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**Public version** 

#### **Determination**

#### Baxter International Inc and Gambro AB [2013] NZCC 13

**The Commission:** Dr Mark Berry

Sue Begg

Dr Jill Walker

**Summary of application:** Baxter International Inc. seeks clearance to acquire Gambro AB's

New Zealand business as part of a global acquisition of Gambro

AΒ

**Determination:** Under section 66(3)(a) of the Commerce Act 1986, the

Commerce Commission gives clearance for Baxter International Inc. to acquire Gambro AB subject to the divestment undertaking dated 18 July 2013 provided by Baxter International Inc under

section 69A of the Commerce Act 1986

**Date of determination:** 30 July 2013

Confidential material in this report has been removed. Its location in the document is denoted by [ ].

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#### The proposal

- 1. On 15 March 2013 Baxter International Inc (Baxter) applied for clearance<sup>1</sup> to acquire Gambro AB, through the purchase of 100% of the shares in Gambro's parent company, Indap Holding AB. By agreement with Baxter, a decision on the application was required by 31 July 2013.
- 2. On 18 July 2013 we received an undertaking from Baxter<sup>2</sup> that it would divest its worldwide continuous renal replacement therapy (CRRT) business. We consider the competition effects of the undertaking in the proposed divestment section below.

#### Our framework

3. Our approach to analysing the competition effects of the proposed acquisition is based on the principles set out in our Mergers and Acquisitions Guidelines.<sup>3</sup>

The substantial lessening of competition test

- 4. As required by the Commerce Act 1986, we assess mergers using the substantial lessening of competition test.
- 5. This test asks whether a merger is likely to substantially lessen competition in a market by comparing the likely state of competition if the merger proceeds (the scenario with the merger, often referred to as the factual), with the likely state of competition if the merger does not proceed (the scenario without the merger, often referred to as the counterfactual).<sup>4</sup>
- 6. A lessening of competition is generally the same as an increase in market power the ability to raise price above the price that would exist in a competitive market (the 'competitive price'), or reduce non-price factors such as quality or service below competitive levels.
- 7. As a result, determining the scope of the relevant market or markets can be an important tool in determining whether a substantial lessening of competition is likely. This is because the more closely substitutable two products are, the closer the competition between them and the greater the competitive constraint between those products.
- 8. We define markets in the way that we consider best isolates the key competition issues that arise from the merger. In many cases this may not require us to precisely

Under s 66 of the Commerce Act 1986.

Under s 69A of the Commerce Act 1986.

<sup>&</sup>lt;sup>3</sup> Commerce Commission, *Mergers and Acquisitions Guidelines*, July 2013. Our recently published revised Mergers and Acquisitions Guidelines retain the same broad analytical framework outlined in our 2004 Guidelines.

<sup>&</sup>lt;sup>4</sup> Commerce Commission v Woolworths Limited (2008) 12 TCLR 194 (CA) at [63].

<sup>&</sup>lt;sup>5</sup> Or below competitive levels in a merger between buyers.

define the boundaries of a market. A relevant market is ultimately determined, in the words of the Act, as a matter of fact and commercial common sense.<sup>6</sup>

#### When a lessening of competition is substantial

- 9. Only a lessening of competition that is substantial is prohibited. A lessening of competition will be substantial if it is real, of substance, or more than nominal. Some courts have used the word 'material' to describe a lessening of competition that is substantial.
- 10. Consequently, there is no bright line that separates a lessening of competition that is substantial from one that is not. What is substantial is a matter of judgement and depends on the facts of each case. Ultimately, we assess whether competition will be substantially lessened by asking whether consumers in the relevant market(s) are likely to be adversely affected in a material way.

#### When a substantial lessening of competition is likely

11. A substantial lessening of competition is 'likely' if there is a real and substantial risk, or a real chance, that it will occur. This requires that a substantial lessening of competition is more than a possibility, but does not mean that the effect needs to be more likely than not to occur.<sup>9</sup>

#### The clearance test

- 12. We must clear a merger if we are satisfied that the merger would not be likely to substantially lessen competition in any market. <sup>10</sup> If we are not satisfied including if we are left in doubt we must decline to clear the merger. <sup>11</sup>
- 13. We may accept undertakings to dispose of assets or shares. <sup>12</sup> If divestment undertakings are accepted by us, they are deemed to form part of the clearance.
- 14. As set out in our divestment guidelines, <sup>13</sup> upon receiving a divestment undertaking we will consider whether the proposed divestment is sufficient to remedy any substantial lessening of competition that would otherwise arise.

<sup>&</sup>lt;sup>6</sup> Section 3(1A). See also *Brambles v Commerce Commission* (2003) 10 TCLR 868 at [81].

Woolworths & Ors v Commerce Commission (2008) 8 NZBLC 102,128 (HC) at [127].

Woolworths & Ors v Commerce Commission (HC) above n 7 at [129].

Woolworths & Ors v Commerce Commission (HC) above n 7 at [111].

Commerce Act 1986, s 66(1) of the Commerce Act 1986.

In Commerce Commission v Woolworths Limited (CA), above n 4 at [98], the Court held that "the existence of a 'doubt' corresponds to a failure to exclude a real chance of a substantial lessening of competition". However, the Court also indicated at [97] that we should make factual assessments using the balance of probabilities.

Under s 69A(2) of the Commerce Act 1986 we are only able to accept structural undertakings. This means that we are unable to accept behavioural undertakings.

<sup>&</sup>lt;sup>13</sup> Commerce Commission, *Mergers and Acquisitions Guidelines*, Attachment F, July 2013.

#### **Parties**

#### **Baxter International Inc (Baxter)**

#### Baxter's global operations

- 15. Baxter is a large, multinational manufacturer and distributor of medical equipment, consumables and pharmaceuticals. Baxter is headquartered in the United States and operates four specialised business units:
  - 15.1 Bio-sciences which manufactures plasma based and recombinant proteins for the treatment of blood related conditions and immune disorders.
  - 15.2 Medication delivery which manufactures products used in the delivery of fluids and drugs to patients including intravenous fluids, fluid administration sets, pre filled vials and syringes.
  - 15.3 Renal which manufactures and distributes products and consumables for the treatment of chronic kidney disorders including dialysis equipment, consumables and solutions.
  - 15.4 Pharmacy services which provides compounding services to hospital pharmacies.
- 16. In 2012, Baxter's worldwide sales amounted to \$14.2 billion.

#### Baxter's New Zealand operations

- 17. In New Zealand, Baxter operates warehouse distribution centres and compounding pharmacy plants in each of Auckland and Christchurch.
- 18. Baxter supplies equipment for Haemodialysis (HD), peritoneal dialysis (PD), and continuous renal replacement therapies (CRRT), along with a range of associated medical equipment and supplies to New Zealand customers. Baxter sells HD and CRRT machinery in New Zealand under a distribution agreement with Nikkiso Co., Ltd (Nikkiso).
- 19. In 2012, Baxter's renal therapy sales in New Zealand were \$[ ]million.

#### Gambro AB (Gambro)

- 20. Gambro is a Swedish based manufacturer of medical supplies and equipment and operates in more than 100 countries worldwide. It is owned by Indap Holdings AB. The products supplied by Gambro are used in the treatment of a range of conditions and include HD and CRRT, liver dialysis, and myeloma kidney therapy.
- 21. Gambro is not active in the supply of PD products. Gambro divested its PD business to Fresenius AG in 2010.
- 22. In New Zealand, Gambro had sales of \$[ ]million in 2012.

#### Fresenius AG (Fresenius)

- 23. Fresenius is a German based supplier of dialysis and other medical therapies which is active in 100 countries worldwide. Fresenius' operations are a mixture of manufacturing and pharmaceutical (responsible for dialysis products, infusion therapies, clinical nutrition and IV drugs), and hospital operation and associated services.
- 24. Fresenius provides all three forms of renal replacement therapy worldwide; however, Fresenius is not active in the supply of CRRT in New Zealand.
- 25. In 2012, Fresenius' New Zealand sales were approximately \$[ ]million.

#### **Nikkiso**

26. Nikkiso is a Japanese based manufacturer of medical and industrial equipment. Its medical business focuses on the manufacture, sale, and maintenance of HD and CRRT dialysis machines, dialysers, blood tubing lines, blood glucose controllers and related products. Nikkiso does not sell any dialysis products directly into New Zealand. Its CRRT and HD machines are sold in New Zealand by Baxter under a distribution agreement.

#### **Background**

- 27. 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 hormone production. Renal Replacement Therapy (RRT), a generic term that refers to dialysis, is an artificial process that performs the key functions of healthy kidneys where a patient suffers kidney deterioration or failure.
- 28. 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.
- 29. There are three main types of renal replacement therapies:
  - 29.1 PD, where the blood is filtered through the membrane of the abdominal cavity and does not leave the body;
  - 29.2 HD, where toxic elements are removed from the blood as it is filtered through a system outside of the body; and
  - 29.3 CRRT, which is similar to the HD treatment but is continuous and therefore acts more slowly and provides more controlled fluid and blood pressure balance.
- 30. CRRT is used to treat acute kidney injury in an intensive care unit (ICU); while both PD and HD are used by the renal unit of a hospital, or in the home, to treat chronic

kidney disease. End-stage chronic kidney disease is usually fatal unless treated with dialysis or transplantation.

#### **Market Definition**

- 31. For the purposes of this decision we consider that the relevant markets are the national markets for the supply of:
  - 31.1 HD treatment systems;
  - 31.2 CRRT machines;
  - 31.3 CRRT fluids; and
  - 31.4 CRRT consumables.
- 32. Baxter and Gambro do not compete for the supply of PD treatment systems in New Zealand. As a result there is no aggregation in this market and so we only consider this market in the context of assessing whether HD and PD are in the same relevant market.

#### Our approach to market definition

- 33. Market definition is a tool that provides a framework to help identify and assess the close competitive constraints the merged firm would likely face. Determining the relevant market requires us to judge whether, for example, two products are sufficiently close substitutes as a matter of fact and commercial common sense to fall within the same market.
- 34. To help us establish whether customers would switch sufficient purchases to alternative products, we use the hypothetical monopolist test as a conceptual tool. This test asks whether a hypothetical sole supplier of a set of products would profitably increase prices for at least one of the merging firms' products by at least a small, but significant, amount. <sup>14</sup> This small, but significant, amount is often referred to as a SSNIP a small, but significant, non-transitory increase in price.
- 35. In general, the smallest set of products in which the SSNIP can be profitably sustained is defined as the relevant product market.

#### The applicants view of the relevant markets

- 36. Baxter submitted that the relevant markets affected by this transaction are the national markets for:
  - 36.1 HD treatment systems; and
  - 36.2 CRRT treatment systems.

The test assumes that all other prices are held at current levels.

#### Our view of the relevant markets

37. We agree with the merging parties that there are separate markets for CRRT, HD and PD treatments.

CRRT is considered to be in a separate market to PD and HD treatments

- 38. CRRT is considered to be in a separate market from the chronic kidney disease treatments (HD and PD). As noted above:
  - 38.1 CRRT is used to treat a different kidney disease, and so CRRT treatments are not prescribed to the same patients as those using either PD or HD treatments. In other words, CRRT treatments do not have the same functional use as PD and HD treatments;
  - 38.2 CRRT treatments are administered and procured, or ordered through the District Health Board (DHB), by the ICU of a hospital. HD and PD treatments are ordered by the nephrologist and procured, or ordered through the DHB, by the renal unit; and
  - 38.3 the monitors and consumables cannot be substituted between PD, HD and CRRT machines.
- 39. In regard to CRRT products that is, the machine and the related fluids and consumables<sup>15</sup> we do not consider it appropriate to group these products together as one CRRT 'system' as suggested by the merging parties. CRRT treatments do not appear to be purchased on a system or a price per treatment (PPT) basis.<sup>16</sup> DHBs do not usually tender for the supply of all of these components as a bundle. This is due to:
  - 39.1 the ability of different manufacturer's CRRT consumables, fluids and machines to be used together;
  - 39.2 CRRT machines being purchased outright by the DHBs rather than leased or provided for free with an associated requirement to purchase all related consumables and fluids from the supplier; and
  - 39.3 CRRT treatments being administered to ICU patients continuously for different periods of time and therefore different quantities of each consumable are required for each patient.
- 40. CRRT machines sold by the various competitors differ and have specific uses within an ICU. This means that hospitals may obtain machines from several manufacturers to ensure that they are able to provide patients with the most appropriate therapy.

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Such as the bloodlines, catheters, waste bags, adapters, spikes, etc.

This is the case even though suppliers tend to offer all CRRT components. If a company does not manufacture one or more of the components, it procures these from third parties. Gambro manufactures the majority of CRRT products while Baxter only manufactures the CRRT fluids and distributes the remainder of the products on behalf of other companies.

- Although technically each individual CRRT component could constitute a separate 41. market, for the purposes of this analysis, we have grouped the CRRT products according to:
  - 41.1 the supply of CRRT machines;
  - the supply of CRRT fluids; 17 and 41.2
  - 41.3 the supply of CRRT consumables.

#### PD and HD treatments are considered separately

- 42. We consider that PD and HD treatments constitute separate markets. As noted above, the merging parties do not overlap in the provision of PD treatments as Gambro sold its PD business to Fresenius in 2010.
- 43. The industry does not view HD and PD systems as substitutes but rather as complementary treatments. PD treatments have a limited lifespan and patients must eventually be migrated onto an HD system.
  - 43.1 Although there are patients at the margin who might have the choice between PD and home HD treatments when beginning dialysis, the initial choice between HD and PD is largely based on clinical considerations. Some patients are clearly medically unsuitable for one or other of the treatments.<sup>19</sup> As home HD requires an assistant, the lack of a HD assistant may mandate PD. Patients who have transportation problems to a HD centre or live a great distance from a centre may also prefer PD.
  - 43.2 Patients are often put on a PD system initially because PD can be used within two weeks whereas HD requires approximately three months of surgical preparation.<sup>20</sup> Learning to use the PD system is also easier and provides greater lifestyle flexibility (especially in terms of travel) since it does not require a machine.
  - 43.3 Once a choice has been made between the HD and PD treatment, switching is unlikely except for clinical considerations (including, as noted, the end of the PD usage lifespan). This is because of the surgery required to ready the

The dialysate fluids that are used in CRRT treatments are a lactate based solution and a bicarbonate based fluid. These fluids are pre-prepared and packaged ready to use typically in 5 litre bags.

<sup>18</sup> Approximately 2 – 5 years.

This can be because of age, weight, vascular access problems or the presence of other diseases or medical problems.

<sup>20</sup> About 2 weeks before dialysis begins, a catheter is inserted with one end in the membrane that lines the abdomen, and the other extending a few inches away from the skin. The catheter is permanent, is accessible any time and is sealed when not in use. The main method of accessing the bloodstream for HD is through an arteriovenous fistula. The fistula is created by joining an artery and a vein, typically in the forearm. This is done anywhere from two months to a year before dialysis, so the fistula can "mature." The arteriovenous graft and venous dialysis catheter methods are temporary and more prone to malfunctions and risk of infection than the fistula, so not often used.

patient for either PD or HD, and the retraining required to switch treatments. Both the surgery and retraining are costly.

44. We consider that each HD component<sup>21</sup>used in renal therapies might technically constitute a separate market, depending on the degree of supply side substitution. However, we do not consider it necessary to form a firm view on the relevant product markets. We consider that HD treatment systems best illustrate the competitive characteristics of the market.

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- 45. Tenders typically require submissions for the treatment system as a bundle. Apart from one example, all PD and HD purchases in New Zealand are made under a price per treatment (PPT) system whereby the DHB pays a single price and this covers all components, servicing, consumables and training. Even where the components are charged separately and not on a PPT basis, the consumables are sold as a bundle from a single supplier.<sup>22</sup>
- 46. DHBs do not seek piecemeal supply of components because of:
  - 46.1 the limited interoperability between components for different machines;
  - 46.2 the standardisation of use;
  - the reduction of wastage as each treatment session has a standard set of consumables;
  - 46.4 the logistics of home delivery to patients; and
  - 46.5 better pricing for a bundle of products.

Home and in-centre HD treatments can be considered together

- 47. We further considered whether home HD and in-centre HD systems should be considered separately. Although these systems perform the same function, home HD systems do not require the patient to visit the hospital for their regular dialysis treatments. This allows the patients much more flexibility and is appropriate for patients living further away from hospitals.
- 48. Home HD and in-centre HD systems are considered together in this analysis because DHBs tender for both systems together and there is no price difference per treatment between these systems. Suppliers of HD systems in New Zealand are required to provide both systems to be considered as a supplier to the DHBs.

The HD machine is not sold to the DHB but rather provided free of charge. The PPT of the consumables factor in the lease costs of the machine.

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Such as the machine, bloodlines, catheters, waste bags, adapters, spikes, etc.

#### With and without scenarios

#### With the acquisition

49. With the acquisition, Baxter will acquire Gambro AB, through the purchase of 100% of the shares in Gambro's parent company, Indap Holding AB.

#### Without the acquisition

50. We consider that without the acquisition, the likely scenario is the status quo.

#### **Competition analysis**

#### The supply of HD treatment systems in New Zealand

- 51. We are satisfied that the merger would not likely lead to a substantial lessening of competition in the market for HD treatments. The merged entity will continue to face vigorous competition from Fresenius post acquisition. In addition, Baxter's low market share indicates that it is not a significant competitive constraint on either Gambro or Fresenius.
- 52. Further, Baxter has had limited success re-selling Nikkiso HD systems due to the level of competition between Gambro and Fresenius, and the [

].

#### Existing competition

53. Table 1 below outlines the current market shares in the HD treatment systems market.

Table 1: Market shares for HD treatment systems (2011 & 2012)

	2011 Revenue	2011 M/S	2012 Revenue	2012 M/S
Baxter	\$[ ]	[]%	\$[ ]	[ ]%
Gambro	\$[ ]	[]%	\$[ ]	[ ]%
Merged entity	\$[ ]	[ ]%	\$[ ]	[ ]%
Fresenius	\$[ ]	[]%	\$[ ]	[ ]%
Total	\$[ ]	100%	\$[ ]	100%

54. Table 1 shows that with the acquisition, the merged entity will have a market share of approximately [ ]%, with Fresenius accounting for the remaining [ ]%. We note

- that the actual aggregation of market share is very small (less than [ ]%), with Baxter sales of HD machines, and [ ] sales of HD consumables. achieving [
- 55. As outlined above, HD machine and consumable sales in New Zealand are made on a system based, price per treatment. This means that DHBs purchase a given number of 'treatments' at a set price which covers the machine and the necessary fluids and consumables. Generally, DHBs enter into a contract with a supplier following a competitive tender process.
- 56. Currently, Baxter [ ]. Whilst Baxter has made some sales of individual components of the system, [ ]in 2010, \$[ lin 2011, and \$[ lin 2012). In contrast, Gambro has contracts with [ ] DHBs and made sales in 2012 of \$[ ]. The DHBs interviewed by the Commission [ ].
- 57. The majority of DHBs spoken to by us considered that they currently only had two options when seeking a HD supplier, Gambro and Fresenius. We consider that Fresenius is likely to continue to provide a competitive constraint on the merged entity. 23
- With the acquisition, most DHBs considered that they were unlikely to be 58. disadvantaged by the removal of a third HD option. In some cases, 24 DHBs saw considerable advantage in having two suppliers (Fresenius and the merged entity) who offered both a HD and a PD treatment as they would be able to seek a bundled tender for all of their renal therapy needs. For example, Health Alliance, which is responsible for the procurement of renal therapies for all of the Auckland DHBs, informed us that it will be aligning all current contracts for HD and PD therapies and seeking a single supplier for all Auckland renal therapies.<sup>25</sup>

#### Pipeline products

- 59. We have considered whether or not the proposed acquisition would result in the loss of potential competition arising from Baxter's investment in new HD products. Baxter informed us that it is in the process of introducing a new home based HD treatment system called Vivia which is expected to launch in [ ]. We have considered the impact that the launch of this home based HD system would have in the market without the acquisition.
- 60. Purchasers of HD treatment systems do not seek separate supply of home based and in-centre HD treatments, instead requiring its supplier to provide a single HD offering. This is due to the high prevalence of HD treatments being provided incentre and the preference of practitioners and patients for PD to be used in the

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     [
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24 Interview with [ DHB, 11 April 2013 Interview with [ ], 19 April 2013.

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home.<sup>26</sup> Further, although home-based dialysis is considered more beneficial to the patient and less costly to provide, in-centre HD is the prevailing form of HD treatment. For example, [ ] but was not considered as a supplier primarily because they were only able to offer a home HD system.

61. We consider that without the acquisition, the launch of Baxter's Vivia home HD system is unlikely to have a material impact on the level of competitive constraint it exerts on Gambro and Fresenius.

#### Conclusion on HD system market

62. We consider that the proposed acquisition is not likely to have the effect of substantially lessening competition in the national market for the supply of HD treatment systems.

#### The supply of CRRT products

- 63. As outlined above, unlike HD and PD therapies, CRRT is not purchased on a system-wide basis. Rather, customers mix and match their machine, consumables and fluid suppliers.
- 64. For the reasons set out below, we consider that, but for the proposed divestment, we are not satisfied that the proposed acquisition will not have, or would not be likely to have, the effect of substantially lessening competition in the national markets for the supply of:
  - 64.1 CRRT machines;
  - 64.2 CRRT fluids; and
  - 64.3 CRRT consumables.

#### Existing competition

65. Table 2 below outlines the market shares for CRRT machines, consumables, and fluids.

Table 2: Market shares for CRRT machines, consumables, and fluids (2011)

	CRRT Machines		CRRT Consumables			CRRT Fluids			
	Revenue	Market share	Revenu	ıe	Market share		Reve	nue	Market share
Baxter	\$[ ]	[]%	\$[	]	[]%		\$[	]	[]%
Gambro	\$[ ]	[]%	\$[	]	[ ]%		\$[	]	[ ]%
Merged	\$[ ]	100%	\$[	]	100%		\$[	]	100%

We note that advances in HD technology are resulting in smaller and more practical HD machines, improving their ability for both in centre and in home use.

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Entity									
Total	\$[	]	100%	\$[	]	100%	\$[	]	100%

#### The supply of CRRT Machines

- 66. Currently, Baxter and Gambro are the only parties selling CRRT machinery into New Zealand, with Gambro selling its own machine, and Baxter selling a machine manufactured by Nikkiso. Fresenius does not supply CRRT machinery or consumables into New Zealand.<sup>27</sup>
- 67. Unlike HD and PD, where the machine is supplied as part of a wider dialysis system, CRRT machinery is usually purchased outright by an ICU and only replaced when it has reached the end of its useful life. As a consequence, an ICU's CRRT machine fleet will be made up of machines of different ages which are replaced at different times.
- 68. Currently, Baxter offers [ ] CRRT machinery to customers who sign up for exclusive fluid supply contracts. The Auckland DHB informed us that [ ].
- 69. Gambro offers discounts to its CRRT fluid pricing if the customer purchases the entirety of its CRRT requirements (machines, consumables and fluids) from Gambro.
- 70. Baxter has submitted that the push for discounted or free machines is driven more by the needs of hospitals rather than by Baxter. Baxter asserts that hospitals have a preference to minimise capital expenditure and channel as much expenditure as possible through their operational budgets. [
- 71. Baxter has submitted that its ability to compete effectively in the sale of CRRT machines has been hampered by quality issues experienced with the Nikkiso CRRT machine as well as the [
  - ]. However, Nikkiso confirmed that the quality issues have now been addressed.

].

- 72. This means that without the acquisition, in the future it is likely Baxter would be a more effective competitor in the CRRT machine market than at present. This increase in competition would be lost with the acquisition.
- 73. Fresenius, which does participate in CRRT markets in other parts of the world, does not supply in New Zealand and does not intend to do so in the short-to-medium term.

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<sup>&</sup>lt;sup>27</sup> Although we have been informed by DHBs that there are a small number of Fresenius machines in operation in New Zealand.

74. There is some potential for [ ], which supply CRRT machines in other countries, to enter the CRRT machine market in the future. [ 1.28

#### The supply of CRRT consumables

- 75. Baxter and Gambro are currently the only suppliers of CRRT consumables in New Zealand. Consumables cover a range of products that connect the CRRT machine and fluids to the patient, including tubing and filters.
- 76. Baxter's CRRT consumables are broadly interchangeable with Gambro's (with some limited exceptions) and, as such, customers currently have a choice of these suppliers. With the acquisition, Baxter would be the sole supplier of CRRT consumables in New Zealand.

#### The supply of CRRT fluids

- 77. As with machines and consumables, Baxter and Gambro are the only suppliers of CRRT fluids in New Zealand.
- 78. CRRT customers interviewed by us raised access to fluids as their key concern with the proposed acquisition. Customers often enter into contracts with either Baxter or Gambro for the supply of fluids. These contracts can be of a longer term (up to 6 years) although some will come up for renewal in a shorter timeframe.
- 79. Furthermore, CRRT fluids are classed as a medicine in New Zealand and as a consequence, regulatory approval is required before they can be sold in New Zealand. While such approval is not onerous when the fluids are already approved for use overseas, we consider that they would potentially delay entry by an alternative supplier of CRRT fluids.

#### Conclusion on CRRT markets

- 80. We consider that, but for the proposed divestment, we are not satisfied that the proposed acquisition will not have, or would not be likely to have, the effect of substantially lessening competition in the national markets for the supply of:
  - 80.1 CRRT machines;
  - 80.2 CRRT fluids; and
  - 80.3 CRRT consumables.
- 81. We consider that entry by an alternative supplier of any of CRRT machines, consumables, or fluids, is not likely in the short to medium term. While there is some potential for CRRT suppliers active in Australia to enter in the medium term, we do

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<sup>&</sup>lt;sup>28</sup> Interviews with [ ], 12 April and 1 May 2013.

not consider that this potential entry would be sufficient to constrain the merged entity.

#### The proposed divestment

#### Introduction

- 82. Baxter has proposed a divestment to remedy competition concerns arising from the proposed acquisition. As set out in the Divestment Guidelines, where we consider that the proposed acquisition is likely to result in a substantial lessening of competition in the relevant market, we consider whether the Applicant's proposed divestment undertaking would remedy the competition concerns identified. We have assessed the composition, asset and purchaser risks associated with Baxter's divestment proposal.
- 83. We consider that the divestment proposal submitted by Baxter does not present any significant level of composition or asset risk. The makeup of the divestiture business is such that the eventual purchaser will be able to offer the full suite of CRRT products, [ ].
- 84. We consider that the divestment package proposed by Baxter presents some level of purchaser risk, given the lack of a confirmed upfront buyer. However, we do not consider that this purchaser risk is materially different to any other divestment package where there is no upfront buyer.
- 85. We have assessed the potential purchasers of the divestiture business and we are satisfied that suitably experienced and independent purchasers exist for the divestiture business.

#### The divestment offer

86. On 18 July 2013 we received an undertaking from Baxter (Attachment 1), under s 69A of the Act that Baxter would divest its worldwide CRRT business.

87. Baxter is proposing to divest at the option of the purchaser:

87.1	[					];
87.2	[		29		];	
87.3	I			];		
		-	1			

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87.4	[	];		
87.5	[			
			];	
87.6	[			];
87.7	[		]; and	
87.8	[			]

#### **Composition risks**

- 88. Composition risks are risks that a divestment proposal may be too limited in scope, or not appropriately configured, to attract either a suitable purchaser or to allow a successful business to be operated in competition with the merged entity.
- 89. We consider that given the makeup of the divestment business, the divestee would have the ability to supply the market with a full range of CRRT machines, consumables and fluids.
- 90. We consider that the scope of the proposed divestment is wide and covers almost the entirety of Baxter's CRRT business. Key factors such as [ ] are included and the successful purchaser will [ ]. In addition, the divestment business contains [ ] at the option of the purchaser.
- 91. One of the key issues of concern in the composition of the divestment business is whether or not it gives the successful purchaser the ability to obtain CRRT fluids (if fluids are not already manufactured by the purchaser) on such terms that will enable it to offer a competitive alternative to the merged entity in the market for the supply of CRRT fluids.
- 92. Post-acquisition, the successful purchaser will have [
  ]:
  92.1 [ ]; or
  92.2 [ ].

93.	Initially, it is expected that the purchaser's fluid supply requirements would be median [	ţ
94.	Baxter does not manufacture the majority of the components of its CRRT offering; instead it distributes these products on behalf of a number of third parties. <sup>30</sup> [ ]:	
	94.1 [ ]; or	
	94.2 [ ].	
95.	In its undertaking to us, Baxter has committed to [	
	] with the purchaser to enable them to offer the same CRRT products as Baxter does currently.	
96.	We consider that the scope of the divestment undertakings is sufficient to enable to purchaser to offer a competitive alternative to the merged entity in CRRT markets New Zealand. [  ].	
Asset	risks	
97.	Asset risks are risks that the competitive capability of a divestment business will deteriorate prior to completion of the divestment.	
98.	Under the divestment undertaking:	
	98.1 [	
	98.2 [ ]; and	
	98.3 [ ].	
99.	Therefore, we consider that there is little risk of asset deterioration prior to divestment.	

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[ ].

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#### **Purchaser risks**

- 100. We analyse the main purchaser risks, namely that:
  - 100.1 a purchaser acceptable to us may not be available, and/or
  - 100.2 the Applicant has an incentive to sell to a weak competitor for a low price rather than to a strong competitor.
- 101. In some cases there may be little or no interest from potential purchasers. This might indicate that the assets are unattractive to potential purchasers which may cast doubt on the effectiveness of the undertaking.
- 102. A buyer acceptable to us needs to have certain attributes that enable it to be an effective competitor in the relevant market. Examples of attributes that may make a buyer acceptable are set out below.
  - 102.1 It is independent of the merged entity.
  - 102.2 It possesses or has access to the necessary expertise, experience and resources to be an effective long term competitor in the market.
  - 102.3 The acquisition of the divested shares or assets by the proposed buyer does not raise competition concerns.
- 103. On 6 June 2013 Baxter informed us that it had narrowed the field of potential purchasers to two parties, both of whom it considered credible purchasers of the CRRT business.

104.	Baxter informed us that it had receive	ved bids from [
	] as it wanted to e	nsure that the final bidder would be a credible
	competitor in renal markets. The tw	o companies selected for the final round of
	shortlisting were Nikkiso, and [	]. At the completion of the shortlisting
	process, Baxter selected Nikkiso as it	ts preferred purchaser. We understand that,
	along with Nikkiso, [ ] were a	also considered to be acceptable purchasers by
	Baxter (although they were ultimate	ly unsuccessful).

Is a purchaser acceptable to us likely to be available?

105.	We understand that Baxter and Nikkiso have commenced detailed negotiations over
	the purchase of the CRRT business [
	].

106.	The successful purchaser, [	], are all active in the supply of rena
	replacement therapies. Nikkiso [	] is
	also a worldwide company but has no pre	esence in [ ].

107. The CRRT machines currently sold by Baxter are manufactured by Nikkiso. As outlined in paragraph 91 above, it is important that the successful purchaser has

access to a competitive source of CRRT fluids. Under the Divestment Undertaking provided by Baxter, it commits [
].

108. We consider that the three shortlisted parties would be likely to have the necessary skills, experience and resources to be an effective competitor in CRRT markets.

#### Conclusion on purchaser risk

109. As with any divestment proposal where there is no upfront purchaser, we consider that the package presented by Baxter carries a level of purchaser risk. However, the level of purchaser risk is not sufficient to outweigh our conclusion that the divestment proposal will remedy the competition concerns in New Zealand CRRT markets.

#### **Overall conclusion**

- 110. Having considered the proposed divestment, we consider that the divestment is likely to remedy the competition concerns identified in the CRRT markets by providing sufficient constraint on the merged entity to remove the potential competitive harm. We have found no significant risks associated with the divestment.
- 111. Accordingly, we are satisfied that the proposed acquisition with the divestment, will not have, or would not be likely to have, the effect of substantially lessening competition.

#### **Determination on notice of clearance**

112. Pursuant to s 66(3)(a) of the Commerce Act 1986, the Commerce Commission determines to give clearance to Baxter International Inc to acquire Gambro AB via Indap Holding AB, subject to the divestment undertaking dated 18 July 2013 provided by Baxter International Inc under s 69A of the Commerce Act 1986.

Dated this 30<sup>th</sup> day of July 2013

Dr Mark Berry Chairman

# BAXTER INTERNATIONAL INC THE COMMERCE COMMISSION

### **DIVESTMENT UNDERTAKING DEED**

DEED dated 2013

#### **PARTIES**

Baxter International, Inc (Baxter)

The Commerce Commission (NZCC)

#### Background

- (A) Baxter is the ultimate parent company of a group of companies that provide medical products and services worldwide, including in New Zealand. Baxter's primary business activities include the manufacture and supply of a range of plasma-based proteins for various purposes, products for regenerative medicines, vaccines and a range of intravenous solutions, administration sets and premix drugs. Baxter also provides renal replacement therapies, predominantly for peritoneal dialysis.
- (B) Gambro AB (**Gambro**) develops, manufactures and supplies products and therapies for HD, CRRT, liver dialysis, myeloma kidney therapy, related water systems and other extracorporeal therapies. Gambro is not active in peritoneal dialysis.
- (C) Pursuant to the Share Purchase Agreement, Baxter has agreed to acquire the entire share capital of Indap Holding and as a result Gambro will become a wholly-owned subsidiary of Baxter (**Proposed Transaction**).
- (D) On 15 March 2013, Baxter gave notice to the NZCC pursuant to Section 66(1) of the Act seeking clearance for the Proposed Transaction (**Clearance Application**).
- (E) Baxter does not accept that the Proposed Transaction will, or is likely to, result in a substantial lessening of competition in any relevant market. However, without admission, Baxter offers to dispose of the Divestment Assets in the form of this undertaking pursuant to section 69A of the Act and on the terms specified in this undertaking (**Undertaking**).

#### OPERATIVE PROVISIONS

#### 1. DEFINED TERMS AND INTERPRETATION

- 1.1 A term or expression starting with a capital letter which is defined in the Dictionary in Part 1 of Schedule 1 (**Dictionary**) has the meaning given to it in the Dictionary.
- 1.2 Part 2 of Schedule 1 sets out the rules of interpretation for this Undertaking.

#### 2. COMMENCEMENT AND TERMINATION OF UNDERTAKING

- 2.1 This Undertaking comes into effect when the Undertaking is executed by Baxter and is accepted by the Commission under section 69A of the Act.
- 2.2 Except with respect to the transfer, grant or provision of licences, agreements, transitional services or the fufilment of any other obligations continue after Closing in

accordance with this Undertaking, the obligations in this Undertaking are discharged on Closing.

#### 3. DIVESTMENT UNDERTAKING

- 3.1 Baxter commits to divest, or procure the divestiture of the Divestment Business by the end of the Trustee Divestiture Period as a going concern to a Purchaser and on terms of sale approved by the NZCC in accordance with the procedure described in Clause 10.2.
- 3.2 To carry out the divestiture, Baxter commits to find a Purchaser and to enter into a final binding sale and purchase agreement for the sale of the Divestment Business within the First Divestiture Period. If Baxter has not entered into such an agreement at the end of the First Divestiture Period, Baxter shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business in the Trustee Divestiture Period in accordance with the procedure described in Clause 11.13.
- 3.3 Baxter shall be deemed to have complied with this Undertaking if:
  - (A) by the end of the Trustee Divestiture Period, Baxter has entered into a final binding sale and purchase agreement;
  - (B) the NZCC approves the Purchaser and the terms in accordance with the procedure described in Clause 10.2; and
  - (C) the Closing of the sale of the Divestment Business takes place within a period not exceeding 3 months after the approval of the Purchaser and the terms of sale by the NZCC.
- 3.4 If Baxter or the purchaser approved by the NZCC pursuant to clause 10 is required to obtain a Foreign Divestiture Clearance and for this reason Closing cannot occur within the 3 month period referred to in clause 3.3(C), that period is extended until all Foreign Divestiture Clearances are obtained.

#### 4. PRESERVATION OF VIABILITY, MARKETABILITY AND COMPETITIVENESS

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

#### 5. HOLD-SEPARATE OBLIGATIONS OF PARTIES

- 5.1 Baxter commits, from the Effective Date until Closing, to keep the Divestment Business separate from the businesses it is retaining and to ensure that Key Personnel of the Divestment Business including the Hold Separate Manager have no involvement in any business retained and vice versa. Baxter shall also ensure that the Personnel do not report to any individual outside the Divestment Business.
- 5.2 Until Closing, Baxter shall assist the Compliance Auditor in ensuring that the Divestment Business is managed as a distinct and saleable entity separate from the businesses retained by Baxter. Baxter shall appoint a Hold Separate Manager who shall be responsible for the management of the Divestment Business, under the supervision of the Compliance Auditor. The Hold Separate Manager shall manage the Divestment Business independently and in the best interest of the business with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by the Parties.

#### 6. RING-FENCING

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

#### 7. NON-SOLICITATION

7.1 Baxter undertakes, subject to customary limitations, not to solicit, and to procure that Related Companies do not solicit, the Key Personnel transferred with the Divestment Business for a period of two years after Closing.

#### 8. DUE DILIGENCE

- 8.1 In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Business, Baxter shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process:
  - (A) provide to potential purchasers sufficient information as regards the Divestment Business;
  - (B) provide to potential purchasers sufficient information relating to the Personnel and allow them reasonable access to the Personnel.

#### 9. REPORTING

- 9.1 Baxter shall submit written reports in English on potential purchasers of the Divestment Business and developments in the negotiations with such potential purchasers to the NZCC and the Compliance Auditor no later than 10 days after the end of every month following the Effective Date (or otherwise at the NZCC's request).
- 9.2 To the extent that this has not already happened by the Effective Date, Baxter shall inform the NZCC and the Compliance Auditor on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of an information memorandum to the NZCC and the Compliance Auditor before sending the memorandum out to potential purchasers.

#### 10. THE PURCHASER

- 10.1 Baxter must notify the NZCC at least 20 business days prior to the end of the First Divestiture Period of the identity of the proposed Purchaser.
- 10.2 The Purchaser, in order to be approved by the NZCC, must:
  - (A) be independent of and unconnected to the Parties;
  - (B) have the financial resources, proven expertise and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors; and
  - (C) neither be likely to create, in the light of the information available to the NZCC, prima facie competition concerns nor give rise to a risk that the implementation of the Undertaking will be delayed, and must, in particular, reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business

(together the **Purchaser Requirements**).

10.3 The final binding sale and purchase agreement, and any agreement referred to in Schedule 3, section 3(G), shall be conditional on obtaining the NZCC's approval. When Baxter has reached an agreement with a purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), to the NZCC and the Compliance Auditor. Baxter must be able to demonstrate to the NZCC that the purchaser meets the Purchaser Requirements and that the Divestment Business is being sold in a manner consistent with the Undertaking. For the approval, the NZCC shall verify that the purchaser fulfils the Purchaser Requirements and that the Divestment Business is being sold in a manner consistent with the Undertaking. The NZCC may approve the sale of the Divestment Business without one or more of the Assets or Personnel, if this does not materially affect the NZCC's decision to give clearance for the Proposed Transaction.

#### 11. COMPLIANCE AUDITOR AND DIVESTITURE TRUSTEE

11.1 Baxter shall appoint a Compliance Auditor to carry out the functions specified in the Undertaking for a Compliance Auditor.

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

#### Proposal by Baxter

- 11.4 No later than one week after the Effective Date, Baxter shall submit a list of one or more persons whom Baxter proposes to appoint as the Compliance Auditor to the NZCC for approval. In the circumstances contemplated by Clause 11.2, no later than one month before the end of the First Divestiture Period, Baxter shall submit a list of one or more persons whom Baxter proposes to appoint as Divestiture Trustee to the NZCC for approval. Each proposal shall contain sufficient information for the NZCC to verify that the proposed Trustee fulfils the requirements set out in Clause 11.3 and shall include:
  - (A) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under this Undertaking;
  - (B) the outline of a work plan which describes how the Compliance Auditor or Divestiture Trustee intends to carry out its assigned tasks; and
  - (C) an indication whether the proposed Trustee is to act as both Compliance Auditor and Divestiture Trustee or whether different entities are proposed for the two functions.

#### Approval or rejection by the NZCC

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

#### New proposal by Baxter

11.6 If all the proposed Trustees are rejected by the NZCC, Baxter shall submit the names of at least two more individuals or institutions within one week of being informed of the rejection, in accordance with the requirements and the procedure set out in Clauses 11.2, 11.3 and 11.5.

11.7 Baxter may be required to obtain equivalent or similar approvals from other competition authorities. Should any such approval not be compatible with the NZCC's approval, Baxter may submit one or more alternative proposed Trustee(s) in the manner set out in Clause 11.4 and the NZCC will approve or reject those persons in the manner set out in Clause 11.5.

#### Appointment of approved Trustee

11.8 Upon obtaining all necessary approvals referred to in Clauses 11.5 or 11.7 the Trustee shall be appointed within one week, in accordance with the mandate approved by the NZCC.

#### Trustee nominated by the Commission

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

#### Functions of the Trustee

11.10 The Trustee shall assume its specified duties in order to ensure compliance with the Undertaking. The NZCC may, on its own initiative or at the request of the Trustee or Baxter, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations of this Undertaking.

#### **Duties and obligations of the Compliance Auditor**

- 11.11 The Compliance Auditor shall:
  - (A) propose in its first report to the NZCC a detailed work plan describing how it intends to monitor compliance with the obligations and conditions of this Undertaking;
  - (B) oversee the on-going management of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by Baxter with the conditions and obligations of this Undertaking.
- 11.12 To that end the Compliance Auditor shall:
  - (A) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Business, and the keeping separate of the Divestment Business from the business retained by the Baxter, in accordance with Clause 4 and 5.1:
  - (B) supervise the management of the Divestment Business as a distinct and saleable entity, in accordance with Clause 5.2;
  - (C) (i) in consultation with Baxter, determine all necessary measures to ensure that Baxter does not after the Effective Date obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary

nature relating to the Divestment Business, in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business, and (ii) decide whether such information may be disclosed to Baxter as the disclosure is reasonably necessary to allow Baxter to carry out the divestiture or as the disclosure is required by law;

- (D) monitor the splitting of assets and the allocation of personnel between the Divestment Business and Baxter or Related Companies;
- (E) assume the other functions assigned to the Compliance Auditor under the conditions and obligations in this Undertaking;
- (F) propose to Baxter such measures as the Compliance Auditor considers necessary to ensure Baxter's compliance with the conditions and obligations of this Undertaking, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Business, the holding separate of the Divestment Business and the non-disclosure of competitively sensitive information:
- (G) review and assess potential purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process, (i) potential purchasers receive sufficient information relating to the Divestment Business and the Personnel in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process, and (ii) potential purchasers are granted reasonable access to the Personnel;
- (H) provide to the NZCC, sending Baxter a non-confidential copy at the same time, a written report within 15 days after the end of every month. The report shall cover the operation and management of the Divestment Business so that the NZCC can assess whether the business is held in a manner consistent with the Undertaking and the progress of the divestiture process as well as potential purchasers. In addition to these reports, the Compliance Auditor shall promptly report in writing to the NZCC, sending Baxter a non-confidential copy at the same time, if it concludes on reasonable grounds that Baxter is failing to comply with this Undertaking;
- (I) within one week after receipt of the documented proposal referred to in Clause 10.2, submit to the NZCC a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Business after the sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations of this Undertaking, in particular, if relevant, whether the sale of the Divestment Business without one or more Assets or not all of the Personnel affects the viability of the Divestment Business after the sale, taking account of the proposed purchaser.

#### Duties and obligations of the Divestiture Trustee

11.13 Within the Trustee Divestiture Period, the Divestiture Trustee shall sell at no minimum price the Divestment Business to a purchaser, provided that the NZCC has approved both the purchaser and the final binding sale and purchase agreement in accordance

with the procedure laid down in Clause 10.2. The Divestiture Trustee shall include in the sale and purchase agreement such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall protect the legitimate financial interests of Baxter, subject to Baxter's unconditional obligation to divest the Divestment Business at no minimum price in the Trustee Divestiture Period.

11.14 In the Trustee Divestiture Period (or otherwise at the NZCC's request), the Divestiture Trustee shall provide the NZCC with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Compliance Auditor (if the Compliance Auditor is different from the Divestiture Trustee) and a non-confidential copy to Baxter.

#### Duties and obligations of Baxter

- 11.15 Baxter shall provide and shall cause its advisors to provide the Trustee with all such cooperation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of Baxter's or the Divestment Business' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Undertaking and Baxter and the Divestment Business shall provide the Trustee upon request with copies of any document. Baxter and the Divestment Business shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.
- 11.16 Baxter shall provide the Compliance Auditor with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business which are currently carried out at headquarters level. Baxter shall provide and shall cause its advisors to provide the Compliance Auditor, on request, with the information submitted to potential purchasers, in particular give the Compliance Auditor access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. Baxter shall inform the Compliance Auditor on possible purchasers, submit a list of potential purchasers, and keep the Compliance Auditor informed of all developments in the divestiture process.
- 11.17 Baxter shall grant or procure Related Companies grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale, the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the divestiture process. Upon request of the Divestiture Trustee, Baxter shall cause the documents required for effecting the sale and the Closing to be duly executed.
- 11.18 Baxter shall indemnify the Trustee and its employees and agents (each an **Indemnified Party**) and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to Baxter for any liabilities arising out of the performance of the Trustee's duties under the Commitments, except to the extent that

- such liabilities result from the willful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.
- 11.19 At the expense of Baxter, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to Baxter's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should Baxter refuse to approve the advisors proposed by the Trustee the NZCC may approve the appointment of such advisors instead, after having heard Baxter's reasons for that refusal. Only the Trustee shall be entitled to issue instructions to the advisors. Clause 11.18 shall apply mutatis mutandis. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served Baxter during the First Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

#### Replacement, discharge and reappointment of the Trustee

- 11.20 If the Trustee ceases to perform its functions under the Undertaking or for any other good cause, including the exposure of the Trustee to a conflict of interest:
  - (A) the NZCC may, after hearing the Trustee, require Baxter to replace the Trustee; or
  - (B) Baxter, with the prior approval of the NZCC, may replace the Trustee.
- 11.21 If the Trustee is removed according to Clause 11.20, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in Clauses 11.1 to 11.9.
- 11.22 Beside the removal according to Clause 11.20, the Trustee shall cease to act as Trustee only after the duties and obligations under the Undertaking with which the Trustee has been entrusted have been implemented. However, the NZCC may at any time require the reappointment of the Compliance Auditor if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

#### 12. REVIEW CLAUSE

- 12.1 The NZCC may, where appropriate, in response to a request from Baxter showing good cause and accompanied by a report from the Compliance Auditor:
  - (A) grant an extension of the time periods foreseen in the Undertaking, or
  - (B) waive, modify or substitute, in exceptional circumstances, one or more of the clauses of this Undertaking,
    - on the basis that the alteration would not have materially affected NZCC's clearance decision.

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

#### 13. DISCLOSURE OF UNDERTAKING

- 13.1 Baxter and the NZCC agree that Schedule 2 will remain confidential at all times.
- 13.2 Baxter acknowledges that the NZCC may, subject to Clause 13.1:
  - (A) make the Undertaking publicly available; and
  - (B) from time to time publicly refer to this Undertaking.
- 13.3 Notwithstanding Clause 13.1, nothing in this Undertaking prevents the NZCC from disclosing such information as:
  - (A) is required by law; or
  - (B) is consistent with its statutory functions and powers.

#### 14. RELEASE OF PERSONNEL

- 14.1 The obligations in this Clause 14 apply if the Divestment Business is divested as contemplated by this Undertaking.
- 14.2 Subject to Clause 14.1, Baxter must release the Personnel, with effect from the Closing from any obligation to provide services to Baxter and any non-compete or similar restraint of trade obligation, to the extent that such obligation would otherwise prevent the person from performing his or her contemplated role in relation to the Divestment Business.

#### 15. PROVISION OF INFORMATION TO THE NZCC

- 15.1 Without limiting any other clause of this Undertaking, at the NZCC's direction Baxter will, and will procure that its directors, employees, agents or contractors identified by the NZCC will:
  - (A) furnish information to the NZCC that is relevant to this Undertaking;
  - (B) produce documents to the NZCC within Baxter's custody, control, or power that are relevant to this Undertaking; and
  - (C) attend the NZCC at a time and place appointed by the NZCC to answer any questions the NZCC may have (including by telephone if more convenient),

as directed by the NZCC in relation to this Undertaking.

15.2 Nothing in this Clause 15 requires the provision of information or documents in respect of which Baxter has a claim of legal professional privilege.

#### 16. OBLIGATION TO PROCURE

16.1 Where the performance of an obligation under this Undertaking requires a Related Company of Baxter to take or refrain from taking some action, Baxter will procure that Related Company to take or refrain from taking that action, as the case may be.

#### 17. NOTICES

17.1 Any notice, demand, consent or communication given or made under this Undertaking to the NZCC should be sent to:

Commerce Commission Attention: The Registrar

Address: 44 The Terrace PO Box 2351 Wellington 6140 New Zealand

Fax No: (04) 924 3700

Email: registrar@comcom.govt.nz

or to any other address which the NZCC subsequently notifies to Baxter.

17.2 Any notice, demand, consent or communication given or made under this Undertaking to the NZCC should be sent to:

Name: Baxter International, Inc Attention: General Counsel

Address: One Baxter Parkway, Deerfield, Illinois 60015

Fax: 224 948.2450

Email: david\_scharf@baxter.com

#### And

Name: Baxter Healthcare Pty Limited

Attention: Richard McNamee

Address: 1 Baxter Drive, Old Toongabbie, NSW, 2146

Fax: + 61 2 8845 1688

Email: richard\_mcnamee@baxter.com

#### With an email copy sent to:

Name: Jones Day Attention: Nick Taylor

Address: Aurora Place, Level 41, 88 Phillip Street, Sydney NSW 2000

Email: njtaylor@jonesday.com

or to any other address which the NZCC subsequently notifies to Baxter

#### 18. MISCELLANEOUS

- 18.1 Baxter confirms that in entering into the obligations recorded in this Deed it intends to create binding and enforceable legal obligations for the benefit of the NZCC.
- 18.2 This Undertaking is governed by New Zealand law and the parties accept the exclusive jurisdiction of the New Zealand courts.

18.3 This Undertaking may be executed by an exchange of electronic copies (whether by email or facsimile or otherwise) and execution of this Undertaking by that means is valid and sufficient execution.

.

#### **SCHEDULE 1: DEFINED TERMS AND INTERPRETATION**

#### 1. DICTIONARY

In this document:

**ACCC** means the Australian Competition and Consumer Commission.

Act means the Commerce Act 1986.

**Assets** means each of the items in Part 3(A) to (E) of Schedule 3.

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

**Business Day** means a day other than a Saturday, Sunday or public holiday on which banks are open for business in New Zealand.

**Closing** means the transfer of the legal title of the Divestment Business to the Purchaser.

Compliance Auditor means one or more natural or legal person(s), independent from the Parties, who is approved by the NZCC and appointed by Baxter, and who has the duty to monitor Baxter's compliance with the conditions and obligations of this Undertaking. This person is commonly referred to in the EEA as a "monitoring trustee" and Baxter may elect to propose the same person as Compliance Auditor under this Undertaking as under the undertaking given to the ACCC and as monitoring trustee under commitments to a competition authority in another country.

**CRRT** means continuous renal replacement therapy.

**Dictionary** means this dictionary in Part 1 of Schedule 1.

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

Divestment Assets means each of the items in Part 3(A) to (G) of Schedule 3.

**Divestment Business** means Baxter's global CRRT business as defined in Schedule 3.

**Effective Date** means the closing of the Proposed Transaction in accordance with the Share Purchase Agreement.

First Divestiture Period has the meaning provided in confidential Schedule 2.

**Foreign Divestiture Clearance** means an approval from a competition authority in any relevant jurisdiction to the closing of the divestiture of the Divestment Business with a purchaser approved by the NZCC pursuant to clause 10..

**Gambro** means Gambro AB, a company established in Lund, Sweden, which is wholly owned by Indap Holding.

**HD** means hemodialysis.

**Hold Separate Manager** means the person appointed by Baxter at a global level for the Divestment Business to manage the day-to-day business under the supervision of the Compliance Auditor.

**Indap Holding** means Indap Holding AB, a Swedish company indirectly held by private equity funds managed by EQT Partners AB and the investment company, Investor AB.

**Indemnified Party** has the meaning provided in Clause 11.18.

**Key Personnel** means all personnel necessary to maintain the viability and competitiveness of the Divestment Business including, relevant to New Zealand, two R&D staff located in Belgium, two R&D staff located in Switzerland and two technical staff located in France.

**NZCC** means the Commerce Commission.

PD means peritoneal dialysis.

Parties means Baxter and Gambro.

**Personnel** means all personnel currently employed in the Divestment Business, including Key Personnel. For the avoidance of doubt, if a staff member were to choose to depart in the ordinary course of business, then any replacement staff member would be included amongst the Personnel.

**Purchaser** means an entity approved by the NZCC as acquirer of the Divestment Business in accordance with the Purchaser Requirements.

**Purchaser Requirements** has the meaning provided in Clause 10.1.

**Proposed Transaction** has the meaning provided in Paragraph (C) of the Background.

**Related Company** has the meaning provided in the *Companies Act 1993*.

**Share Purchase Agreement** means the share purchase agreement dated 4 December 2012 between Indap Holding and Baxter.

**Trustees** means the Compliance Auditor and the Divestiture Trustee and **Trustee** means either of them.

**Trustee Divestiture Period** has the meaning provided in confidential Schedule 2.

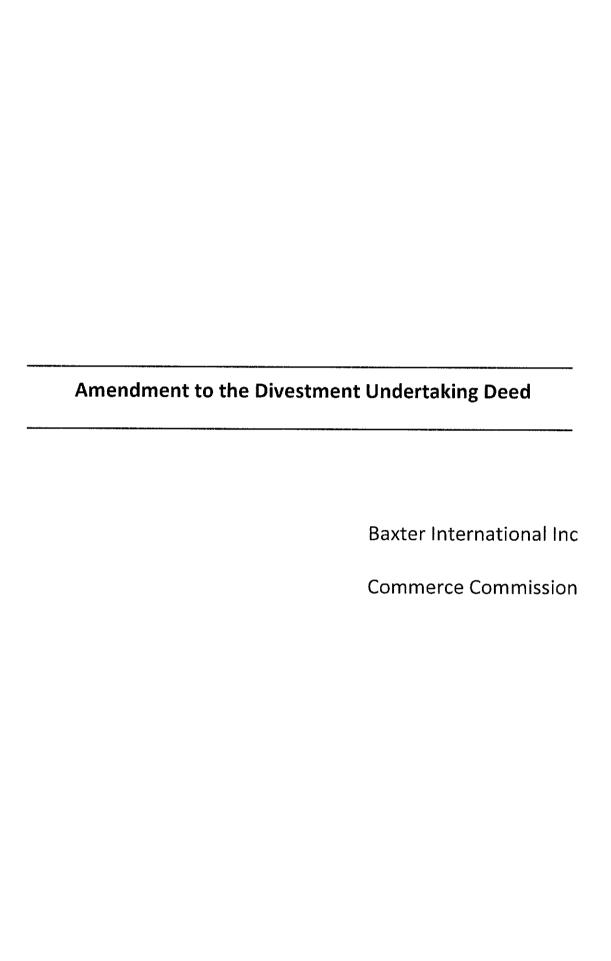
#### 2. INTERPRETATION

In the interpretation of this Undertaking, the following provisions apply unless the context otherwise requires:

- A. a reference to this Undertaking includes all of the provisions of this deed including its schedules and annexes:
- B. headings are inserted for convenience only and do not affect the interpretation of this Undertaking;
- C. if the day on which any act, matter or thing is to be done under this Undertaking is not a Business Day, the act, matter or thing must be done on the next Business Day;
- D. a reference in this Undertaking to any law, legislation or legislative provision includes any statutory modification, amendment or reenactment, and any subordinate legislation or regulations issued under that legislation or legislative provision;
- E. a reference in this Undertaking to any company includes its Related Companies;
- F. a reference in this Undertaking to any agreement or document is to that agreement or document as amended, novated, supplemented or replaced;
- G. a reference to a Clause, part, annex, schedule or attachment is a reference to a clause, part, annex, schedule or attachment of or to this Undertaking;
- H. an expression importing a natural person includes any company, trust, partnership, joint venture, association, body corporate or governmental agency;
- I. where a word or phrase is given a defined meaning, another part of speech or other grammatical form in respect of that word or phrase has a corresponding meaning;
- J. a word which denotes the singular also denotes the plural, a word which denotes the plural also denotes the singular, and a reference to any gender also denotes the other genders;
- K. a reference to the words 'such as', 'including', 'particularly' and similar expressions is to be construed without limitation;
- L. nothing in this Undertaking is to be construed to the disadvantage of a party because the party was responsible for the preparation of this Undertaking or any part of it, or put the relevant part of the Undertaking forward; and
- M. a reference to: (i) a thing (including, but not limited to, a chose in action or other right) includes a part of that thing; (ii) a party includes its successors and permitted assigns; and (iii) a monetary amount is in New Zealand dollars.

## SIGNATURE PAGE Executed and delive

Executed and delivered as a deed.	
Executed as a deed by Baxter International Inc:	
Signature Authorised Representative	
Print Name and Title	



2013

#### **Parties**

Baxter International, Inc (Baxter)

Commerce Commission (Commission)

#### **Background**

- On 15 March 2013 Baxter gave notice under s 66(1) of the Commerce Act 1986 to the New Zealand Commerce Commission seeking clearance to acquire the entire share capital of Indap Holding AB.
- On 18 July 2013 Baxter executed a Divestment Undertaking Deed in favour of the Commission pursuant to which Baxter will dispose the Divestment Business (as defined in the Divestment Undertaking Deed).
- On 18 July 2013 the Commission accepted the divestment undertaking under s 69A
  of the Commerce Act 1986 and on 30 July 2013 Baxter was given clearance to
  acquire Gambro AB subject to the divestment undertaking.
- 4. Baxter wishes to vary the Divestment Undertaking Deed under s 69AC of the Commerce Act 1986 as recorded in this Amendment by amending clause 3.3(C) of the 18 July 2013 Divestment Undertaking Deed.

#### **Amendment to Divestment Undertaking Deed**

- 5. With effect from the date this Amendment is accepted by the Commerce Commission, clause 3.3(C) of the 18 July 2013 Divestment Undertaking Deed is deleted and replaced with the following:
  - 3.3(C) the Closing of the sale of the Divestment Business takes place by 3 February 2014.
- 6. In all other respects the provisions of the 18 July 2013 Divestment Undertaking Deed to the Commerce Commission are unchanged and remain in full force and effect.

Signed by Baxter International Inc:

Signature Authorised Representative

condente VILL President, General Coursel and Corporate Secretary

Print Name and Title