]
Vascular Access	✓
Fluids	✓

Compatibility of dialyzers and bloodlines with HD monitors:

GENERAL PRODUCT COMPATIBILITY HD	
Compatibility of HD monitors with other suppliers' sub-components	
Bloodlines	✓[55]
Dialyzer	✓
Vascular Access	✓
Fluids	✓[56]

Compatibility of dialyzers and bloodlines with APD or CAPD machines:

[54] Only one manufacturer offers a monitor that is compatible with the sets of another manufacturer.

[55] While dedicated bloodlines are not substitutable with each other and not compatible with other monitors, suppliers typically sell a range of dedicated bloodlines for various monitors. For example, Nipro makes bloodlines for several different brands of machine.

[56] Only few manufacturers offer a monitor that is only compatible with their own fluids or the fluids of some of their competitors.

GENERAL PRODUCT COMPATIBILITY APD	
Compatibility of PD pump machines with other suppliers' sub-components	
Tubing	-[57]
Fluids	-[58]

GENERAL PRODUCT COMPATIBILITY CAPD	
Compatibility of PD bag warmers with other suppliers sub-components	
Tubing	✓
Fluids	✓

12.16 From a supply side perspective, manufacturers of tubing (e.g. Nipro), fluids (e.g. Baxter) and vascular access products can switch between supplying different brands of machine within a therapy and between manufacturing products used in different therapies. The manufacturers of concentrates, filters and dialyzers can substitute between the supply of products within the respective therapy.

12.17 Baxter takes the view that it would not be appropriate to treat the individual components of each CRRT, HD and PD as separate markets. As noted above, the primary test for whether different products are in the same market is whether they are supply or demand side substitutable. However, closely complementary products can also be in the same market if:

(D) there are significant economies for the supplier or the customer that they be purchased together in the one transaction; or

(E) even if they are not purchased in a single transaction, if the predominant form of competition occurs as customers choose between the total life cycle costs of using one branded system of machines and other products used with it compared with another branded system of machines and other products used with it.

12.18 Baxter submits that it would not be appropriate to treat the individual components of each of CRRT, HD and PD as separate markets.

12.19 *Suppliers tend to offer all components*. Typically, CRRT suppliers offer all (or most) CRRT components, HD suppliers offer all (or most) HD components, and

[57] These tubing sets are specific to the machine of a particular manufacturer, *i.e.*, the tubing sets provided by one supplier cannot be used with the machine from another supplier

[58] PD bags, transfer sets and caps are manufacturer-specific, and manufacturers recommend the use of their fluids with their machine and transfer sets, but patients can connect their catheter to other suppliers' transfer sets and therefore different bag systems. Alternatively, if the transfer set is from another supplier than the PD bags, adaptors exist to match the differing connectors.

PD suppliers also offer all (or most) PD components. If they do not manufacture one or more of these, they are able to procure them from third parties, although it is not necessary for suppliers to offer all components to compete. However, there are examples of some firms who do not manufacture machines but who manufacture most major brands of tubing and dialysers.

12.20 *Framework agreements and Price-Per-Treatment contracts*. For chronic HD, hospitals and other purchasers often do not purchase monitors, disposables and fluids separately, but enter into "price per treatment" contracts with suppliers or agreements by which machines are loaned by the manufacturer on condition that tubing, dialysers, filters or fluids are purchased from the same supplier.[59] In the former case, the agreement covers both the sale (or lease, Baxter will have the equipment on loan or placement or short term rent) of the monitor as well as the supply of disposables and fluids for a certain period of time.

12.21 Nonetheless, the Parties will provide separate data for PD, HD, CRRT and within those therapies (i) machines for HD, PD and CRRT, (ii) disposables for PD, HD and CRRT and (iii) fluids for PD, CRRT and HD, respectively.

Geographic market

12.22 The products in this case are internationally traded:

- No HD, PD or CRRT machines are manufactured in New Zealand. Baxter's CRRT machine, for example, is imported from Germany and Gambro's is imported from Sweden. The HD machine supplied in New Zealand by Baxter is purchased from Nikkiso in Japan and Gambro imports its HD monitors from Italy and Sweden.
- The consumables sold in New Zealand are also wholly imported with, for example, Baxter's tubing, filters and dialysers imported from Italy and Gambro's 'kits' imported from its manufacturing facilities outside New Zealand.
- All manufacturers import the full range of fluids to New Zealand. Baxter transports its most common types of fluids from its facility near Sydney in NSW throughout Australia and to neighbouring countries such as New Zealand and various other pacific nations.
- There is an even closer link within Baxter's Australian and New Zealand business which is managed as an integrated business.

12.23 The fact that there is so much international trade and no items manufactured in New Zealand demonstrates that the competitive constraints upon the Australian and New Zealand business include the potential for competition from suppliers located throughout the world.

12.24 Nevertheless, Baxter anticipates that the NZCC would also likely request data on

[59] In some cases the contract provides that the ownership of the machine transfers to the hospital after a certain quantity of fluids or tubing has been purchased.

the current New Zealand sales shares and, because this is a merger of Trans-Tasman Effect, combined Australian and New Zealand figures are provided. In providing these figures, Baxter considers that they should be given less weight in the NZCC's analysis than the global figures.

Functional Dimension

12.25 Both Gambro and Baxter distribute HD and CRRT machines, bloodlines, filters/dialysers and fluids manufactured by third parties, although Gambro manufactures the vast majority of its own products. In the case of Baxter, a minor exception to this is in relation to CRRT fluids which Baxter both manufactures and distributes.

Temporal Dimension

12.26 As discussed in the customer section below, this is a tender based industry and the awards typically last approximately 5 years. For this reason, the temporal dimension is the forward looking 5 year period.

Summary

12.27 This Submission presents estimates for each of the areas of overlap between Gambro and Baxter, being the Australia & New Zealand combined figures and New Zealand sales in, 2010, 2011 and 2012 of[60]:

- CRRT machines;
- CRRT disposables (tubing and filters);
- CRRT fluids;
- HD machines;
- HD tubing;
- HD dialysers; and
- HD concentrates.

12.28 Nevertheless, there are concurrent competitive constraints within, between and beyond these industry segments.

13. Where relevant, please explain how products or services are differentiated within

[60] Figures are not presented for vascular access because these product lines are less concentrated than for the other categories of products shown and the value of sales is lower than these categories. As well as the principal brands of renal therapies, other companies such as Arrow, Covidien, Medcomp, Bard/Vascath and Vygon supply these products.

the market(s).

For further information on market definition and differentiated products, please refer to Part 3 of the Mergers and Acquisitions Guidelines.

13.1 The products are all branded technology products, the closest fields of competition are between suppliers of HD therapies inter se and CRRT therapies inter se. Nevertheless, there are significant brand differences. For instance, refer to the issues particular to Baxter's Aquarius machine identified in paragraphs 4.10 and 4.11 above.

Vertical Integration

14. Provide details of any creation or strengthening of vertical integration that would result from the proposed merger. Please use organisational charts or diagrams to illustrate the structure of the ownership and/or control of the participants and the vertical relationships in question.

For further information on vertical integration, please refer to Part 10.1 of the Mergers and Acquisitions Guidelines.

14.1 No significant vertical effects

PART 4: COUNTERFACTUAL

15. In the event that the proposed merger does not take place, describe what is likely to happen to the business operations of the merger parties and the market/industry.

For further information on the counterfactual, please refer to Part 4 of the Mergers and Acquisitions Guidelines.

15.1 Within the relevant timeframe identified above, Fresenius is likely to remain the leader in HD sales and Gambro is likely to remain the leader in relation to CRRT. **[ ]**

PART 5: COMPETITION ANALYSIS

Please answer questions 16-28 below in respect of each market identified in question 12 above.

Existing competitors

16. Identify all of the relevant competitors in the market(s), including near competitors and importers in the market(s), and describe how they all compete in the market(s).

Fresenius (CRRT, HD and PD)

16.1 Fresenius AG is a publicly listed German company with approximately 150,000 employees and operations in 100 countries worldwide. There are four business segments in the Fresenius corporate group being Fresenius Medical Care (Fresenius) (dialysis products and care), Fresenius Kabi (infusion therapy, clinical nutrition and IV drugs), Fresenius Helios (hospital operation) and Fresenius Vamed (engineering and services for hospitals and health care facilities).

16.2 Fresenius is the world's leading provider of products and services for individuals undergoing dialysis because of chronic kidney failure.[61] It is a vertically integrated company that provides a complete solution for patients – from research and development to manufacturing dialysis products to providing complete therapy options within Fresenius' own clinics. Fresenius provides integrated services in over 120 countries, which includes around 3000 dialysis clinics and 40 production sites worldwide. During FY 2012, its revenue was approximately NZD16.68 million.

16.3 Fresenius identifies itself as holding the number one market position for a number of major product groups in RRT:[62]

MARKET POSITION IN MAJOR PRODUCT GROUPS

Table 7

	Rank 1	*Rank 2*	*Rank 3*
Dialyzers	Fresenius Medical Care	Gambro	Nipro
Dialysis machines	Fresenius Medical Care	Nikkiso	Gambro
Concentrates for hemodialysis	Fresenius Medical Care	Fuso	Gambro
Bloodline systems	Fresenius Medical Care	Gambro	Kawasumi
Products for peritoneal dialysis	Baxter	Fresenius Medical Care	Terumo

Source: Company data and estimates

Fresenius Medical Care 2011

16.4 Fresenius has been active in Australia since 1996 when it set up headquarters

[61] Fresenius At a Glance 2012, available at: http://www.fresenius.com/documents/At_a_glance_2012.pdf.

[62] Fresenius Medical Care Profile 2011, available at: http://www.Fresenius-ag.com/files/Kurzprofil2011_en.pdf

for the South East Asian region in Sydney and began offering HD and PD products.[63] Since then Fresenius has sought to improve market position through acquisition. In 1996 Fresenius purchased a production plant in Smithfield from Ajax Chemicals at which time it commenced to manufacture HD fluids.[64] In 2010 it made a major expansion in Australia by acquiring Gambro's PD business and Baxter's private HD therapy centers.

16.5 In addition to its HD and PD machines, Fresenius has a SLEDD device and a CRRT machine to complement its SLEDD therapy, called the Multifiltrate CRRT machine. The Multifiltrate CRRT machine has had two trials in Victoria, Australia in 2012 but has not yet been sold in Australia or New Zealand (as far as Baxter is aware). Fresenius products in relation to CRRT also include consumables (sets and filters), fluids and catheters. A Fresenius Acute Machine and Acute Kits have been registered with the TGA.

B Braun (CRRT and HD)

16.6 B Braun is a multinational health organization based in Germany. During FY2011, its revenue was approximately NZD 7,266 million. B Braun's renal division Avitium AG, offers a full line of kidney dialysis offerings. The division focuses on treatment systems for AKI, HD as well as therapeutic apheresis.

16.7 The B. Braun Australia Group services Australia, New Zealand and the Pacific Islands. B. Braun Australia has been operating since 1982 and in 2011, B. Braun New Zealand transitioned to a stand-alone legal entity - a wholly owned subsidiary of the B. Braun Australia Group.

16.8 B Braun's CRRT machine Diapact is available in Australia and New Zealand and Baxter understands that there are still 5-6 of these machines in Australia from the early 2000s.

16.9 B Braun has recently been recruiting for sales and marketing personnel, including a Sales & Marketing Manager, for RRT products in 2012 and prior to this role being advertised, B Braun recruited an ANZ Business Manager from Baxter's own renal staff. B Braun has taken part in a number of recent tenders in Australia and New Zealand (including trialing an HD device in November 2011 at Middlemore Hospital) and it is evident that they are increasing their operations in the region.

Regional Health Care Group (CRRT & HD)

16.10 Regional Health Care Group is a privately owned Australian group in the healthcare and research and development sector. It sources and distributes products (including for renal treatments) across Australia and New Zealand to hospitals and patient's homes. It is not only an effective competitor in its own

[63] ACCC v Baxter Healthcare Pty Ltd [2005] FCA 581 at 90.

[64] ACCC v Baxter Healthcare Pty Ltd [2005] FCA 581 at 90.

right but its business model (ie as a local distributor of a broad range of imported medical products) is one that could be replicated as a means to bring other renal product manufacturers' products to Australia. Regional Health Care Group has annual revenues in excess of AUD300 million.

NxStage Medical Inc (HD)

16.11 Headquartered in Lawrence, Massachusetts, NxStage Medical, Inc. (**NxStage**) is a medical device company that develops, manufactures and markets innovative systems for the treatment of end-stage renal disease, acute kidney failure and fluid overload. NxStage's primary product, the NxStage System One was designed to satisfy an unmet clinical need for a system that can deliver the therapeutic flexibility and clinical benefits associated with traditional dialysis machines in a smaller, portable, easy-to-use form that can be used in a variety of settings, including patient homes, as well as more traditional care settings such as hospitals and dialysis clinics. The System One is targeted for home hemodialysis and a range of dialysis therapies including more frequent, or "daily," dialysis, which clinical literature suggests provides patients better clinical outcomes and improved quality of life.[65]

16.12 NxStage also sells needles and blood tubing sets primarily to dialysis clinics for the treatment of ESRD but identifies the System One as its greatest market opportunity.[66] NxStage's System One is currently distributed in Australia and New Zealand through the Regional Health Care Group and has been since 2011. NxStage also has a CRRT machine that is available in other jurisdictions and that Baxter understands may soon be launched in Australia and New Zealand.

TekMed Healthcare (CRRT)

16.13 It is understood that TekMed, an Australian medical company, has in recent years made significant inroads into the Australian market and may soon do so in New Zealand. It distributes the InfoMed HF400/440 CRRT machine and there are approximately 12 to 25 of these InfoMed CRRT machines in Australia, with the majority within the Royal Darwin Hospital ICU and two units in Melbourne. TekMed also recently tendered the InfoMed device in New Zealand for a CRRT tender (although unsuccessfully). TekMed sell all the consumables associated with the device apart from CRRT fluids.

16.14 The advantage of this CRRT machine is that, unlike with the Aquarius and Prismaflex machines, which require nurses to hang up and take off heavy bags once filled, the InfoMed CRRT machine has a hose that can remove the waste fluid directly into a drain.

[65] NxStage 2011 Annual Report

[66] NxStage 2011 Annual Report

Nipro (HD)

16.15 Nipro is headquartered in Osaka, Japan and mainly engages in the manufacture, development and sale of dialysis related products. Baxter distributes some of Nipro's dialysis products in Australia. The agreement is non-exclusive and Nipro also sells its own dialysers and other HD products directly in ANZ and through the Regional Medical Group referred to above and Sutherland medical.

Nikkiso Co. Ltd (CRRT and HD)

16.16 Nikkiso is headquartered in Tokyo, Japan. Its Medical Division engages in the manufacture and sale of HD and CRRT products. As further discussed in Section 20 below, Baxter currently distributes the Nikkiso HD machine fleet within Australia and New Zealand. The distribution agreement can be converted by Nikkiso into a non-exclusive agreement at will and it is open for Nikkiso to commence distribution of its own products in Australia or New Zealand or appoint an alternate distributor to Baxter to do so. Nikkiso also manufactures the Aquarius CRRT machine that Baxter distributes in Australia and New Zealand.

Market share

17. Outline the estimated market shares in terms of sales, and, where relevant, volume and productive capacity, of the merger parties and competitors identified above. Please include:

- the estimated total value of the domestic market; and
- the source of the data provided.

17.1 Sales shares are a "rear vision mirror" view of which companies provided the best value in the previous round of tenders. As noted above, the primary means of selling renal replacement products is through tenders which typically last around 5 years (although some renal products are sold pursuant to supply agreements). They are of limited value in assessing the current and future level of competition because:

- vigorous competitors from previous tenders may not appear at all in the sales figures if as few as one or two suppliers made an even more competitive offer and won the totality of the business;
- if a new competitor enters a market or is ready, willing and able to do so, they may immediately constitute a competitive constraint even though they may not appear in the share figures until the next round of tenders is complete; and
- in relation to CRRT, it does not take account of the past technical difficulties and likely recovery of sales of Baxter's Aquarius machines discussed in

paragraph **Error! Reference source not found.**.

17.2 All of the above factors are relevant in relation to renal replacement therapies in Australia and New Zealand. The presentation of "post transaction" figures below is only a notional concept that reallocates the past sales figures on the basis of the post-transaction asset ownerships.

17.3 The share figures presented in this section by Baxter are sourced from Baxter and Gambro's actual sales together with Gambro's estimates of the other suppliers' sales for 2011 and accordingly do not take into account competitors whose renal machines have been sold in previous years and are currently being used in Australia and New Zealand (as further discussed in Section 16). The actual sales figures are confidential to each of Baxter and Gambro and the estimates of other parties' sales are confidential to Gambro. The sales figures upon which the shares are based are supplied to the NZCC separately on an external counsel only basis in Annexure F to this Submission.

17.4 The intention has been to: (a) include HD technical services revenue together with revenue for the sale of HD machines and, similarly, CRRT technical services revenue together with revenue for the sale of CRRT machines; (b) include sterile solutions with CRRT fluids and HD concentrates (respectively); and (c) exclude needles and catheters from the categories for dialysers, filters and tubing.

17.5 The presentation of the data is sensitive to exchange rate fluctuations, to what appears to be at least the same degree of sensitivity as the likely variability of the estimates of other parties' sale figures.

17.6 In summary the data is fit-for-purpose where the role of sales shares is as a starting point for a more thorough analysis of the competitive dynamics of the industry. Although the data is not necessarily accurate to one percentage point, it does correctly identify where one party sells the majority of a particular product category, who are the other significant double-digit suppliers and some new entrant suppliers such as NxStage.

17.7 The figures below are based on dollar figure sales. Volume data for 2011 has also been provided. The parties have engaged specialists to verify these figures and will also provide 2010 figures as soon as these are available, which will be shortly. 2012 estimates for competitors are not yet available. The underlying process used by Gambro for its market intelligence survey (and that has been used by Baxter to compile its market share estimates for this Submission) is not yet complete and is not expected until later this year. However, to assist the NZCC with its investigation, the Parties will as soon as possible provide their own sales and volume figures for 2012.

Australia & New Zealand Sale Shares

17.8 Sales shares for CRRT are as follows:

CRRT Machines	Pre-transaction	Post-transaction (based on 2011

	2011	data)
		]
Total	*100%*	*100%*

CRRT Disposables (tubing and filters)	Pre-transaction	Post-transaction (based on 2011 data)
	2011	
Total	*100%*	*100%*

CRRT Fluids	Pre-transaction	Post-transaction (based on 2011 data)
	2011	
Total	*100%*	*100%*

17.9 Sales shares for HD are as follows:

HD Machines	**Pre-transaction**	**Post-transaction (based on 2011 data)**
	2011	
Total	*100%*	*100%*

HD Tubing	**Pre-transaction**	**Post-transaction (based on 2011 data)**
	2011	
Total	*100%*	*100%*

HD Dialysers	**Pre-transaction**	**Post-transaction (based on 2011 data)**
	2011	
Total	*100%*	*100%*

HD Concentrates	Pre-transaction	Post-transaction (based on 2011 data)
	2011	
Total	*100%*	*100%*

New Zealand Sale Shares

17.10 Sales shares for CRRT are as follows:

CRRT Machines	Pre-transaction	Post-transaction (based on 2011 data)
	2011	
Total	*100%*	*100%]*

CRRT Machines	Pre-transaction	Post-transaction (based on 2011 data)
	2011 (NZD)	
Total		

CRRT Machines	Pre-transaction	Post-transaction (based on 2011 data)
	2011	
Total		

CRRT Disposables (tubing and filters)	Pre-transaction	Post-transaction (based on 2011 data)
	2011	
Total	*100%*	*100%*

CRRT Disposables (tubing and filters)	Pre-transaction	Post-transaction (based on 2011 data)
	2011	
Total		

CRRT Disposables (tubing and	Pre-transaction	Post-transaction (based on 2011 data)
	2011	

filters)		
Total		

CRRT Fluids	**Pre-transaction**	**Post-transaction (based on 2011 data)**
	2011	
Total	*100%*	*100%*

CRRT Fluids	**Pre-transaction**	**Post-transaction (based on 2011 data)**
	2011	
Total		

CRRT Fluids	**Pre-transaction**	**Post-transaction (based on 2011 data)**
	2011	

Total		

17.11 Sales shares for HD are as follows:

HD Machines	**Pre-transaction**	**Post-transaction (based on 2011 data)**
	2011	
Total	*100%*	*100%*

HD Machines	**Pre-transaction**	**Post-transaction (based on 2011 data)**
	2011	
Total		

HD Machines	**Pre-transaction**	**Post-transaction (based on 2011 data)**
	2011	
Total		

HD Tubing	**Pre-transaction**	**Post-transaction (based on 2011 data)**
	2011	
Total	*100%*	*100%*

HD Tubing	**Pre-transaction**	**Post-transaction (based on 2011 data)**
	2011	
Total		

HD Tubing	**Pre-transaction**	**Post-transaction (based on 2011 data)**
	2011	
Total		

HD Dialysers	Pre-transaction	Post-transaction (based on 2011 data)
	2011	
Total	*100%*	*100%*

HD Dialysers	Pre-transaction	Post-transaction (based on 2011 data)
	2011	
Total		

HD Dialysers	Pre-transaction	Post-transaction (based on 2011 data)
	2011	
Total		

HD Concentrates	Pre-transaction	Post-transaction (based on 2011 data)
	2011	

Total	*100%*	*100%*

HD Concentrates	**Pre-transaction**	**Post-transaction (based on 2011 data)**
	2011	
Total		

HD Concentrates	**Pre-transaction**	**Post-transaction (based on 2011 data)**
	2011	
Total		

Constraint by existing competitors

18. To what extent do you consider that the merged entity would be constrained in

its actions by the conduct of existing competitors in the markets affected? Where relevant please include a full discussion and examples of:

- the ease with which customers may switch between suppliers, and, if so, how readily;
- any local or overseas firms that are not currently producing the product, or providing the service in the market, but could enter the market quickly (using essentially their existing productive capacity) in a response to an attempt by suppliers to raise prices or reduce output or quality (near competitors and importers); and
- the extent to which existing competitors, near competitors and importers could expand in the market, and any difficulties that they might face in doing so.

For further information on existing competition, please refer to Part 5 of the Mergers and Acquisitions Guidelines.

18.1 The relevant markets are largely tender based. There is a major opportunity for entry on a significant scale each time the New Zealand District Health Boards conduct a tender (see Section 24). In the immediate term until a new tender is called it is possible for new entrants to demonstrate new technologies and for customers to acquire products off tender (see Section 24). Similarly, where there are individual pricing agreements these often include clauses permitting the customer to acquire new technologies out of contract. The fact that there is so much international trade and no items manufactured in New Zealand demonstrates that the competitive constraints upon the New Zealand business include the potential for competition from suppliers located throughout the world, including those identified in Section 16).

18.2 **[ ]**

Potential Competition

Conditions of entry

19. Please explain the requirements for new entry and/or importers in the relevant market(s), including:

- breakdown of the estimated costs;

  Estimated costs might include, for example, raw materials, machinery, specialised assets, sunk costs and/or any other costs which may be necessary for new entry.

- anticipated timeframes;

- regulatory requirements;
- frontier requirements (e.g. tariffs, import licensing, quarantine requirements); and
- business requirements involved.

Please provide the source for any data used.

19.1 The Baxter business in New Zealand is a distribution business and incremental costs of a medical supplier to distribute the relevant products would be slim, especially if undertaken in partnership with a manufacturer.

19.2 An example of this is the Regional Health Care Group that has recently made significant inroads in Australia. It is a privately owned Australian group in the healthcare and research and development sector. It sources and distributes products (including for renal treatments) across Australia and New Zealand to hospitals and patient's homes. It is not only an effective competitor in its own right but its business model (ie as a local distributor of a broad range of imported medical products) is one that could be replicated as a means to bring other renal product manufacturers' products to New Zealand. Regional Health Care Group has annual revenues in excess of AUD300 million.

19.3 For instance, NxStage's System One is currently distributed in Australia through the Regional Health Care Group and has been since 2011. In addition, Kimal's Hygieia CRRT machine is distributed and supported by Regional Healthcare Solutions in Australia as are Nipro products.

19.1 The New Zealand Medicines and Medical Devices Safety Authority (**'Medsafe'**) is the regulatory body responsible for administering the *Medicines Act 1981* (NZ) (**'the Act')** and the *Medicines Regulation 1984* (NZ) (**'the Regulation'**) which provide the legislative framework regulating the supply of, inter alia, medicines and medical devices in New Zealand. Both categories are likely to be relevant to the products discussed in this Submission.

19.2 *Registration of Medicines.* Pursuant to Section 3 of the Act, a product other than a medical device within the meaning of Section 2 of the Act, will generally be a "medicine" if it has a "therapeutic purpose" (defined in Section 4 of the Act).

19.3 *Registration of Medical Devices.* Pursuant to Section 2 of the Act, a product will generally be a "medical device" if it exerts its therapeutic purpose by physical rather than pharmacological means. Products considered to be medical devices in other countries may be medicines in New Zealand.

19.4 In contrast to medicines, medical devices are likely to be affected by legislation other than the Act and the Regulation. Such legislation must be complied with before the devices can be legally supplied. For example, all medical devices must be notified to the WAND (Web Assisted Notification of Devices) database

established under the *Medicines (Database of Medical Devices) Regulations 2003* (NZ). Notification to the WAND database is free and there is no on-going fee.

19.5 In relation to medicines, depending on the risk attributed to the medicine, the fee for a New Medicine Application (**'NMA'**) can be up to NZD 88,875.

19.6 Indicative timelines for the processing for NMAs can be summarized as follows:

- Initial evaluation – to be completed by Medsafe within 200 calendar days of the receipt of payment. The outcome of the initial evaluation usually results in a Request for Information (**'RFI'**).
- RFI #1 response time – applicants are given 200 calendar days to submit their response to an RFI.
- Evaluation of additional information #1 – to be completed by Medsafe within 120 calendar days of receipt.
- RFI #2 response time – applications are given 120 calendar days to submit their response to the second RFI.
- Evaluation of additional information #2 – to be completed by Medsafe within 120 calendar days.

19.7 Once the evaluation has been completed, the product will be forwarded for the gazettal process or referred for consideration at the next Medicines Assessment Advisory Committee meeting.

20. Include a full discussion on:

- any factors that could impede entry; and
- what might prompt new entry post-merger.

For further information on market entry and barriers to entry, please refer to Part 6 of the Mergers and Acquisitions Guidelines.

20.1 In Baxter's view, there are no factors that would materially impede entry. **[ ]** This is discussed below.

Machines

20.2 The HD machines[67] that Baxter currently supplies to customers in Australia (it does not currently have a machine footprint in New Zealand) are manufactured by, and purchased from, the Japanese based company Nikkiso pursuant to an

[67] Together with instruments and ancillary products including spare parts.

agreement entered into in February 2008. Although this agreement only covers Australia and New Zealand, there are similar agreements in a range of other jurisdictions.

20.3 The initial term of the agreement is for seven years, following which it becomes an ever-green agreement with successive one year terms unless either party chooses to terminate the agreement. A copy of the agreement is available if the NZCC wishes to view it.

20.4 On the face of the agreement, it is exclusive in two senses:

- Nikkiso appoints Baxter as its sole exclusive distributor of its HD machine in ANZ (although Nikkiso may continue to supply HD machines to other parties in ANZ pursuant to pre-existing contracts); and
- Baxter (and its affiliates) must not promote or sell directly in-centre HD machines that compete directly with the Nikkiso machines.

20.5 However, Nikkiso can convert the agreement into a non-exclusive distributorship if Baxter does not achieve the Annual Minimum Purchase Target of 50 machines in 2008 and 2009 combined and 50 machines per year there-after.

20.6 Although Baxter is a distributor of both HD and CRRT machines manufactured by Nikkiso, the sales share figures in Section 17 demonstrate that Baxter has been historically much better able to re-sell CRRT machines than HD machines. This is despite the difficulties with the CRRT machines discussed in paragraphs **Error! Reference source not found.** and **Error! Reference source not found.**. A key element of whether a distribution business can be successful is the wholesale price paid by the distributor to the manufacturer under the supply agreement and whether this is competitive.

20.7 The two largest suppliers of HD machines in New Zealand (Fresenius and Gambro) supply machines manufactured by them overseas. Competition between those two competitors is vigorous, indeed, so vigorous that Baxter has often found it is difficult to earn any margin at all over the fixed wholesale price that Baxter must pay to Nikkiso for the machines. Consequently, Baxter has sold a limited number of machines and it has not reached the Annual Minimum Purchase Target under the agreement with Nikkiso and Nikkiso could convert the agreement into being a non-exclusive agreement at will.

20.8 After the acquisition of Gambro, Baxter expects that competition between Gambro and Fresenius for the supply of HD machines would continue to be vigorous. If there were any opportunity for Nikkiso's machines to profitably increase sales, Nikkiso could convert the agreement into a non-exclusive agreement and either supply machines directly itself or appoint another distributor, for instance potentially Regional Health Care Group.

20.9 Consequently, the acquisition would not cause a lessening of competition and it is even possible that the transaction could precipitate an increase in competition if it prompted Nikkiso to sell machines itself in New Zealand or appoint another distributor on wholesale terms that would potentially make the sale of Nikkiso

machines in New Zealand a more viable business model.

Tubing, filters/dialysers & fluid

20.10 The tubing, filters and fluid that Baxter currently supplies are manufactured by, and purchased from, another Japanese based company called Nipro which is unrelated to Nikkiso. Baxter's ability to vigorously compete with Fresenius, Gambro and others to supply of these items in New Zealand has been limited in the same way as it has been for machines.

20.11 Unlike the agreement with Nikkiso for HD machines, the agreement with Nipro for the supply of consumables is already non-exclusive and it would immediately be possible for whoever supplies Nikkiso machines in New Zealand to negotiate a supply of the consumables from Nipro or, indeed, it would also be possible for these items to be separately supplied into New Zealand.

Potential Competitors and Likelihood, Extent and Timeliness of Entry (the LET test)

21. Please name any likely businesses (including overseas businesses) you are aware of that do not currently supply the market but which you consider could supply each of the relevant market(s). Discuss the likelihood of such entry.

21.1 Competitors that Baxter is aware of but (to its knowledge) do not currently supply New Zealand are TekMed, Asahi, Kimal, Nipro and Nikkiso (see also Section 17).

22. To what extent do you consider that potential entry would be sufficient to constrain the merged entity in the markets affected?

22.1 **[ ]**

23. How long would you expect it to take for entry to occur, and for market supply to increase, in respect of each of the potential entrants named in question 21 above? Provide reasons for your estimates.

For further information on the LET test, please refer to Part 6.3 of the Mergers and Acquisitions Guidelines.

23.1 The potential for entry is a significant competitive constraint. Suppliers already vigorously compete **[ ]**. Baxter considers entry would be economic, timely and

likely especially if an existing supplier sought to charge more and provide less.

Countervailing Power of Buyers

24. To what extent do you consider that the merged entity would be constrained in its actions by the conduct of buyers in the markets affected? Where relevant, please include:

- a full discussion on the ability of buyers to self supply or import, and the alternative sources of supply available to buyers; and
- evidence of buyers seeking alternative supply and/or switching suppliers.

24.1 RRT products are not purchased directly by patients. The parties' customers in New Zealand are district health boards and public hospitals, who are predominantly sophisticated buyers that in large part procure RRT products through tenders for significant volumes of sales. Each of these significant tenders provides a regular, natural 'launch pad' for new HD or CRRT suppliers. In some cases (primarily in CRRT) products are also acquired by the individual hospitals through supply contracts.

24.2 The structure and pricing of the tenders in HD and CRRT vary depending on the customer. They can be structured on a line by line (where prices are given on a per product basis) or price per treatment (**PPT**) basis. In PPT pricing there is a single unit price per treatment that typically covers a combination of monitors, consumables and technical service. Typically, the body issuing the tender will specify a set of products and suppliers will tender to supply all of those products on a PPT basis.

24.3 **[ ]** The tender may also call for a range of ancillary products (bandages, swabs, garbage bags) that Baxter and Gambro will source from third parties.

24.4 In almost all cases, suppliers will be sole listed or dual listed and the customer will ensure that the agreement with the supplier will include provisions whereby the customer is permitted to acquire new technology off tender or in the event the product supplied is not clinically suitable (estimated to be around 5-10% of overall purchases). Nevertheless, entry is facilitated through the new technology exception which enables new suppliers to enter in a small way, prove themselves and bid for the next tender. There are no volume commitments from the customer and Baxter generally agrees to supply anything that is requested. In New Zealand, the District Health Boards are also permitted to purchase off-tender if required by the New Zealand government.

24.5 There are important differences in tendering between CRRT and HD.

HD

24.6 New Zealand has 20 District Health Boards which make purchasing decisions, of which around 12 purchase HD products. Gambro understands that in the coming years, consolidation amongst these District Health Boards is likely. Each of the District Health Boards tender around once every 5 years usually on a PPT basis.

24.7 There is only one private HD clinic in New Zealand in Auckland (Nephrocare), which is a stand-alone facility not related to the private hospital. Nephrocare is run by the Parties' competitor Fresenius.

CRRT

24.8 In New Zealand, District Health Boards usually go out to tender for their CRRT needs. Tenders are awarded as typically outright purchase contracts (i.e. not PPT).

24.9 See Annexures D and E for tables summarizing tenders in which the Parties participated since January 2010..

25. If you consider that there is a constraint from buyers, identify the top five buyers by sales and/or volume (including overseas companies/importers) in the relevant market(s). Where there are significant differences in the size of the buyers please provide details for five medium and five small buyers.

For further information on the countervailing power of buyers, please refer to Part 7.3 of the Mergers and Acquisitions Guidelines

25.1 Baxter's top ten ANZ customers in each of PD, HD and CRRT are attached at Annexure G to this Submission. Contact details for Gambro's top ten HD and CRRT customers appear under Section 29 of this Submission. Contact details for some of Baxter's HD buyers in New Zealand are also set out in Section 29. Baxter will provide the contact details for its New Zealand CRRT customers shortly.

Coordinated Market Power

26. Identify and discuss the various characteristics of the market that, post-merger, you consider would either facilitate or impede coordination.

For further information on the coordinated market power, please refer to Part 9 of the Mergers and Acquisitions Guidelines.

26.1 In Baxter's view, there are no characteristics that would facilitate coordination. The factors that would impede coordination are: (a) the fact the products are differentiated; (b) market shares are very different inter se; (c) there is significant potential for new entry and for buyers to foster new entry or otherwise structure tenders processes to disrupt coordination.

Efficiencies

27. If applicable, provide a description of any efficiencies that you believe the acquisition could bring. Would such efficiencies enhance rivalry, or offset the impact of a lessening of competition? Please include a full discussion on:

- how the merger would facilitate the realisation of efficiency improvements. Specify the steps the combined entity anticipates it would take, and the timeframe needed, to achieve the efficiencies. Where relevant, include a discussion of the risks and costs involved;
- the magnitude of the efficiencies, whether the impact would be on fixed, variable or other costs, and generally how the cost structure of the merged entity would change;
- whether such efficiencies could be realised without the merger, or over a longer timeframe; and
- whether, and the extent to which, such efficiencies would be passed on to the customers of the merged entity.

For further information on efficiencies, please refer to Part 7.4 of the Mergers and Acquisitions Guidelines

27.1 Baxter considers there will be some efficiencies in increasing overall sales going through a distribution network. However, the other material contained in this Submission obviates the need for a consideration of how significant these efficiencies would be. The submissions do not rely on efficiencies.

Other Factors

28. Where relevant, provide a description of any other features of the market(s) that should be taken into account in considering the effect of the proposed merger.

28.1 All the products that are relevant to this merger are extensively traded on a global basis and any competitors present anywhere in the world already pose a competitive constraint upon the merging parties and the other parties already

selling products in New Zealand.

28.2 The products are predominantly purchased by sophisticated buyers through tenders for significant volumes of sales. Each of these significant tenders provides a regular, natural 'launch pad' for new HD or CRRT suppliers. The purchasing agencies also have the ability to foster entry if new entrants do not step forward to bid of their own volition.

28.3 With respect to CRRT machines, consumables and fluids there will not be any diminution in the competition because:

(A) **[ ]**

(B) The potential for competitive entry and expansion is substantial with a number of existing suppliers in other countries able to sell in New Zealand.

(C) There is the potential for Fresenius to compete for CRRT patients using its existing New Zealand PD and HD product offerings and also through entering the CRRT space.

28.4 With respect to HD machines, consumables and fluids there will not be any diminution in the competition because:

(A) The over-whelming competitive dynamic in the supply of HD in New Zealand is between Gambro and Fresenius who are both manufacturer/distributors.

(B) **[ ]**

(C) **[ ]**

(D) There is extensive scope for entry or expansion into New Zealand by suppliers who do not currently sell HD machines in New Zealand or whose current sales are limited.

PART 6: FURTHER INFORMATION AND SUPPORTING DOCUMENTATION

29. Provide the contact details of relevant competitors, buyers and suppliers and any other relevant market participants in the form of the example table shown below.

29.1 Baxter contact details:

	Name of company	**Contact details**	**Relevant contact person**
	Both legal and trading names	**Postal and physical address, telephone and fax, website**	**Name, position and contact details including telephone phone, fax, email**
[ ]	**[ ]**		**[ ]**
[ ]	**[ ]**		**[ ]**
[ ]	**[ ]**	**[ ]**	**[ ]**
[ ]	**[ ]**	**[ ]**	**[ ]**

29.2 Gambro contact details for 2012 customers:

	Name of company	**Contact details**	**Relevant contact person**
	Both legal and trading names	**Postal and physical address, telephone and fax, website**	**Name, position and contact details including telephone phone, fax, email**
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30. Please provide a copy of the most recent annual report for each of the merger parties. If an annual report is not available, please provide a copy of the audited financial statements of the merger parties (profit and loss account, showing total turnover and profit before tax, and balance sheet). If the merger only relates to a segment of the business of the merger parties, please also provide a copy of any management accounts for the relevant business segment.

30.1 The 2011 annual report for Baxter is set out in Annexure H. The 2011 annual report for Gambro (English translation) is set out in Annexure I.

PART 7: CONFIDENTIALITY

31. If you wish to request confidentiality for specific information contained in or attached to the notice, please state why you consider the information to be confidential and state the reasons for your request in terms of the criteria set out in the Official Information Act 1982.

31.1 **[ ]**

32. Provide a separate schedule of all confidential information claimed in the application.

The Commission requires applicants to provide a separate schedule listing all

the confidential information so the Commission can process confidentiality requests quickly.

32.1 See schedule.

33. Provide two copies of the application. One copy must be a confidential version and the other a public version.

- In the confidential version of the application any information for which confidentiality is sought must be highlighted in bold and contained in [square brackets].
- In the public version the confidential information should be removed from within the square brackets, with the brackets remaining, thus [ ].

A hard copy, and an electronic copy of the confidential version and the public version both in Microsoft Word format and in PDF format, should be sent to the email address: registrar@comcom.govt.nz.

For further information on the Commission's confidentiality policy and procedures, please refer to the Mergers and Acquisitions Clearance Process Guidelines.

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