PUBLIC VERSION

NOTICE SEEKING CLEARANCE OF A BUSINESS ACQUISITION PURSUANT TO SECTION 66 OF THE COMMERCE ACT 1986

24 April 2015

The Registrar
Business Acquisitions and Authorisations
Commerce Commission
PO Box 2351
WELLINGTON

Pursuant to s66(1) of the Commerce Act 1986 notice is hereby given seeking **clearance** of a proposed business acquisition.

PUBLIC VERSION

TABLE OF CONTENTS

PUBLIC VERSION

EXECUTIVE SUMMARY

1.1 Pfizer Inc. ("**Pfizer**") seeks clearance to acquire all of the shares in Hospira Inc. ("**Hospira**"). This will be implemented by a subsidiary of Pfizer (Perkins Holding Company) merging with and into Hospira, with Hospira surviving as a wholly-owned subsidiary of Pfizer (the "**Proposed Transaction**").

1.2 Pfizer is a global research based biomedical and pharmaceutical company active in discovering, developing, manufacturing, marketing and selling innovative medicines for humans.

1.3 Hospira is a global provider of injectable pharmaceutical drugs and infusion technologies that it develops, manufactures and distributes worldwide. Hospira was formerly the "hospital products" division of Abbott and has a particular focus on speciality injectable pharmaceuticals.

1.4 In New Zealand:

(a) Pfizer operates through its wholly owned subsidiaries, Pfizer New Zealand Limited and Pfizer PFE New Zealand (together "**Pfizer NZ**"); and

(b) Hospira operates through its wholly owned subsidiary, Hospira NZ Limited ("**Hospira NZ**"). Its products are distributed in New Zealand by Healthcare Logistics.

1.5 The following key dynamics are evidenced in the pharmaceutical industry in New Zealand:

(a) There are a significant number of large, sophisticated and well resourced existing pharmaceutical companies active in the industry. Many of these are significant global companies, supplying into New Zealand, in some cases through New Zealand based distributors. A full list of these competitors is set out at Appendix 5.

(b) As is the case in many other developed countries, public health authorities - the key customers of pharmaceutical companies - are facing increasing budgetary pressure due to increased demand for health services, including from ageing populations.

(c) This, in turn, has seen originator (or innovative) pharmaceutical companies face fierce competition from suppliers of generic medicines. In New Zealand the use of generic medicines has increased to the point where they account for 73% of acquired medicines.

(d) Ease of generic entry: The abbreviated Medsafe process for approval to supply generic pharmaceuticals in New Zealand means that the time taken, and cost involved, in bringing a generic medicine to market are not significant. Consequently, this means there is a large number of global pharmaceutical companies who are well placed, and easily able, to enter the New Zealand market.

(e) Countervailing power of PHARMAC: All market participants are constrained by the high degree of regulation in the New Zealand pharmaceutical industry, in particular by the role performed by PHARMAC and the purchasing power of the District Health Boards ("**DHBs**"). By effectively acting as a monopsonist purchaser, PHARMAC is able to drive low prices, sponsor entry into New Zealand and flex demand to achieve optimal purchasing outcomes.

1.6 The Parties only overlap in:

(a) gentamicin based medicines (a form of aminoglycoside);

(b) heparin based medicines (a form of anticoagulant);

(c) morphine based medicines (a form of narcotic); and

(d) phenytoin based medicines (a form of anti-epileptic),

albeit in each case, their respective products are not clinically substitutable.

1.7 In each of the four cases where the parties overlap at the molecule level, their respective products are not in fact clinically substitutable. As a result, the Proposed Transaction has no competitive effect in those four molecule areas:

(a) In the case of gentamicin, the Parties supply substantially different doses of gentamicin - Hospira's presentation contains 10mg of gentamicin per ml and Pfizer's 40mg per ml. The difference is such that these two presentations are not clinically substitutable.

(b) In the case of heparin, the clinical indication of each SKU is different as, among other things, administering an incorrect dosage (ie concentration) can lead to fatal haemorrhaging. The Parties do not overlap in the supply of heparin SKUs and so do not impose competitive constraint on one another.

(c) In the case of morphine based medicines, Pfizer's product is an oral solution which is self-administered at home. It is less potent than Hospira's injectable morphine medicines which are used in a hospital setting, predominantly in operating theatres, emergency departments and intensive care units where patients can be closely monitored for adverse reactions.

(d) In the case of phenytoin based medicines, the Parties' products have completely different clinical indications. Pfizer's tablet and oral liquid medicines are used for out-patient maintenance therapy in epileptics to prevent seizures. By contrast, Hospira's injectable medicines are used in hospitals to treat actively fitting patients.

1.8 The Parties also overlap as potential competitors only in:

(a) cytarabine based medicines (a form of antimetabolite);

(b) doxorubicin based medicines (a form of antineoplastic antibiotic);

(c) epirubicin based medicines (a form of antineoplastic antibiotic);

(d) methotrexate based medicines (a form of antimetabolite);

(e) methylprednisolone based medicines (a form of systemic corticosteroid); and

(f) piperacillin/tazobactam based medicines (a form of broad spectrum penicillin).

1.9 In all six molecule areas where the Parties overlap as potential competitors, the Proposed Transaction will not have any adverse effect on competition. In each case, the Parties either currently do not impose any meaningful constraint on one another (meaning there is no merger effect) and/or there will remain a sufficient number of other potential competitors post-merger for the Proposed Transaction not to alter the prevailing competitive conditions.

1.10 For all of the molecule areas where the Parties overlap as actual or potential competitors, PHARMAC has significant countervailing power.

Conclusion

1.11 For the reasons outlined above, and as outlined further in this application for clearance, the Proposed Transaction is not likely to have the effect of substantially lessening competition in any market in New Zealand.

PART A: TRANSACTION DETAILS

PARTY DETAILS

2. The Applicant

2.1 This notice is given by Pfizer.

2.2 Details for Pfizer are:

Pfizer Inc.
235 East 42nd Street
New York, NY10017
USA

http://pfizer.com (NZ website http://www.pfizer.co.nz/)

Attention:	Marc Brotman
Position:	Vice President and Assistant General Counsel
Telephone:	**[ ]**
Email:	**[ ]**

2.3 All correspondence and notices in respect of this application should be directed in the first instance to:

Russell McVeagh
Barristers & Solicitors
PO Box 8
AUCKLAND 1140

Attention:	Sarah Keene / Christopher Graf
Telephone:	09 367 8133 / 09 367 8104
Email:	sarah.keene@russellmcveagh.com / christopher.graf@russellmcveagh.com

2.4 A diagram showing the organisational structure of Pfizer and its subsidiaries is set out in Confidential Appendix Two.

2.5 There are no pre-existing links between Pfizer and Hospira (together the "**Parties**") or as between any of their respective group companies.

3. The other merger party

3.1 The other party is Hospira.

3.2 Details for Hospira are:

Hospira Inc.
275 North Field Drive
Lake Forest
Illinois 60045
USA

http://hospira.com/en/
(NZ website http://www.hospira.co.nz/english/default.aspx)

Attention:	Michael Johannesen
Position:	VP and Associate General Counsel
Telephone:	**[ ]**
Email:	**[ ]**

3.3 All correspondence and notices in respect of this application should be directed in the first instance to:

Chapman Tripp
Barristers & Solicitors
10 Customhouse Quay
PO Box 993
WELLINGTON 1140

Attention:	Grant David
Telephone:	04 498 4908
Email:	grant.david@chapmantripp.com

3.4 A diagram showing the organisational structure of Hospira and its subsidiaries is set out in Confidential Appendix Three.

About the Parties

Pfizer

3.5 Pfizer is a global research-based biomedical and pharmaceutical company active in the development, manufacture, distribution and sale of human medicines.

3.6 As a research-based company, the bulk of Pfizer's business is targeted at the research and development of innovative new pharmaceuticals across a broad product portfolio. To this end, two of Pfizer's three business divisions are focused on discovering, developing and marketing new human medicines.

3.7 Pfizer's three global business divisions are:

Global Vaccines, Oncology and Consumer Health - This division focuses on the development and commercialisation of vaccines, products for oncology and consumer healthcare. Each of these three product areas operates as a separate global business, as they demand different skills and specialisations.

Global Innovative Pharmaceuticals - This division focuses on the development and commercialisation of all other novel medications created by Pfizer, across product areas such as immunology and inflammation, cardiovascular and metabolic, neuroscience and pain, rare diseases, and women's and men's health.

Global Established Pharma - This division includes brands that have lost patent exclusivity, or are expected to lose exclusivity in the near future, including sterile injectables and biosimilars (which, as described at 13.14, are in some ways akin to a chemical pharmaceutical for which the patent or exclusivity period has expired). **[ ]** unlike some other pharmaceutical companies, eg Novartis' Sandoz business, does not have a dedicated generics business.

3.8 In New Zealand, Pfizer operates through its subsidiaries, Pfizer New Zealand Limited and Pfizer PFE. Pfizer New Zealand employs around **[ ]** personnel across its biopharmaceutical and consumer businesses, with the majority of employees based in Pfizer's head office in Mount Eden, Auckland.

3.9 Pfizer does not have any manufacturing operations in New Zealand.

3.10 **[ ]**

Hospira

3.11 Hospira is a global developer, manufacturer and distributor of injectable pharmaceutical drugs and infusion technologies. It was formed as the "hospital products" division of Abbott Laboratories before being divested in 2004, and retains that focus in its business operations. Hospira focuses predominantly on generic and biosimilar products (see 7.12), rather than novel (innovator) pharmaceuticals.

3.12 Hospira focuses on three main areas:

(a) Specialty Injectable Pharmaceuticals - Hospira's specialty injectable pharmaceutical products represented approximately 69% of Hospira's net global sales in 2013.[1] This product group consists primarily of generic injectable pharmaceuticals, but also includes a minority of branded products. Biosimilar pharmaceuticals are also included in this category.

(b) Medication Management Products (commonly referred to as medical devices) including infusion systems, IV sets, and IV clinical integration and safety software.

(c) Other pharmaceuticals (consisting mainly of large volume intravenous solutions, nutritionals and contract manufacturing services).

3.13 In New Zealand, Hospira operates through its subsidiary, Hospira NZ Limited. Hospira **[ ]**

3.14 Hospira does not have any manufacturing facilities in New Zealand.

3.15 Hospira's products are distributed in NZ by its New Zealand distribution partner, Pharmacy Retailing (NZ) Limited, trading as Healthcare Logistics. **[ ]**

[1] United States Securities and Exchange Commission, Hospira, Inc. Form 10-K for the Fiscal Year ended December 31 2013.

THE PROPOSED TRANSACTION

4. Transaction details

Outline and structure of the transaction

4.1 On 5 February 2015, Pfizer, Perkins Holding Company ("**Sub**"), a wholly owned subsidiary of Pfizer, and Hospira entered into an Agreement and Plan of Merger ("**Merger Agreement**"). Pursuant to the Merger Agreement, upon completion, Sub will merge with and into Hospira, with Hospira being the surviving company. As a result, Hospira will become a wholly owned subsidiary of Pfizer.

4.2 The Proposed Transaction is valued at approximately US$17 billion (NZ$22.5 billion).

4.3 Completion of the Proposed Transaction is subject to a number of conditions precedent, including approval by relevant regulators and other customary provisions.

Rationale for the merger

4.4 Like other research-based pharmaceutical companies, **[ ]** At the same time, in the face of the increasing care needs of ageing populations, health care providers, most notably public health care providers, are demanding lower prices. Public health buying models, such as PHARMAC in NZ (see 10.11), also continue to exert significant downward pricing pressure on pharmaceutical suppliers.

4.5 Against this background, Pfizer has identified many strategic, operational, financial and cultural benefits that are likely to arise from the Proposed Transaction.

4.6 Importantly, the Proposed Transaction will enable Pfizer to build a presence in complementary products, namely:

(a) generic sterile injectables, a sector which Pfizer considers presents important growth opportunities, and in which Pfizer hopes to increase its presence through the acquisition of Hospira's product line; and

(b) biosimilars, a relatively new sector in which Hospira has acquired early expertise. Pfizer intends to take advantage of its greater scale and development capabilities to expand the reach of Hospira's products (which are currently distributed primarily in the United States) to Europe and other markets, including New Zealand.

4.7 Pfizer forecasts substantial financial and operational synergies, with the Proposed Transaction delivering approximately EUR 600 million (over NZ$900 million) in annual cost savings globally by 2018. **[ ].**

Ancillary agreements

4.8 There are no ancillary agreements associated with the Proposed Transaction.

5. Copies of transaction documents

5.1 A copy of the Merger Agreement entered into on 5 February 2015 is provided at Confidential Appendix 4.

6. Notification of other competition agencies

6.1 **[ ]**

PART B: THE INDUSTRY

7. Background to the industry

7.1 Pharmaceuticals can be divided into two broad categories: prescription pharmaceuticals and over-the-counter ("**OTC**") pharmaceuticals. As their name suggests, prescription medications require a doctor's prescription, while OTC pharmaceuticals can be purchased without a prescription.[2]

7.2 This clearance application relates solely to prescription medications, because Hospira does not supply OTC pharmaceuticals. Rather, Hospira's overwhelming focus is on hospital medicines.

7.3 Hospital medicines are purchased by DHBs either for the purpose of treating patients in hospital, or prescribing those medications to hospital patients so that, upon discharge, they can self-administer their medication at home. In New Zealand the price for hospital medications is, in the vast majority of cases, determined via contractual arrangements between PHARMAC and the relevant pharmaceutical supplier. This process is discussed in detail at 10.14.

7.4 Hospital medicines, in turn, are broadly comprised of two distinct forms of pharmaceuticals:

Small molecule drugs

7.5 Small molecule drugs may take various forms, such as injections, capsules, oral fluids etc. However, all are comprised of chemicals formulated to a standard recipe.

7.6 This type of pharmaceutical comprises the vast majority of pharmaceuticals currently supplied in New Zealand (and globally).

7.7 Innovative small molecule drugs that meet the criteria for intellectual property protection (that is, they are new, inventive, and useful), will be protected for a fixed term by patent law. During this fixed term period, no other competing company is permitted to commercialise a drug that infringes on the intellectual property-holder's patent.

7.8 Upon expiry of these exclusive patent terms, any competitor is then able to commercialise drugs that are identical to the drug for which the patent has expired. These 'follow-on' drugs, made pursuant to the same chemical formula as the original drug, are called generics. Generics are typically much less expensive than their 'originator' counterparts.

7.9 The limited competitive overlaps arising out of the Proposed Transaction all concern medicines that are off-patent and, for the most part, are old medicines.

Biopharmaceuticals

Biologics

7.10 A **biologic** medicine is a medicine produced from a living organism, such as a yeast, bacteria or animal cell. These 'biologics' (or biopharmaceuticals) are proteins such as hormones, enzymes, antibodies, vaccines and allergens, which interact with the body to produce a therapeutic outcome.[3] Unlike conventional chemical pharmaceuticals, which

[2] New Zealand Commerce Commission, *Mylan Inc. / Abbott Laboratories Inc.* [2014] NZCC 40 at [6].
[3] European Commission, *What you Need to Know about Biosimilar Medicinal Products: Process on Corporate Responsibility in the Field of Pharmaceuticals Access to Medicines in Europe: A Consensus Information Document*, 2013, at 7.

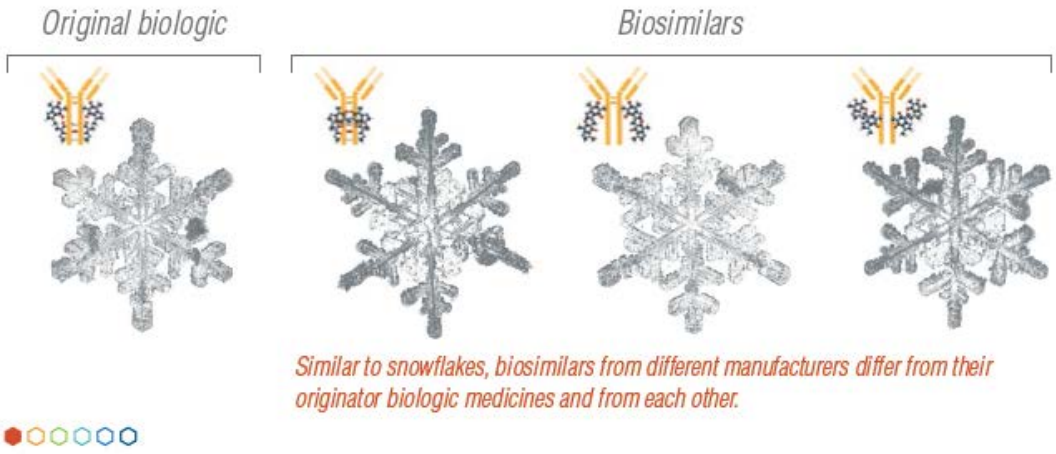
can be produced simply by combining chemicals according to a standard 'recipe' or formula, most biologics are produced through genetic engineering. A particular gene(s) is inserted into a cell, causing it to produce the desired protein and release it into the fluid solution outside of the cell. The solution is then filtered to isolate the desired protein, which can then be used medicinally. This is called recombinant DNA technology.

7.11 Biologics are large molecules, often 200 to 1,000 times the size of a small molecule (chemical) drug. As the manufacturing process is much more complex than the production of chemical pharmaceuticals,[4] the development, production and end price of biologics are all substantially more expensive. In New Zealand some biologic medicines cost upwards of $50,000 per patient per year.[5]

Biosimilars

7.12 A **biosimilar** is a generic equivalent of a biologic. However, while small molecule generics need only combine the requisite chemicals according to the standard chemical 'recipe', as biologics are produced from living cells, they are subject to the same natural variability as all living matter, meaning no two biologic proteins are identical. A biosimilar is a "comparable version of an approved biologic medicine",[6] which, as illustrated below in Figure 1, only differs structurally from the 'reference product' in non-material ways. The biosimilar mimics the originator biologic drug and so is not strictly speaking "equivalent".

Figure 1: Biologic/Biosimilar cell structures



Source: Amgen - Biologics and Biosimilars: an overview, available here.

7.13 Biosimilars undergo extensive clinical testing to ensure comparability. Despite this, biosimilars can differ from their reference biologic in clinically significant ways. In this regard, Medsafe (the regulatory body responsible for granting approvals to market drugs in New Zealand, discussed further at 10.2) has noted:

> Unlike generic chemical medicines where the chemical structure is identical to that of the innovator a biosimilar medicine does not usually have an identical structure to the innovator. As a consequence even though a biosimilar medicine may be assessed to be similar in terms of the quality, safety and efficacy of the reference product the immunogenicity profile *may* preclude switching between products.

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[4] See, for example, the discussion of the European Commission on the complexities in the development of biologics in COMP/M.5868, *Teva / Ratiopharm*, (3 August 2010) at [28]-[32].
[5] Pharmaceutical Management Agency, *Fact sheet: Biologics and biosimilars*, (2 December 2014) at [1].
[6] Pharmaceutical Management Agency, *Fact sheet: Biologics and biosimilars*, (2 December 2014) at [1].

Medical devices

7.14 Medical devices are defined in s 3A of the Medicines Act 1981 as any device or apparatus intended to be used in, on or for human beings for a therapeutic purpose, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means. They include for example: surgical instruments, infusion pumps, heart rate monitors, medical imaging kits, prosthetics and orthopaedic implants, and hearing aids.

7.15 Only Hospira is active in the supply of medical devices in New Zealand.

8. Industry dynamics

8.1 For the most part, the research-based pharmaceutical industry is globalised, with a large number of multinational companies active across much of the world. The many challenges faced by the global research-based pharmaceutical industry will therefore be applicable in New Zealand. Some of the more material challenges, and which are applicable in New Zealand, are outlined below.

Growing costs faced by health providers

8.2 In many countries, including New Zealand, customers of pharmaceutical companies are facing increased budgetary pressure as a result of increasing demand for health services including from ageing populations.

8.3 In New Zealand the ageing population, and a workforce that is ageing along with the population, was identified by the Ministry of Health in its *Briefing to the Incoming Minister of Health* (2014) as being a key factor in the constrained funding environment for the foreseeable future.[7] As the population grows and ages, DHBs are placed under increasing pressure to provide medicines and services within their operating budgets. This means that PHARMAC, the monopsony purchaser/price negotiator of pharmaceuticals on behalf of DHBs (discussed in further detail at 10.11) is increasingly incentivised to continue to drive the prices of pharmaceuticals down.

Increased competition from generic drugs

8.4 Originating pharmaceutical companies continue to face particularly strong competition in New Zealand from suppliers of generic drugs. New Zealand has one of the highest proportions of generic medicines by volume, at 73 percent in 2011, compared with the OECD average of 41 percent, which helps keep public health costs down.[8]

9. Industry participants

Manufacturers

9.1 The manufacture of pharmaceuticals involves the conversion of the Active Pharmaceutical Ingredients ("**APIs**") of those drugs into a form that can easily be given to a patient. This conversion will involve the addition of certain other ingredients with the requisite chemical properties and then the compression of the mixture into a tablet, the filling of a gel capsule, or the dissolution of the mixture in a solvent.[9]

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[7] Ministry of Health's *Briefing to the Incoming Minister of Health* (2014) at (v).
[8] Ministry of Health's *Briefing to the Incoming Minister of Health* (2014) at 4.
[9] New Zealand Institute of Chemistry, *The Pharmaceutical Industry*, accessed at http://nzic.org.nz/ChemProcesses/chem_processes.html.

9.2 These different forms of drugs are substitutable only to a very minimal degree on the supply side. This is especially so in the case of injectables because their production requires a completely aseptic (sterile) environment, including the use of autoclaving machinery. For example, to switch from manufacturing a medicine in a vial form to an ampoule form requires a different production line, using different machinery, ingredients and processes. As these sterile machines need to be authorised and registered, Pfizer estimates that it would take up to approximately **[ ]** to procure the requisite machinery, build it into the production line, obtain the necessary regulatory approvals for the machinery and get it operating to the high standard required.

9.3 Relatively few pharmaceutical manufacturing sites remain in New Zealand. Only Douglas Pharmaceuticals ("**Douglas**") and API Consumer Health have manufacturing facilities in New Zealand. None of those manufacture the APIs themselves.

9.4 However, an absence of manufacturing facilities is no obstacle to the efficient and timely entry of pharmaceutical manufacturers and suppliers into the New Zealand market, as evidenced by the large number of well resourced and multinational pharmaceutical conglomerates currently active in New Zealand, either directly or through distributors and wholesalers. These companies include AstraZeneca Plc, Fresenius, GlaxoSmithKline Plc, Johnson & Johnson, Merck & Co, Mylan Inc., Novartis International AG (and its generics business, Sandoz), Roche Holding AG, and Sanofi-Aventis (a full list of competitors present in New Zealand is provided at Appendix 5). These companies have broad and established international product offerings, and to the extent that they do not offer a certain product in New Zealand but offer that product overseas, could obtain the necessary regulatory approvals to commence supply of that product in New Zealand in a timely and cost-effective manner (see discussion at 10.7).

Distributors

9.5 Distributors of pharmaceuticals transport prescription and OTC pharmaceuticals between the last point of manufacture and the wholesaler. In the hospital channel, distributors will often supply products directly from the last point of manufacture to DHBs.

9.6 Certain pharmaceutical manufacturers, such as Douglas,[10] have vertically integrated distribution, but for the remainder there are a number of third-party distributors operating in New Zealand, such as Pharmaco, Healthcare Logistics, and Multichem NZ.

Wholesalers

9.7 Pharmaceutical wholesalers procure prescription and OTC pharmaceutical products from distributors or manufacturers, and supply them to end-customers such as hospitals, pharmacies, and retailers of OTC pharmaceuticals.

9.8 There are a number of wholesalers operating in New Zealand, including CDC Pharmaceuticals Ltd, Pharmacy Wholesalers (BOP) Ltd, ProPharma (part of the EBOS Group), and Onelink (also part of the EBOS Group).

Hospitals

9.9 In general, hospitals procure pharmaceuticals directly from the pharmaceutical companies themselves, rather than from intermediate wholesalers. Certain wholesalers with sufficient scale, such as Onelink, specialise in providing pharmaceuticals to hospitals (notably the DHBs in the Auckland region).[11]

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[10] See, www.douglas.co.nz/distribution

[11] New Zealand Commerce Commission, *CDC Pharmaceuticals Limited / Pharmacy Wholesalers (Central) Limited* [2014] NZCC 21 at [23.3].

10. Regulatory dimension

10.1 The Commission is familiar with the regulatory framework of the pharmaceutical industry, having recently considered it in the application by Mylan Inc. to acquire Abbott Laboratories Inc.[12] For completeness, an overview of the regulatory landscape, as relevant to the Proposed Transaction, is outlined below.

Initial regulatory approval

The role of Medsafe

10.2 The New Zealand Medicines and Medical Devices Safety Authority ("**Medsafe**") is tasked with the regulation of therapeutic products in New Zealand, and ensuring those products' ongoing safety and fitness-for-purpose.

10.3 All medicines supplied in New Zealand must be approved by Medsafe prior to their marketing and sale in this country.[13] This includes biologics and biosimilars. To this end, Medsafe requires the pre-marketing submission by pharmaceutical companies or their representatives of "data that satisfactorily establish the quality, safety and efficacy of the product, for the purposes for which it is to be used".[14]

10.4 Differing regulatory burdens are imposed by Medsafe on small molecule generics and biosimilars. Registration of small molecule generics is much simpler than it is for biosimilars, which, as set out below, require substantially more documentation, incur higher application fees, and require a longer evaluation period, in order to gain regulatory approval.

Chemical (small molecule) pharmaceuticals

10.5 The amount of information that must be submitted along with each New Medicine Application ("**NMA**") is increased with the level of risk associated with the medicine, in gradations of low, medium or high. Non-biologic (ie chemical) generics are classed as intermediate-risk.

10.6 When applying for Medsafe approval for a new prescription medicine, a pharmaceutical company can make either a full or abbreviated NMA:

(a) Abbreviated applications are available where Medsafe is able to review the regulatory evaluation reports of other jurisdictions.

(b) A full NMA requires Medsafe to review the full medicine dossier of the pharmaceutical in question - essentially starting from scratch.

10.7 The abbreviated evaluation is a less costly and more expeditious process.[15] While timeframes vary, Pfizer estimates that the average timeframe for gaining registration under an abbreviated application is **[ ]**. As the vast majority of pharmaceutical companies in New Zealand are large international firms, it is common for them already to have received overseas regulatory approvals before regulatory approval is sought for New Zealand. Indeed, in 2014, 60% of "intermediate risk medicine" applications (ie the risk level attributed to small molecule pharmaceuticals) received by Medsafe were abbreviated applications.[16]

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[12] NZCC, *Mylan / Abbott*.
[13] Medicines Act 1981, s 20(2).
[14] http://www.medsafe.govt.nz/other/about.asp
[15] Medsafe, *New Zealand Regulatory Guidelines for Medicines - Part C: Requirements for application types*, Edition 6.16, September 2014, at [2.5.1].
[16] http://www.medsafe.govt.nz/regulatory/Performance2014.asp

Biologics and biosimilars

10.8 Biologic medicines (including biosimilars) are classified as high-risk for the purposes of the NMA process. Above and beyond the data typically required of a higher-risk chemical medicine, applications for registrations of biosimilars must be accompanied by the data required by annexes to the "CHMP[17] Guidelines on similar biologic medicinal products containing biotechnology-derived proteins as an active substance" promulgated in the EU. These guidelines require extensive proof of manufacturing quality and comparability with the originator product.[18]

10.9 The application fees for these products are higher than for other pharmaceuticals with Type III fees (the highest) reserved for "Biological, or biotechnological products (ie, vaccines, serums and allergens, medicinal products derived from human blood or plasma, immunological medicinal products, and products derived from biotechnology)".[19]

10.10 **[ ]**

Funding of hospital medicines

10.11 The supply and funding of products for use in hospitals is controlled by PHARMAC.

10.12 PHARMAC is the New Zealand government agency with the responsibility of deciding, on behalf of District Health Boards (**DHBs**), which medicines, medical devices and related products are supplied and subsidised.

10.13 Relevant to this application, PHARMAC has two primary functions:

(a) It manages the Combined Pharmaceutical Budget ("**CPB**") on behalf of DHBs. The CPB exists to fund subsidies for community medicines (those medicines dispensed by a pharmacist), as well as vaccines, haemophilia treatments and cancer medications given in hospitals. PHARMAC will negotiate with pharmaceutical manufacturers, and agree upon a subsidy that will be paid to the pharmaceutical manufacturer, as well as any fees covering distribution and pharmacy dispensing services.

(b) It also negotiates the prices of all hospital medicines and medical devices, which are funded directly through DHB hospitals and not included in the CPB. PHARMAC will negotiate with pharmaceutical manufacturers for a national price at which all DHBs must purchase the pharmaceutical in question (unless they are able to negotiate a further discount or rebate from the supplier).

10.14 In both cases, there are various options open to PHARMAC by which it may decide upon the preferred pharmaceutical manufacturer or manufacturers to supply a given medicine or dose or presentation of medicine. PHARMAC can either:[20]

(a) issue a tender, in which the winner or winners of the tender is/are awarded the right to benefit (often exclusively) from the subsidy or fixed price for a set period of time (typically three years); or

(b) through alternative commercial proposals from suppliers, where PHARMAC considers it may get better terms other than through a tender process.[21]

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[17] Committee for Medicinal Products for Human Use
[18] http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/01/WC500180219.pdf
[19] http://www.medsafe.govt.nz/regulatory/Guideline/Full%20-%20NZ%20Regulatory%20Guidelines%20for%20Medicines.pdf at 22.
[20] NZCC, *Mylan / Abbott*, at [22] to [23].

10.15 PHARMAC will then place the product (with reference to its API) and its brand name (or supplier) on the Pharmaceutical Schedule. The Pharmaceutical Schedule lists all the medicines and therapeutic products subsidised by the Government. It lists the formulations, doses and subsidy/fixed price of the medicine, as well as any prescribing guidelines or access criteria.[22] Relevant to the Proposed Transaction, section H of the Schedule lists the medicines contracted to be provided in public hospitals at specified prices. Section H is better known as the Hospital Schedule.

10.16 Some of the medicines covered in this application for clearance may also be listed on the Community Schedule (section C of the Schedule), although they will still be predominantly used in hospitals. Where that is the case, PHARMAC may award separate tenders for the two schedules, but where a price is agreed at which a medicine is added to both the Hospital Schedule and the Community Schedule the same supplier will almost always span both and invariably at the same price across both schedules. That being the case, in this application for clearance Pfizer focuses on the Hospital Schedule where the vast majority of sales of the affected medicines are made.

10.17 Although PHARMAC negotiates prices at which public health authorities such as the DHBs can purchase, those purchasers can then negotiate further discounts (typically through confidential rebates), further driving price down.

10.18 The way in which PHARMAC selects suppliers of hospital (including cancer) medicines impacts the manner in which competition operates in connection with the supply of these medicines by pharmaceutical companies. In particular, for medicines where PHARMAC awards an exclusive supply agreement, typically for three years, to a single firm, competition most commonly occurs when market participants bid to win the sole supply contract.[23] Specifically, this exclusivity can manifest either as:

(a) the right to be the sole source of subsidised supply in the case of medicines subsidised through the CPB, meaning any other competitor products will incur a greater cost to patients; or

(b) in the case of hospital medications, the right to Hospital Supply Status ("**HSS**") for a set period, usually three years. An HSS pharmaceutical is listed on the Hospital Schedule along with a Discretionary Variance ("**DV**") Limit. This DV Limit sets out the percentage of equivalent non-HSS pharmaceuticals that DHBs are permitted to purchase over the course of the HSS contract.

10.19 PHARMAC's effect on the pharmaceutical industry in New Zealand has been substantial. It has had the effect of consolidating 20 DHBs into a single monopsony purchaser/procurement manager, with significant countervailing buyer power. It has successfully used this buyer power to leverage price decreases from pharmaceutical suppliers. By way of example:

(a) in the first year of PHARMAC's expanded role of managing all hospital medicines and contracting nationally for medical devices, PHARMAC achieved net annual savings of $25.62 million;[24] and

(b) through its management of the CPB, it has increased the number of treatments being funded while creating savings of more than $5 billion over the last ten years.[25]

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[21] While a supplier may have *de facto* exclusivity for a given medicine, or more commonly a given dose/presentation of medicine, by virtue of being the only supplier listed on the schedule, that position can change at any time as PHARMAC can, and does, introduce further suppliers without any notice to those already listed on the schedule.

[22] Pharmaceutical Management Agency, *Fact sheet #14: Inside the Pharmaceutical Schedule,* at 1.

[23] See for example NZCC, *Mylan / Abbott*, at [60].

[24] Pharmaceutical Management Agency, *Annual Report for the year ended 30 June 2014*, June 2014, at 2.

10.20 Indeed, PHARMAC has pushed prices of medicines to such low levels in New Zealand that supply is only profitable for generics companies with low cost bases, which has caused some market participants to withdraw supply in several of the areas where the Parties' New Zealand activities overlap. In many cases, those suppliers retain Medsafe registrations, meaning they could easily resume supply were it profitable to do so. For others whose Medsafe registrations have lapsed, as outlined at 10.7, refreshing a registration for generic pharmaceuticals is straightforward and relatively inexpensive.

10.21 PHARMAC is therefore in a very powerful position in connection with the acquisition of hospital (and other) medicines.

[25] Pharmaceutical Management Agency, *Annual Report for the year ended 30 June 2014*, June 2014, at 2.

PART C: COMPETITIVE ASSESSMENT

11. Medical devices

11.1 The Parties do not overlap in the supply of medical devices in New Zealand. Therefore, medical devices are not considered further in this application.

12. Biopharmaceuticals

No actual overlaps

12.1 There are no actual overlaps in biopharmaceuticals as between the Parties in New Zealand:

(a) Pfizer currently has four biologic products registered in New Zealand: BeneFIX (for treatment of deficiency of a clotting protein, factor IX); Enbrel (for the treatment of inflammatory conditions such as rheumatoid arthritis and ankylosing spondylitis); Genotropin (a human growth hormone); and Xyntha (used to prevent bleeding in patients with haemophilia A).

(b) As it focuses on biosimilars, Hospira does not market any originator biologics. Further, Hospira's only biosimilar registered for sale and marketing in New Zealand (Nivestim, a Filgrastim molecule based biosimilar) does not overlap with any of Pfizer's biologics, and is not currently supplied by Hospira in New Zealand on account of Sandoz holding an HSS contract for it.

No potential overlaps

12.2 In previous pharmaceuticals cases, the Commission (in common with the European Commission ("**EC**")) has indicated that a full assessment of the competitive position of the Parties requires an analysis of products that are not yet on the market but are at an advanced stage of development. Pfizer has therefore assessed whether any overlaps arise between pipeline biologic/biosimilar products that are at a sufficiently advanced stage of development, such that they can be considered as a possible future competitive constraint.[26]

12.3 For a pipeline overlap to be considered sufficiently likely to be relevant to the Commission's assessment, there must be a real and substantial prospect of the product being launched within a sufficiently proximate timeframe.

12.4 While the development of all pharmaceuticals is an inherently risky and uncertain endeavour, the development of biologics/biosimilars involves a greater amount of risk and uncertainty than chemical pharmaceuticals.[27] In particular:

(a) The process by which a biosimilar product gets to market is significantly more prolonged than it is for a generic chemical medicine. Developing a biosimilar can take 8 - 10 years.[28] By contrast, regular generic drugs take 3 - 5 years.

(b) The development cost is also much higher, costing anywhere between US$100 million and US$200 million for a biosimilar, compared with between US$1 million and US$5 million for a regular generic drug.[29]

(c) Biosimilars must undergo rigorous comparability studies, in which their efficacy and similarity to the originator biologic is closely scrutinised, bringing further complexity and risk.

12.5 **[ ]**

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[26] This was concluded by the EC in *Teva / Ratiopharm*, at [29].
[27] EC, *Teva / Ratiopharm*, at [29].
[28] Federal Trade Commission. Emerging health care issues: follow-on biologic drug competition. June 2009 Report. Available at: http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf.
[29] Federal Trade Commission. Emerging health care issues: follow-on biologic drug competition. June 2009 Report. Available at: http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf.

12.6 This, coupled with the very real risk of delays in the process to launch, means that no pipeline overlaps capable of being characterised as a source of potential competitive constraint arise.

13. Pharmaceuticals

Overview

13.1 The Parties' chemical pharmaceuticals businesses are largely complementary. While Pfizer has a broad product base encompassing both hospital drugs and consumer medications, supplied as capsules, tablets, oral liquids, injections, creams, and gels, Hospira is heavily focused on generic specialty injectable pharmaceuticals (where Pfizer is a relatively minor player). Accordingly, competitive overlaps between the Parties are very limited.

Existing competitors

13.2 There are numerous significant international pharmaceutical manufacturers and suppliers currently present in New Zealand, all of whom are well resourced and have wide global portfolios of pharmaceuticals. There is also a further set of New Zealand or regionally focused pharmaceutical companies, typically active in the supply of generic pharmaceuticals, in New Zealand.

13.3 Appendix 5 sets out all of the competitors who are active in markets where the Proposed Transaction gives rise to competitive overlaps (including potential competitive overlaps).

Potential competition

13.4 Many international pharmaceutical manufacturers do not currently supply certain chemical pharmaceuticals in their global portfolios into New Zealand, including those who may previously have held a Medsafe registration that has lapsed. As outlined in further detail at 10.4, it is a relatively simple proposition for that company to obtain (or refresh) the requisite Medsafe registration for generics in order to commence supply of a drug into New Zealand in a timely manner: approval in respect of small molecule generics takes only around 12 months for abbreviated applications and is not costly, especially in the context of the value of supply that can be attained on account of PHARMAC's control over purchasing decisions of the 20 DHBs.

13.5 Moreover, entry is possible without local manufacturing facilities. Overseas pharmaceutical companies are able to supply their products without any material investment in the local market by using New Zealand based distributors. There are several well established distributors active in New Zealand (see 9.5).

Countervailing buyer power

13.6 All pharmaceutical companies are constrained by the regulatory regime for the purchase of hospital medicines, namely the monopsony power of PHARMAC.

13.7 PHARMAC does not itself purchase pharmaceuticals from suppliers. Instead, it:

(a) manages the CPB, the budget set by the Minister of Health with which PHARMAC funds subsidies for community medicines (medicines dispensed by a pharmacist) as well as cancer treatments, haemophilia treatments and vaccinations; and

(b) decides which pharmaceuticals are funded for use by hospitals, and manages the funding available for new investments in hospital medicines.

13.8 Pharmaceuticals funded for use in hospitals will be listed in the Hospital Schedule. If a hospital medicine is not listed on this Hospital Schedule, it is unlikely to achieve significant sales in New Zealand. When listing a product on the Hospital Schedule,

PHARMAC negotiates with pharmaceutical suppliers for the best possible price and access terms it can procure for that particular drug.

13.9 To this end, and as set out at 10.14, PHARMAC employs a range of strategies to extract value from pharmaceutical suppliers, including running tenders (in which pharmaceutical companies must compete for sole or joint supply), requests for proposals (which are used to generate competition between suppliers for the subsidy of certain medicines, where tendering is not appropriate),[30] and alternative commercial proposals.

13.10 The Hospital Schedule lists, according to therapeutic use, the active chemical in question, the brand (or manufacturer's name, in the case of a generic), and the price at which that pharmaceutical can be purchased direct from the manufacturer by DHBs (or by wholesalers or other distributors, or contract manufacturers that have arrangements with DHBs to compound pharmaceuticals). Where a pharmaceutical (ie the active chemical) is listed, but no brand and/or price is listed, each DHB may purchase any brand and/or pay any price that the DHB negotiates with the relevant pharmaceutical supplier.

13.11 PHARMAC can also award a pharmaceutical Hospital Supply Status ("**HSS**") for a set period (usually three years). An HSS pharmaceutical is listed on the Hospital Schedule along with a DV Limit. This DV Limit sets out the percentage of equivalent non-HSS pharmaceuticals that DHBs are permitted to purchase over the course of the HSS contract. This is typically set at 1%, meaning 99% of the drug (and dose) in question must be purchased from the HSS holder. Occasionally, for medicines where patients may be sensitive to differences between specific types of medicines, the DV limit will be increased to 5%.

Approach to market definition

Product Dimension

13.12 To the extent that the Parties' New Zealand activities overlap (which is limited), the overlap areas primarily concern generic sterile injectables. All of the overlap products are used predominantly or exclusively in hospitals.

13.13 Market definition is a tool that provides a framework for assessment of competitive effects. Consistent with that proposition the Commission has previously recognised that, for pharmaceutical products, the approach to market definition will vary depending on the particular characteristics of the relevant products.[31] In some previous decisions, in common with the approach adopted by the EC, the Commission has accepted that a narrower approach to market definition (ie narrower than the broad approach of Anatomical Therapeutic Classification ("**ATC**") level 3 ("**ATC3**")) is often required.[32] This has particularly been the case in respect of oncology drugs, owing to the limited substitutability between different molecules and the different treatment regimes required for different types of cancer (discussed in greater detail at 13.40).

13.14 Generic sterile injectables collectively comprise a heterogenous set of entirely different molecules (generics) that are not substitutable but are administered by the same route.[33] The approach to market definition will therefore be guided by these product characteristics. A "one size fits all" approach is unlikely to be suitable, even if the competitive assessment is unlikely to be materially altered by the precise market definition adopted.

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[30] http://www.pharmac.health.nz/assets/factsheet-05-contract-negotiation.pdf
[31] NZCC, *Mylan/Abbott*, at [26].
[32] See, for example, NZCC, *Mylan / Abbott*, at [26].
[33] Moreover, there is further differentiation between the products due to the different presentations offered.

13.15 Pfizer submits that while it is not necessary to finally decide the precise question of market definition, the appropriate approach to market definition for such generic medicines is to start from the molecule level. A number of factors suggest that this is an appropriate approach in the present case.

13.16 First, as the EC has noted (*Teva/Ratiopharm)* in connection with its approach to mergers concerning medicines in this area:[34]

> [I]n recent cases involving generic companies the Commission, based on its market investigation, has tended to identify competition issues – where such issues arose – more often at the molecule level, at the ATC4 level, or on the basis of a group of molecules.
>
> For all those products which were specifically investigated in the market investigation, the ATC3 level rarely appeared to be the correct range of products for analyzing competition. In the genericised pharmaceutical markets concerned by the notified transaction, the Parties achieved significant market shares, in a large majority of cases, only when such markets were looked at the molecule level. In most cases, responses to the market investigation, whether from competitors, customers, insurers or national authorities, indicated that demand for medicinal products based on established and well-known pharmaceutical molecules is specific to the molecule in question (and its galenic form, see below), at least for prescription products and products for hospital use.

13.17 Moreover, such a starting point is consistent with the way in which PHARMAC conducts its negotiations for the DHBs' purchasing requirements. Suppliers are invited to tender at the level of SKU - that is the particular strength, presentation and quantity per unit - and certainly no wider than by molecule.

13.18 That said, in each case the relevant market definition will ultimately be shaped by the particular characteristics of the medicines in question. And in some cases a molecule level market definition may be too broad, particularly in a hospital context where different presentations and dosages are used for materially different clinical applications.

13.19 This too is reflected in supply-side considerations. Among other things, on account of both technical and regulatory factors, it is not easy for a manufacturer to switch from making one presentation to another. For example, making a medicine in a vial requires a different production line, involving different machinery, ingredients and manufacturing processes, compared with manufacturing it in an ampoule form. From a regulatory perspective, each presentation of a molecule requires a different Medsafe registration.

Geographic Dimension

13.20 In previous decisions concerning pharmaceuticals, the Commission has found that where the Parties supply on a national basis the geographic market will be national.[35] Pfizer submits that is appropriate in the present case.

Functional Dimension

13.21 In *Glaxo Wellcome/SmithKline Beecham*[36] the Commission observed that pharmaceutical companies in New Zealand import and distribute products to pharmaceutical wholesalers, or direct to major consumers such as hospitals, or retail buying groups. Therefore, the appropriate functional level of the market is that for the manufacture/import and wholesale supply.

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[34] EC, *Teva / Ratiopharm*, at [12], [13].
[35] NZCC, *Mylan / Abbott*.
[36] New Zealand Commerce Commission, *Smithkline Beecham plc / Glaxo Wellcome plc* [2000] at [67]. See also, *Mylan / Abbott*, at [59].

Identification of potential overlaps

13.22 Having regard to the area in which the Parties overlap (generic sterile injectables), consistent with the approach of the EC, Pfizer has assessed overlaps by reference to molecule.

13.23 On a conservative approach, the Parties have identified overlaps as potentially arising where one party currently supplies a product and the other has a current Medsafe registration (even if it does not currently make sales of its product(s) and has no intention to do so).[37] This recognises that, as described in 10.17, in some cases PHARMAC will award supply on an HSS basis (effectively an exclusive supply arrangement), meaning competition in those circumstances occurs most commonly 'for' the market.

13.24 The Parties overlap as potential competitors at the molecule level in the following areas:

(a) Cytarabine (L1B - Antimetabolites);

(b) Doxorubicin (L1D - Antineoplastic antibiotics);

(c) Epirubicin (L1D - Antineoplastic antibiotics);

(d) Methotrexate (L1B - Antimetabolites);

(e) Methylprednisolone (H2A - Systemic Corticosteroids); and

(f) Piperacillin/Tazobactam (J1C - Broad spectrum penicillins).

13.25 Overlaps between the Parties as actual competitors arise for just four molecules:

(a) Gentamicin (J1K - Aminoglycosides);

(b) Heparin (B1B - Heparins);

(c) Morphine (N2A - Narcotics); and

(d) Phenytoin (N3A - Anti-epileptics).

13.26 None of these overlaps (either as potential or actual competitors) has the effect, or likely effect, of substantially lessening competition.

Pipeline overlaps

13.27 The only pipeline overlaps that arise between the Parties (that is, where launch in New Zealand is estimated within the next four years) are in respect of the molecules **[ ]**. Neither of these pipeline overlaps will see the Proposed Transaction alter the prevailing competitive landscape:

(a) **[ ]**

[37] All market shares have been derived from IMS Health's global medical data set in respect of New Zealand, for the 2014 calendar year (or by Pfizer NZ's financial year through to 1 December 2014, so only one month's difference to the calendar year). All data is in USD, converted from NZD to USD at an exchange rate of 0.84303. This market share data covers sales made through both the Hospital and Community Schedules. Please note that while Pfizer has verified that its sales values are based on the correct pricing data, it cannot be certain that this is the case for all market participants (for whom there may be a risk that the IMS dataset is based on out of date pricing).

(b) **[ ]**

13.28 Finally, noting that in the past the Commission has commenced its assessment of other types of pharmaceuticals from on the basis of ATC3, for completeness only, Pfizer provides at Appendix 1, details of further overlaps that arise if an ATC3 approach is adopted. However, in each case, adopting the approach of assessing commercial and practical substitutability, the relevant product market is narrower than ATC3 level, meaning no potential or actual competitive overlaps arise.

13.29 Details of all molecule overlap areas are provided in the following section.

(I) MOLECULE OVERLAPS AS POTENTIAL COMPETITORS

CYTARABINE (Antimetabolites L1B)

Overview of therapeutic area

13.30 Cytarabine is an antimetabolite chemotherapeutic agent. It is a mature and highly genericised drug, having been launched in 1969 and with its patent protection expiring in the early 1980s. It is used in the treatment of leukaemia (including acute and chronic myelogenous and acute lymphocytic leukaemia). It is also used to treat acute myeloid leukaemia and Non-Hodgkins lymphoma. Cytarabine is not commonly used any longer, with the New Zealand market worth only approximately **[ ]** in 2014.

13.31 Substitutability across different molecule based metabolites is limited, as reflected in the PHARMAC tender specifications (which specify a range of antimetabolites across ATC3 class L1B), and in the differing clinical indications, for example, between cytarabine and methotrexate.

The Parties' products

13.32 The Parties currently supply, or have active Medsafe registrations for, the following cytarabine based medicines:

Table 1 - Cytarabine

Drug	API	Clinical Indication	NZ Status
Pfizer			
Cytarabine Injection	Cytarabine (as cytarabine hydrochloride)	Injectable solution primarily for induction and maintenance of remission in acute myelocytic leukaemia of both adults and children, and has also been found to be useful in the treatment of other leukaemias, such as acute lymphocytic leukaemia and chronic myelocytic leukaemia.[38]	Pfizer has 4 doses of injections listed, 3 of which are listed pursuant to HSSs expiring in 2016.
Hospira			
Cytarabine Solution for Injection	Cytarabine (as cytarabine hydrochloride)	Injectable solution primarily used for the induction and remission of leukaemia, particularly for acute myeloid leukaemia, in adults and children.[39]	Hospira does not currently supply cytarabine in New Zealand.

Market definition

13.33 As is the case with other antimetabolites (eg methotrexate), reflecting the different clinical indications of different molecule based medicines the relevant product market ought to be defined no wider than at the molecule level.

Competition assessment

13.34 There is no current overlap between the Parties. Pfizer supplies three of its four cytarabine injections pursuant to HSS contracts expiring in 2016; Hospira's cytarabine product is not listed on the Hospital Schedule or otherwise supplied in New Zealand, and **[ ]**. Hospira therefore does not provide any meaningful competitive constraint on Pfizer.

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[38] http://www.medsafe.govt.nz/profs/datasheet/c/Cytarabineinj.pdf
[39] http://www.medsafe.govt.nz/profs/datasheet/c/Cytarabinenjmp.pdf

13.35 Three of the four injections for which Pfizer is currently listed on the Hospital Schedule are subject to HSSs expiring in 2016, meaning that competition will predominantly occur for the market in June 2016. Actavis could be a potential competitor in that process and there are international suppliers that could obtain registration prior to that date and compete for the tender, including Fresenius-Kabi, a German pharmaceutical company with particular expertise in oncology medicines and which supplies cytarabine in Australia.

13.36 PHARMAC will continue to exert significant countervailing power on the merged entity in this and every market discussed in this application.

DOXORUBICIN (Antineoplastic Antibiotics L1D)

Overview of therapeutic area

13.37 Doxorubicin is a form of antineoplastic antibiotic. These are drugs used in cancer chemotherapy because they interfere with the synthesis of DNA and RNA by cancer cells, which prevents those cells from proliferating. Although they are called 'antibiotics', and do have some limited antibiotic effect (that is, they can kill bacteria), antineoplastic antibiotics are generally not used as antibiotics due to their very high toxicity, which can manifest in blood cell damage, hair loss, and severe cardiac or lung toxicity.

13.38 In addition to being used to treat acute leukaemia, doxorubicin is also used to treat Wilms' tumour, neuroblastoma, soft tissue and bone sarcomas, breast carcinoma, lymphomas of both Hodgkin's and non-Hodgkin's type, bronchogenic (lung) carcinoma, thyroid carcinoma, hepatomas and ovarian carcinoma.

The Parties' products

13.39 The Parties currently supply, or have active Medsafe registrations for, the following doxorubicin based medicines:

Table 2 - Doxorubicin

Drug	API	Clinical Indication	NZ Status
Pfizer			
Adriamycin	Doxorubicin (as doxorubicin hydrochloride)	Produced significant therapeutic responses in various cancers.[40] Mainly used in combination with other cytotoxic drugs. It is typically administered intravenously.	Pfizer does not currently supply. 3 doses of injections are listed with no price or brand specified. The other 2 doses are listed by Actavis pursuant to HSS expiring in 2015.
Hospira			
DBL Doxorubicin Hydrochloride	Doxorubicin (as doxorubicin hydrochloride)	Significant therapeutic responses in various cancers. Mainly used in combination with other cytotoxic drugs. It is typically administered intravenously.	Hospira does not currently supply. 3 doses of injections are listed with no price or brand specified. The

[40] http://www.medsafe.govt.nz/profs/datasheet/a/adriamycininj.pdf

Drug	API	Clinical Indication	NZ Status
			other 2 doses are supplied by Actavis pursuant to HSS expiring in 2015.

Market definition

13.40 So far as Pfizer is aware, the Commission has not previously considered the appropriate market definition for doxorubicin or for antineoplastic antibiotics more generally. The EC, in the context of antineoplastic antibiotics, approached market definition from the position that ATC3 provided too broad a basis for product market definition.[41] The EC has instead used the role and substitutability of individual molecules as a basis for competitive analysis, in particular for genericised oncology products.[42]

Competition assessment

13.41 The Parties only overlap insofar as Pfizer is a potential competitor to Hospira. At present Hospira supplies a very small amount of doxorubicin **[ ]** and this is in a freeze dried version for injection (this is supplied under s29 of the Medicines Act 1981[43]). This freeze dried presentation is specifically used clinically in cases where the solution is not able to be used; for example, in hepatic (liver) cancer, where the freeze dried product is reconstituted into a high concentration solution. 'DC beads' are then soaked in this solution to absorb the doxorubicin before they are implanted into patients. The injectable solution presentation is not concentrated enough for this purpose.

13.42 Pfizer does not currently supply doxorubicin.

13.43 With the Parties not currently supplying any clinical substitutable form of doxorubicin (and only one of them supplying a de minimis amount of non-approved doxorubicin), the Proposed Transaction will not have any appreciable effect on competition for doxorubicin based medicines. Moreover:

(a) Actavis and Janssen-Cilag are currently the main suppliers of doxorubicin in New Zealand (two injections are supplied by Actavis pursuant to HSS contracts expiring in 2015). **[ ] [ ]**.

(b) In respect of these two HSS contracts, and the other forms of doxorubicin which are able to be supplied by any brand, there are a number of other potential competitors with current registrations - for example, Janssen-Cilag, Novartis and Rex Medical Ltd (as well as the incumbent Actavis).

(c) There are also a number of potential competitors who could obtain registrations in a timely manner, and commence supply in New Zealand if it proved profitable (for example, Sandoz and Fresenius-Kabi both supply in Australia). As set out at 10.14, PHARMAC has previously expressed a willingness to approach such potential competitors in order to secure supply on terms it considers satisfactory.

(d) PHARMAC will continue to act as a powerful constraint on the merged entity.

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[41] COMP/M.5555 *Novartis / Ebewe* (22 September 2009).
[42] EC, Teva / Barr, at [18].
[43] In effect, this means that the presentation is only used where an approved medicine is not able to be used, meaning it is used very rarely, not least because of the reporting and compliance protocols associated with using non-approved medicines.

EPIRUBICIN (Antineoplastic Antibiotics L1D)

Overview of therapeutic area

13.44 Epirubicin is a different form of antineoplastic antibiotic. It is used to treat various types of cancer, including: breast cancer; gastric cancer; ovarian cancer; small cell lung cancer; lymphoma (non-Hodgkin's lymphoma); advanced/metastatic soft tissue sarcoma; and superficial bladder cancer.

13.45 The Parties currently supply, or have active Medsafe registrations for, the following epirubicin based medicines:

Table 3 - Epirubicin

Drug	API	Clinical Indication	NZ Status
Pfizer			
Pharmorubicin	Epirubicin (as epirubicin hydrochloride)	Significant therapeutic responses in various cancers. It is typically administered intravenously.[44]	Pfizer does not supply epirubicin in New Zealand.
Hospira			
DBL Epirubicin Hydrochloride Solution for Injection	Epirubicin (as epirubicin hydrochloride)	Produced significant therapeutic responses in various cancers and is given as an injection.[45]	Hospira is currently listed for 3 of 4 doses of injection pursuant to HSS expiring in 2015. The other dose is listed (no HSS) by Novartis Ebewe.

Market definition

13.46 For the same reasons as those outlined in connection with doxorubicin at 13.40, Pfizer submits that the relevant product market is no broader than molecule level.

Competition assessment

13.47 The Parties only overlap insofar as Pfizer is a potential competitor to Hospira. The Proposed Transaction will not have any appreciable effect on competition:

(a) Pfizer has not supplied epirubicin for a long time in New Zealand and **[ ]**. That being the case, the Proposed Transaction will not alter the competitive landscape as regards the supply of epirubicin.

(b) As set out in Table 3, Hospira is currently listed on the Hospital Schedule for 3 of 4 possible doses of epirubicin injection, with HSSs expiring in 2015. Novartis is also currently registered to supply epirubicin and is listed on a non-HSS basis on the Hospital Schedule. At the point Hospira's HSS contracts come up for renewal, Novartis will remain a strong competitor, with active registrations for every presentation Hospira currently supplies. Novartis recently (March 2015) made amendments to a particular registration, reflecting a continued intention to compete in this area.

[44] http://www.medsafe.govt.nz/profs/datasheet/p/Pharmorubicininj.pdf
[45] http://www.medsafe.govt.nz/profs/datasheet/d/dblepirubicinhydrochorideinj.pdf

(c) As well as Novartis, both Actavis and Rex Medical also have registered epirubicin products of identical presentations to Hospira's product (2mg/ml injection).

(d) There are also international suppliers that could easily obtain Medsafe registration in order to compete in the HSS tender.

(e) PHARMAC will continue to act as a powerful constraint on the merged entity.

METHOTREXATE (Antimetabolites L1B)

Overview of therapeutic area

13.48 Methotrexate is a mature and highly genericised antimetabolite chemotherapeutic agent (in use since the 1950s). It is available in two forms - tablet and injectable - with each having distinct clinical applications.

13.49 Methotrexate tablets are used to treat severe psoriasis (a skin condition) and severe rheumatoid arthritis. It is only used to treat these conditions if other treatments have not worked. Methotrexate can also be used to treat some types of cancers; for example, it can be used for the treatment of breast cancer, gestational choriocarcinoma and in patients with chorioadenoma destruens and hydatidiform mole. Methotrexate tablets can also be used in the palliation of acute and subacute lymphocytic leukaemia.

13.50 By comparison, injectable methotrexate is used in the following categories of treatment:

(a) Antineoplastic chemotherapy – treatment of leukaemia with the greatest effect observed in palliation of acute lymphoblastic (stem cell) leukaemias. Also used in this way to treat breast cancer, gestational choriocarcinoma and in patients with chorioadenoma destruens and hydatidiform moles.

(b) High dose therapy – the use of very high doses is made possible by vials for injection containing 500 mg and 1000 mg. Diseases treated with these doses administered in the form of single-drug or combination therapy, include osteogenic sarcoma, acute leukaemia, bronchogenic carcinoma and epidermoid carcinoma of the head and neck.

(c) Psoriasis chemotherapy – because of high risks attending to its use, injectable methotrexate is only indicated in the symptomatic control of severe, recalcitrant, disabling psoriasis which is not adequately responsive to other forms of therapy, but only when the diagnosis has been established, as by biopsy and/or after dermatologic consultations.

The Parties' products

13.51 The Parties currently supply, or have active Medsafe registrations for, the following methotrexate based medicines:

Table 4 - Methotrexate

Drug	API	Clinical Indication	NZ Status
		Pfizer	
Methoblastin (Tablets)	Methotrexate	Treatment of breast cancer, gestational choriocarcinoma, and in the palliation of acute and subacute lymphocytic	Pfizer's methoblastin tabs were delisted from

Drug	API	Clinical Indication	NZ Status
		leukaemia, and acute stem cell leukaemias. Also used to control severe and disabling psoriasis (a chronic inflammatory skin disease), but is only advised in the most extreme cases. It is given as a tablet.	the Hospital Schedule on 1 June 2014, having previously been listed pursuant to a HSS. After being delisted, methoblastin was replaced by Trexate, a Rex Medical tab supplied pursuant to a HSS expiring in 2015.
		Hospira	
DBL Methotrexate Injection	Methotrexate	Sterile injection for antineoplastic chemotherapy, high dose therapy, psoriasis chemotherapy, and rheumatoid arthritis chemotherapy	Currently 2 doses of Hospira's methotrexate injections are listed pursuant to a HSS expiring in 2016. Novartis (Ebewe and Sandoz) are listed in respect of 8 doses of injections (7 of which are pursuant to HSSs).
DBL Methotrexate Tablets	Methotrexate	Treatment of breast cancer, gestational choriocarcinoma, and in the palliation of acute and subacute lymphocytic leukaemia, and acute stem cell leukaemias. Also used to control severe and disabling psoriasis (a chronic inflammatory skin disease), but is only advised in the most extreme cases. It is given as a tablet.	Not currently supplied. Rex Medical is listed in respect of tabs pursuant to HSS expiring in 2015.

Market definition

13.52 So far as Pfizer is aware the Commission has not specifically considered the market for methotrexate. However, the EC approach has been to look to the role and substitutability of the molecules, and the treatment regime required for different types of cancer considered as providing accurate bases for market definition. Specifically in the context of antimetabolites, the EC noted in *Sanofi-Aventis/Genzyme*[46] (referring to *Teva/Barr*[47]) that the appropriate product market ought to be defined at the level of the molecule, including for drugs based on the methotrexate molecule.

13.53 In the present case Pfizer submits that the relevant market for the assessment of the effects, if any, of the Proposed Transaction on methotrexate ought to be defined, at its widest, by reference to molecule base. As methotrexate tablets are not substitutable for injectables on account of their differing clinical indication and extreme side-effects, the

[46] COMP/M. 5999, *Sanofi-Aventis / Genzyme* (12 January 2011), at [48].
[47] EC, *Teva / Barr* (19 December 2008).

relevant product market is more appropriately defined by presentation; however, the competition assessment is unaffected by the precise market definition adopted.

Competition assessment

13.54 Hospira's registrations for injectable offerings are not substitutable with Pfizer's tablet based registration. Novartis will, in any event, remain a strong competitor in respect of injectable methotrexate, supplying seven different dosages of injectable methotrexate under two brands (Sandoz and Ebewe). Reflective of Novartis' continued intention to compete vigorously in this area, it has recently updated its registrations and added several new presentations of methotrexate to the Medsafe registry.

13.55 Therefore, the Parties overlap only as potential competitors in connection with methotrexate tablets.[48] No substantial lessening of competition will arise from this potential overlap:

(a) There is no current overlap between the Parties. Pfizer recently lost supply of its methotrexate tabs (pursuant to an HSS) to Rex Medical. Hospira also does not currently supply methotrexate tabs in New Zealand, again as a result of Rex Medical attaining HSS status in the most recent PHARMAC tender.

(b) When Rex Medical's HSS contract for Methotrexate tablets expires, Pfizer and Rex Medical will continue to compete for supply. There are also various potential international suppliers who would be candidates for obtaining registration and commencing supply in New Zealand, particularly given the fact that (as identified in *Sanofi-Aventis / Genzyme*,[49] referring to *Teva / Barr)*,[50] methotrexate is an established and mature generic drug, making entry into this market a particularly straightforward proposition for international suppliers such as, for example, Boehringer Ingelheim.

(c) PHARMAC will continue to exert significant countervailing power on the merged entity.

METHYLPREDNISOLONE (Systemic Corticosteroids Level H2A)

Overview of therapeutic area

13.56 Methylprednisolone is an API used in certain types of systemic corticosteroids, a broad group of drugs, used for treating a broad range of inflammations, including asthma, dermatological, and non-dermatological conditions.

13.57 Systemic corticosteroids are chemically related to the hormones produced by the adrenal glands (predominantly cortisol and aldosterone). Cortisol is a type of hormone called a glucocorticoid, which influences the metabolism (processing) of carbohydrates, fats, and proteins, as well as inhibiting some portions of the immune response. Glucocorticoids are used in the treatment of a very wide range of inflammatory diseases.

The Parties' products

13.58 The Parties currently supply, or have active Medsafe registrations for, the following Methylprednisolone products:

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[48] At the molecular level, the Parties' combined market shares in methotrexate would be **[ ]**
[49] EC, *Sanofi-Aventis / Genzyme*, at [48].
[50] EC, *Teva / Barr* (19 December 2008).

Table 5 - Methylprednisolone

Drug	API	Clinical Indication	NZ Status
			
Depo-Medrol / Medrol	Methylprednisolone (as methylprednisolone acetate)	An injection used in certain kinds of endocrine, rheumatic and haematologic disorders; collagen, dermatologic, ophthalmic, gastrointestinal respiratory, nervous system and neoplastic diseases; allergic and oedematous states.[51] Medrol is tablet form.	Currently listed pursuant to HSS expiring in 2015.
Depo-Medrol with Lidocaine	Methylprednisolone (as methylprednisolone acetate) and lidocaine (as lidocaine hydrochloride)	Short-term therapy (to 'tide the patient over' in acute episodes) for various kinds of inflammation, such as synovitis of osteoarthritis, rheumatoid arthritis, acute gouty arthritis, epicondylitis, acute nonspecific tenosynovitis, post-traumatic osteoarthritis, and acute and subacute bursitis. Administered as an injection.	Currently listed pursuant to HSS expiring in 2015.
Solu-Medrol	Methylprednisolone (as methylprednisolone sodium succinate)	Used in certain kinds of endocrine, rheumatic and haematologic disorders; collagen, dermatologic, ophthalmic, gastrointestinal respiratory, nervous system and neoplastic diseases; allergic and oedematous states.[52] Sold as a vial of powder accompanied by a solute which hospital staff mix to form a liquid and inject intravenously, intramuscularly, or by intravenous infusion.	Currently listed pursuant to HSS expiring in 2015.
			
Methylprednisolone Sodium Succinate Powder for Injection	Methylprednisolone (as methylprednisolone sodium succinate)	Used in certain kinds of endocrine, rheumatic and haematologic disorders; collagen, dermatologic, ophthalmic, gastrointestinal respiratory, nervous system and neoplastic diseases; allergic and oedematous states, injectable forms.	Hospira is not currently listed on the Hospital Schedule for any dose. It made no sales in 2014, **[ ]**

Market definition

13.59 So far as Pfizer is aware, the Commission has not previously considered methylprednisolone based medicines.

13.60 In Pfizer's submission, the appropriate market definition in respect of systemic corticosteroids is no wider than the molecular level. This is because:

(a) Assessment at the ATC3 or ATC4 level is inappropriate, as those levels capture a range of products that Pfizer does not consider to be substitutable. Complications arising from treatment with glucocorticoids are dependent on the size of the dose and the duration of the treatment, meaning that glucocorticoid-based treatments must be very individualised, and a decision must be made as to whether daily or intermittent treatment is required in each specific case. The

[51] http://www.medsafe.govt.nz/profs/datasheet/d/Depomedrolinj.pdf
[52] http://www.medsafe.govt.nz/profs/datasheet/d/Depomedrolinj.pdf

lowest dose required to achieve the desired effect should be prescribed in each case.[53]

(b) For this reason, differences in dosage, administration and API between products in the systemic corticosteroids group will limit those products' substitutability. In particular, corticosteroids with different APIs have a very different chemical potency: by way of example the anti-inflammatory potency of methylprednisolone is five times greater than that of hydrocortisone; the potency of dexamethasone is 25 times greater than that of hydrocortisone.[54] Given the importance of prescribing only the lowest dose possible in each case, and on a very individualised basis, these molecules (and therefore products) are not directly substitutable. This is reflected in the differing clinical indications between each systemic corticosteroid molecule: hydrocortisone is used for asthma and acute allergic conditions, prednisone for maintenance of a range of inflammatory conditions as well as in certain cancers (such as lymphoma), and dexamethasone is used in relation to trauma, neurosurgery, and brain tumours.

(c) PHARMAC tenders for these products according to API, not the general anti-inflammatory effect of those drugs.

Competition assessment

13.61 The Parties only overlap as potential competitors in the supply of methylprednisolone. No substantial lessening of competition will arise from this overlap:

(a) Hospira is not currently listed on the Hospital Schedule and made no sales in 2014. **[ ]** That being the case, Hospira does not currently provide any competitive constraint on Pfizer as regards methylprednisolone, meaning the Proposed Transaction will have no competitive effect.

(b) In any event, post-merger Pfizer will continue to face competition for the supply of methylprednisolone from a range of international suppliers, including Mylan's Alphapharm brand (which currently supplies in Australia).

(c) PHARMAC will continue to exert significant countervailing power on the merged entity.

PIPERACILLIN/TAZOBACTAM (Broad spectrum Penicillins J1C)

Overview of therapeutic area

13.62 Piperacillin/tazobactam is a combination antibiotic, containing piperacillin, an extended spectrum (broad acting) penicillin; and tazobactam, a drug that inhibits bacteria from producing a particular enzyme that provides resistance to certain antibiotics such as penicillins. It is used to treat particularly serious or resistant strains of bacteria causing: lower respiratory tract infections; urinary tract infections (complicated and uncomplicated); intra-abdominal infections; skin and skin structure infections; bacterial septicaemia; and gynaecological infections.

[53] http://www.medsafe.govt.nz/profs/datasheet/m/Medroltab.pdf
[54] http://www.pharmacorama.com/en/Sections/CRH_ACTH_corticosteroids_2_3.php

The Parties' products

13.63 The Parties currently supply, or have active Medsafe registrations for, the following Piperacillin/Tazobactam medicines:

Table 6 - Piperacillin/Tazobactam

Drug	API	Clinical Indication	NZ Status
	Pfizer		
Tazocin EF	Piperacillin (as piperacillin sodium) and tazobactam (as tazobactam sodium)	Treatment of a wide range of systemic and/or local infections caused by various bacterial strains. It is administered by slow intravenous injection, by infusion, over 20-30 minutes.	Pfizer is currently listed pursuant to HSS expiring in 2016.
	Hospira		
DBL Piperacillin and Tazobactam for Injection	Piperacillin (as piperacillin sodium) and tazobactam (as tazobactam sodium)	Treatment of a wide range of systemic and/or local infections caused by various bacterial strains. It is administered by slow intravenous injection, by infusion, over 20-30 minutes.	Hospira is not currently listed, and does not currently supply in New Zealand.

Market definition

13.64 The Commission has not previously considered the market for piperacillin/tazobactam, or the wider market for broad spectrum penicillins. In Pfizer's view the relevant product market is best approached on the basis of molecule. As noted above, piperacillin/tazobactam is a combination penicillin engineered to target particularly serious (mainly hospital-acquired) infections, as well as infections caused by more resistant bacteria. It is typically reserved by doctors for this purpose. Other penicillins within its ATC3 class are used to treat more routine - and typically less serious - infections such as skin infections, throat infections and respiratory infections.

Competition assessment

13.65 As Hospira is not listed on the Hospital Schedule and does not currently supply piperacillin/tazobactam[55] the Parties only overlap insofar as Hospira is a potential competitor to Pfizer.

13.66 The Proposed Transaction will not substantially lessen competition. Among other things:

(a) At the point that Pfizer's HSS contract expires in mid-2016, there will remain several potential competitors for that product, with four other competitors with a piperacillin/tazobactam injection registered in New Zealand - Douglas, Boucher & Muir, AFT Pharmaceuticals and Mylan Inc. Each of these competitors' injections are of identical dosages to Pfizer's current HSS product and could therefore be easily substituted by PHARMAC. Hospira's product for which it has a current registration (but does not supply) is not an especially close substitute for Pfizer's product, Tazocin EF, which some customers prefer on account of its longer shelf life after being compounded.

[55] **[ ]**

(b) In addition to the list of firms with active registrations in New Zealand, there are also a large number of international competitors who could obtain registrations and begin to compete in this market with relative ease. Examples include Actavis and Novartis (Sandoz).

(c) As noted above at 10.19, PHARMAC will continue to exert significant countervailing power on the merged entity.

(II) MOLECULE OVERLAPS AS ACTUAL COMPETITORS

GENTAMICIN (Aminoglycosides J1K)

Overview of therapeutic area

13.67 Generally speaking, aminoglycosides are used to treat serious infections. They are a group of antibiotic chemicals that display bactericidal (bacteria-killing) activity against a particular class of bacteria called 'aerobic Gram-negative' bacteria (common examples of Gram-negative bacteria are *E-Coli, Salmonella, Legionella* and *Helicobacter*).[56] Each aminoglycoside is isolated from a different species (or genus) of bacteria, resulting in differences in indication and effectiveness between aminoglycosides. For the same reasons, each aminoglycoside has different susceptibilities to bacterial resistance.

13.68 Gentamicin is used to treat serious bacterial infections in many different parts of the body such as chest infections, urinary tract infections and infected wounds or burns. Different aminoglycosides are administered only for specific illnesses and will have substantially different side-effects. For example, gentamicin is generally preferred by physicians when both Gram-positive and Gram-negative cover is needed; amikacin is preferred for routine Gram-negative infections, as it is more effective than other aminoglycosides against that class of organism; and tobramicin is reserved for resistant healthcare-related infections associated with cystic fibrosis, chronic emphysema and lung transplants. Gentamicin's particular characteristics mean that it is used preferentially during hip replacements, as it is more effective against the common infecting organism *Staphylococcus aureus* than other aminoglycosides. Gentamicin is an established and highly genericised medicine, having been in use since 1971.

The Parties' products

13.69 The Parties currently supply, or have active Medsafe registrations for, the following gentamicin medicines:

Table 7 - Gentamicin

Drug	API	Clinical Indication	NZ Status
		Pfizer	
Gentamicin Injection	Gentamicin (as gentamicin sulphate)	Treatment of infections and related conditions caused by one or more susceptible strains of bacteria.[57]	Pfizer is currently listed for one dose (40mg/ml, 2ml ampoule) of

[56] An aerobic bacterium is one that survives and grows in an oxygenated environment. By contrast, anaerobic bacteria survive and grow in environments with no oxygen. 'Gram-negative' bacteria are bacteria that do not retain a violet-coloured stain during the Gram staining method of bacteria differentiation (in which a bacterial sample is covered (stained) with certain coloured stains that are visible under a microscope). 'Gram-positive' bacteria, by contrast, are stained violet by the Gram staining process. Whether a bacteria will be stained violet by the Gram staining method will depend on the composition and thickness of the bacterial cell wall, meaning that the Gram staining method is used to easily determine the cellular structure of a particular bacterium.

[57] http://www.medsafe.govt.nz/profs/datasheet/g/Gentamicininj.pdf

Drug	API	Clinical Indication	NZ Status
		It is normally administered by intramuscular injection, but can also be administered intravenously.	injection pursuant to HSS expiring in 2016.
			
DBL Gentamicin Injection BP	Gentamicin (as gentamicin sulphate)	Treatment of infections and related conditions caused by one or more susceptible strains of bacteria.[58] An injection ideally administered intramuscularly, but can be administered intravenously when an intramuscular injection is not feasible (such as in shocked or severely burned patients).	Hospira is currently listed (no HSS) for one dose (10mg/ml, 1ml ampoule) of injection. It has a registration for, but does not supply, a 40mg/ml, 2ml ampoule or vial.

Market definition

13.70 So far as Pfizer is aware the Commission has not previously considered the appropriate market definition for aminoglycosides. The EC considered aminoglycosides in *Novartis / Chiron.*[59] Although not required to reach a definitive view on the relevant product market, its market investigation confirmed the parties' submission that the ATC3 class was too broad to form the relevant product market.

13.71 In the present case, Pfizer submits that it would also be inappropriate to define the market for aminoglycosides at the ATC3 level. As was found to be the case in the EC's market investigation (and as outlined in 13.68) within the ATC3 class some aminoglycosides are only indicated for the treatment of particular diseases and so it captures products that are non-substitutable in clinical application.

13.72 Accordingly, Pfizer submits that the relevant product market ought, at its widest, to be defined at the molecule level and that a narrower approach, having regard to concentration of dosage may more accurately reflect clinical application. On either basis no competition concerns arise.

13.73 Such an approach is consistent with PHARMAC's subsidy decisions for aminoglycosides, whereby it currently funds gentamicin, amikacin, tobramycin, as well as other aminoglycosides not offered by the Parties, such as streptomycin - reflecting the fact that no two aminoglycosides are indicated for precisely the same clinical application. This, in turn, reflects the importance of hospitals having a full suite of antibiotics (including aminoglycosides) available at any one time in case the patient presents with a resistant strain of bacteria.

Competitive assessment

13.74 The Parties overlap in the manufacture and/or wholesale supply of gentamicin based medicines. However, **[ ]**

13.75 Based on 2014 data, Pfizer had **[ ]** market share by value (and **[ ]** by volume), whereas Hospira had **[ ]** by value (and **[ ]** by volume), giving the market entry a combined market share of **[ ]** (by value). However, those market shares do not provide an accurate representation of the competition position.

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[58] http://www.medsafe.govt.nz/profs/datasheet/d/DBLGentamicinBPinj.pdf
[59] COMP/M.4049, *Novartis / Chiron* (6 February 2006).

13.76 Firstly, Pfizer's market share arises from the fact that it holds an HSS contract for one dose through until 2016. Competition for that supply will occur when the tender next comes up.

13.77 Secondly, the Parties' differing value and volume shares evidence the lack of clinical substitutability between their products (notably, Pfizer's market share by value is materially lower than its share by volume, whereas the opposite applies for Hospira).

13.78 This is due to the fact that Pfizer currently supplies gentamicin injections at a dose of 40mg per ml, while the gentamicin injection supplied by Hospira, and which Hospira has listed on the Hospital Schedule, is 10mg per ml. Such is the difference in dosages that the Parties' respective products currently supplied to DHBs pursuant to PHARMAC arrangements are not clinically substitutable. This is because, clinically, gentamicin is administered (predominantly) as a mg per kg of patient body weight. Many indications require <2.5 mg/kg of bodyweight, such that for pediatric patients there is significant wastage when the 80 mg (i.e. 40 mg per ml in 2 ml) product is used. **[ ]**

13.79 This absence of clinical substitutability is also evidenced by the fact that PHARMAC tenders separately for these two dosages. **[ ]**

13.80 **[ ]**

13.81 In addition to the two different dosages supplied by the Parties, Onelink is also supplying gentamicin in New Zealand. Pfizer believes that it sources this from Fresenius-Kabi's APP division and supplies it in New Zealand under section 29 of the Medicines Act.[60] There are further international suppliers of gentamicin, such as Novartis' Sandoz, who could readily and easily enter New Zealand with this highly genericised and mature drug.

13.82 As noted above at 10.19, PHARMAC will continue to exert significant countervailing power on the merged entity in connection with the supply of gentamicin.

13.83 Given the absence of clinical substitutability between the Parties' respective products, they do not presently exercise any meaningful competitive constraint on one another. This, coupled with the existence of a sizeable pool of potential suppliers of this highly genericised drug, means that the Proposed Transaction will not alter the prevailing competitive landscape as regards gentamicin.

HEPARIN (Heparins B1B)

Overview of therapeutic area

13.84 Heparins are molecules comprised of chains of carbohydrates, and which are used primarily as anticoagulants - drugs that stop blood clots from forming, or prevent existing blood clots from growing larger.

13.85 At a general level, heparin is used to prevent or treat certain blood vessel, heart, and lung conditions. Heparin is also used to prevent blood clotting during open-heart surgery, bypass surgery, kidney dialysis, and blood transfusions.

13.86 Different doses of heparin are used for different purposes, for example:

[60] Medicines Act 1981, s 30. See http://www.legislation.govt.nz/act/public/1981/0118/latest/DLM55429.html

(a) in low doses, typically as a subcutaneous injection, heparin is used as prophylaxis against venous thromboembolic disease ("**VTE**") and deep vein thrombosis ("**DVT**"), especially in patients who must have certain types of surgery or who must remain in bed for a long time; and

(b) in higher doses, heparin is used for full anticoagulation therapy for treatment of thrombotic or thromboembolic disease.

13.87 Heparin is given as an injection under the skin (subcutaneously) or as a slow injection into a vein (intravenously).

The Parties' products

13.88 Pfizer and Hospira do not supply overlapping heparin SKUs. The Pfizer presentations are of different concentrations to those of Hospira, which means they are used in hospitals to meet different clinical needs. As set out in greater detail at 13.97 below, each presentation of heparin has a distinct clinical application, and there is a role in hospitals for each of the SKUs.

13.89 The Parties currently supply, or have active Medsafe registrations for, the following heparin based medicines:

Table 8 - Heparin

Drug	API	Clinical Indication	NZ Status
			
Heparin Sodium Injection BP	Heparin sodium	Prevention and treatment of thromboembolic (of or relating to blood clots) disorders such as, pulmonary embolism, coronary or venous thrombosis, and occlusive vascular disease; as a low-dose regimen to prevent blood clots forming as a result of cardiac and arterial surgery; and as an anticoagulant during blood transfusions, circulation of the blood outside the body dialysis and other techniques, and in blood samples for laboratory purposes. An injection administered intravenously or subcutaneously depending on the pathology.	Currently listed (no HSS) for 2 of 7 doses. 3 of 7 doses are listed with no price or brand.
Heparinised Saline Injection	Heparin sodium	Maintenance of the patency (ie keeping free from obstruction) of intravenous injection devices. Administered by 'flushing' the injection device (such as catheters) with the Heparinised Saline Injection every 4 hours.	Currently listed (no HSS) for 1 dose. 2 further doses are listed with no price or brand.
			
DBL Heparin Sodium Injection BP	Heparin sodium	Prevent and treat clotting disorders such as thrombophlebitis, pulmonary embolism, and occlusive vascular disease. An injection, and may be administered by intermittent intravenous injection, intravenous infusion, or deep subcutaneous injection.	Currently listed (no HSS) for 2 of 7 doses. 3 of 7 doses are listed with no price or brand.

Market definition

13.90 So far as Pfizer is aware the Commission has not previously considered markets for heparin based medicines. Having regard to the very limited clinical substitution between dosages of heparin (as outlined below in detail), Pfizer submits that the appropriate market ought to be defined narrowly, for example, by clinical indication or galenic form ("galenic" refers to a combination of features including dosage, pharmaceutical form, and route of administration, which may limit substitutability as between products comprised of the same API).

13.91 Whether the Proposed Transaction is assessed by clinical indication or more broadly (for example at molecule level), the competitive assessment is unaltered. As indicated above and below, this is very much driven by the highly specific - and differentiated - clinical indications of the Parties' respective heparin products.

Competition assessment

13.92 The Parties overlap in the manufacture and/or wholesale supply of heparin based medicines, where they both currently supply medicines. However, while the Parties both

supply heparin sodium,[61] in the case of heparins it is necessary to consider the individual SKUs provided by the Parties (which do not overlap) and their corresponding different clinical indications. Among other things, anti-coagulants, ie heparins, cause a high proportion of medical error in hospitals. Administering an incorrect dose can lead to haemorrhaging, which can be fatal. As illustrated by table 9 below, this means demand for heparin is very much specific to the dose and strength.

Table 9- Clinical Applications of Heparin by SKU

SKU	Clinical Indication and comments
	
1,000iu/ml, 5ml injection ampoule	This presentation comprises a standard dose. The presentation is either used directly intravenously for anticoagulation initiation, or added to IV bags for maintenance and used intra-operatively. It is considered the 'gold standard' preparation.
5,000iu/ml, 5ml injection ampoule	This SKU has a higher dosage than Pfizer's 1,000iu/ml SKU, and is for dedicated usage in IV bag anticoagulation maintenance. It is easier to use for patients requiring longer maintenance therapy, as there are fewer vials to break and add to solution.
	
1,000iu/ml, 35ml	This SKU is utilized in patients undergoing dialysis to avoid coagulation whilst blood is moving through the dialysis lines, and for use in theatre for anticoagulating implant grafts.
5000iu/ml, 1ml injection ampoule	This SKU has a standard dose of heparin, but in a lower volume, which makes it easier to administer by an IV 'push' for therapy. This is a useful SKU for patients receiving bolus therapy via an in-situ IV line.
25,000iu/ml, 0.2ml injection ampoule	Hospira's 25,000iu/ml, 0.2ml SKU is unique, because it is the only one of the heparin presentations that is indicated for *prophylaxis* (as opposed to treatment) for thromboembolisms (DVT and VTE). This presentation is a low volume dose, designed for subcutaneous injection. That is, it is injected under the skin directly, which obviates the need for an intravenous drip line in less critical patients. Low molecular weight heparin products (*LMWH*) like enoxaparin are now also used for treatment of this condition, but amongst unfractionated or 'standard' heparin products, Hospira's 25,000iu/ml, 0.2ml SKU is the 'gold standard' and is still used in clinical scenarios. This prophylactic indication is unique to Hospira's 25,000iu/ml, 0.2ml heparin product, and it is not substitutable with any of Pfizer's or Hospira's other SKUs.

13.93 That being the case, while the Parties currently hold the only two Medsafe registrations for heparin based medicine, the products registered by the Parties are not substitutable on either the supply or demand side, meaning the Parties do not currently exercise any competitive constraint on one another.

13.94 On the demand side, there are patient safety considerations associated with administering heparins that makes the particular dosage and molecule administered very important, and minimises the substitutability between the products. Doctors wish to give only the concentration of heparin necessary to address the pathology identified in the patient. While it is possible to substitute different concentrations of, for example, heparin sodium by combining and diluting those concentrations, in practice the risk of haemorrhage associated with heparin means that doctors will seek to minimise the number of steps involved in treatment, and therefore prefer to retain a range of heparin concentrations rather than diluting a single dose.

13.95 That is partly for reasons of cost and convenience – it is cheaper and more convenient to use the most appropriate presentation for the task at hand, to minimise wastage and the costs of extra preparation steps. But, from a patient safety perspective, every

[61] Pfizer's heparinised saline injection does not need to be considered as it is a flushing fluid and so has a completely different clinical application.

additional step in the preparation of heparin solution leads to two risks: the risk of contamination of the solution, and the risk of an incorrect dosage calculation. As a result, hospitals tend to minimise the steps involved in preparing heparin solution. They do this by using the SKU which is most appropriate to the application for which the heparin is to be used.

13.96 In many cases, hospital protocols (driven by patient safety) lead to a preference for one SKU over another. Indeed, Pfizer's heparin based medicines are less expensive per international unit (IU) than Hospira's but Pfizer does not consider this has any impact on hospital demand for the individual differentiated SKUs.

13.97 For this reason, different concentrations are not substitutable, and are used in differing clinical circumstances. As noted above, SKUs of 5000iu in 5ml vials are given as a standard dose every 6 hours for thrombosis treatment, and up to once per 24 hours in clot prevention. SKUs of 5000iu in a lower volume (1ml or less) are used for subcutaneous injection. SKUs of larger doses such as 7,500iu or 10,000iu are needed for dramatically larger patients, because the prescribed dose is weight-dependent. Finally, very high volumes, such as 35,000iu (as 1,000iu/ml, 35ml) are used for continuous infusion (ie from a bag) in the operating theatre.

13.98 **[ ]**

13.99 On the supply side, the manufacturing processes for heparins at different doses are often different. High concentration/low volume injections such as Hospira's heparin sodium injections (available in doses of 1,000iu/ml, 5,000iu/ml and 25,000iu/ml) require much more exact manufacturing standards to ensure accuracy of dosage than low concentration/high dose products such as Pfizer's. Pfizer estimates it would take it **[ ]** to set up a new machine, commission the new SKU, collect the relevant stability data, prepare the Medsafe dossier, and obtain Medsafe approval. Cost of the equipment would **[ ]**. The Parties are accordingly not even able to be considered potential competitors in connection with the supply of heparin.

13.100 As noted above at 10.19, PHARMAC will continue to exert significant countervailing power on the merged entity in connection with the supply of heparins.

13.101 For these reasons, neither Party's products are sufficiently substitutable on either a demand or supply side perspective to act as a constraint on the other's. For this reason, the Proposed Transaction will not have any effect on competition in connection with the supply of heparin based medicines in New Zealand.

MORPHINE (Narcotics N2A)

Overview of therapeutic area

13.102 Morphine is a very old and highly genericised from of narcotic. It was first marketed by Merck in 1827 and now exists in over 100 brand names. More generally, narcotics comprise a wide range of opioid derived analgesics that are used in case of acute and chronic pain.

The Parties' products

13.103 The Parties currently supply, or have active Medsafe registrations for, the following Morphine based medicines:

Table 10 - Morphine

Drug	API	Clinical Indication	NZ Status
		Pfizer	
RA Morph Oral Solution	Morphine (as morphine hydrochloride)	Symptomatic relief of moderate to severe pain, especially that associated with neoplastic (tumour-related) disease, myocardial infarction (heart attack), and surgery.[62] It is a liquid for oral administration.	Pfizer is currently listed, pursuant to HSS expiring in 2015.
		Hospira	
DBL Morphine Tartrate Injection	Morphine (as morphine tartrate)	Symptomatic relief of severe and intractable pains of various categories, in terminal cancer patients.[63] It is a solution for injection	Hospira is currently listed, pursuant to HSS expiring in 2015/2016.
DBL Morphine Sulfate Injection BP	API morphine (as morphine sulfate)	Injectable solution for relief of moderate to severe pain not responsive to non-opioid analgesics. It may also be used as a pre-operative medication and as an analgesic adjunct (additional medication) in general anaesthesia.	Hospira is currently listed in respect of 4 of 13 doses of injection pursuant to HSS expiring in 2017. Biomed is currently listed in respect of 4 doses of injection (3 of which are pursuant to HSSs expiring in 2017). 5 doses of injection are listed without a price or brand.

Market definition

13.104 The Commission has not considered the market for morphine based products in the past. The EC's approach has been to define the product market narrowly, for example between fast-release and slow-release narcotics,[64] or by molecule. It has also noted that the market may be sensibly defined still more narrowly, by the "galenic form".[65]

13.105 Pfizer submits that the appropriate market definition in respect of narcotics is at least as narrow as the molecular level, and more properly at the galenic level given the differences in use between the Parties' products, described below. However, the competitive assessment is not altered by the precise approach to market definition adopted.

Competition assessment

13.106 Irrespective of whether the relevant market is defined by molecule or more narrowly, ie by galenic form, there will be no substantial lessening of competition:

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[62] http://www.medsafe.govt.nz/profs/datasheet/r/ramorphsol.pdf
[63] http://www.medsafe.govt.nz/profs/datasheet/d/dblMorphinetartrateinj.pdf
[64] COMP/M.1835, *Monsanto / Pharmacia & Upjohn* (30 March 2000).
[65] EC, *Teva / Ratiopharm*, at [265] to [268].

(a) On a view of the market defined by the products' galenic form, there is no overlap at all between the products supplied by the Parties. In particular, while both the oral solution supplied by Pfizer and the injectable doses supplied by Hospira can be used in a hospital setting, Pfizer's oral liquid is also able to be prescribed to (usually terminal) patients to take home and self-administer. Hospira's injectable doses can only be used in Hospitals and are predominantly used in the operating theatre, emergency department, and intensive care units (where patients can be closely monitored for adverse reactions), while Pfizer's oral formulation is less potent, and is thus safer for use in wards with a lesser ability to monitor patients.

(b) In addition to the difference in administration between these products, the products also differ in respect of the speed at which they act on the body. Pfizer's RA Morph Oral Solution (morphine hydrochloride) is a slower acting solution, the effects of which are felt by the patient less quickly than in the case of Hospira's DBL Morphine Tartrate Injection (morphine tartrate).

(c) When viewed at the molecular level, the combined entity's market share at the molecular (morphine) level is low **[ ]** and only very narrowly exceeds the Commission's concentration indicators (by value), with the top three competitors having combined post-merger market shares of **[ ]**).

(d) Biomed, Multichem NZ Limited, Douglas Pharmaceuticals, and Actavis will continue to compete for the supply of morphine products (ie when HSS supply arrangements come up for renewal). There are also a large number of international competitors able to quickly register narcotics medicines, which, as above, are drugs that have long been genericised, and begin to supply those products in New Zealand in a timely manner.

(e) As noted above at 10.19, PHARMAC will continue to exert significant countervailing power on the merged entity.

PHENYTOIN (Anti-epileptics N3A)

Overview of therapeutic area

13.107 Anti-epileptics are drugs used in the treatment and control of epilepsy. Epilepsy is the term used to cover a group of neurological disorders characterised by epileptic seizures, the severity and outward appearance of which can range from virtually undetectable episodes, to long periods of vigorous shaking.

The Parties' products

13.108 The Parties currently supply, or have active Medsafe registrations for, the following phenytoin based products:

Table 11- Phenytoin

Drug	API	Clinical Indication	NZ Status
		Pfizer	
Dilantin Capsules	Phenytoin: as phenytoin sodium	Control of 'grand mal' seizures (indicated by a loss of consciousness and violent muscle contractions) and psychomotor seizures (which involve a temporary impairment of consciousness accompanied by psychic symptoms including loss of judgment and	API listed, but no price or brand listed (but listed on the Community Schedule).
Dilantin Infatabs	Phenytoin: 'free acid form' (basically,		API listed, but no price or brand

Drug	API	Clinical Indication	NZ Status
	phenytoin without a salt like sodium) in tablet dose	abnormal acts). Dilantin Capsules and Dilantin Infatabs are tablets and Dilantin Paediatric Suspension is an oral liquid.	listed.
Dilantin Paediatric Suspension	Phenytoin: 'free acid form' as oral liquid		API listed, but no price or brand listed.
		Hospira	
DBL Phenytoin Injection BP	Phenytoin (as phenytoin sodium)	Control of status epilepticus (a situation in which a person has experienced a seizure of any type for longer than 5 minutes, or more than one seizure within a 5 minute period), grand mal seizures, psychomotor seizures, and the prevention of seizures occurring during or following neurosurgery. DBL Phenytoin Injection BP is to be administered slowly, and intravenously, by a doctor in a hospital.	API listed, but no price or brand listed.

Market definition

13.109 So far as Pfizer is aware, the Commission has not previously considered markets for phenytoin based medicines.

13.110 The EC has considered anti-epileptics medicines but has not been required to reach a conclusive view on the relevant product market. In *Sanofi-Synthelabo / Aventis*,[66] the EC considered (without reaching a firm view either way) that it might be appropriate to define the product market by reference to the particular class of spasticity treated (in that case being possible distinctions between (i) partial seizures and generalised seizures; and (ii) anti-epileptics used as the sole source of treatment and those approved for use only in conjunction with other drugs).[67]

13.111 In Pfizer's view, the approach contemplated by the EC in *Sanofi-Synthelabo* / *Aventis* - defining the relevant markets according to the clinical indication of the drug in question - provides an effective analytical framework for the present case. The range of products encapsulated is sufficiently wide for there to be no clinical substitutability between the various medicines. Indeed, as the above table indicates, despite being based on the same API molecule, there is no demand side substitutability between Pfizer and Hospira's products:

(a) In its oral presentation, phenytoin will prevent or effectively decrease the incidence and severity of convulsive seizures in a high percentage of cases, with patients exhibiting little tendency to become resistant to its action. Besides its effectiveness in controlling seizures, oral phenytoin frequently improves the mental condition and outlook of epileptic patients and there is also increasing evidence that oral phenytoin is valuable in the prevention of seizures occurring during or after neurosurgery and in the treatment of certain cardiac arrhythmias.

(b) By contrast, phenytoin in injectable presentation is used in hospitals to control severe fitting, as well as the control of status epilepticus, tonic-clonic (grand mal), psychomotor seizures and the prevention of seizures occurring during or following neurosurgery. That is, it treats patients who are actively fitting.

[66] COMP/M.3354, *Sanofi-Synthelabo / Aventis* (26 April 2004).
[67] COMP/M.4402, *UCB / Schwarz Pharma* (21 November 2006).

Competition assessment

13.112 Given their markedly different clinical indications stemming from their different presentations, the Parties' medicines do not overlap. This is supported by the Hospital Schedule itself, which groups products according to therapeutic use. In the Hospital Schedule, the Parties' drugs are listed in different sections, with Pfizer's products being listed under "Control of Epilepsy", and Hospira's product is listed under "Agents for the Control of Status Epilepticus".

13.113 On that basis the Proposed Transaction will have no competitive effect as regards anti-epileptics.

COORDINATED MARKET POWER

13.114 The risk of coordinated effects arising out of the Proposed Transaction is low for all markets in which there are competitive overlaps. The post-merger conditions for concluding that coordinated effects could be liable to arise do not exist in any of the relevant markets. In particular:[68]

(a) products are not typically homogenous - small differences such as concentration of presentation (of which there are many permutations) materially alter price;

(b) innovation is a key feature of the market, and constant developments in how medical care is delivered means that medicine use is subject to change at little or no notice (eg with certain medicines falling from favour as other approaches are deemed more effective);

(c) the transaction does not eliminate a maverick;

(d) there is significant countervailing power from PHARMAC, which due to its buyer power, including ability to manage patient demand, would suffice to defeat any attempts at coordination;

(e) products in the affected markets are off-patent, which limits barriers to entry and expansion (and firms supplying a medicine outside of New Zealand can easily obtain a Medsafe registration for such medicines to commence supply in New Zealand);

(f) pricing is typically not transparent - when prices are negotiated with PHARMAC, either in a tender for HSS or to be otherwise listed on the Hospital and/or Community Schedule, they are submitted by way of RFP and it is not even known who is likely to tender. Even then, there is the further possibility of discounts and rebates off the prices negotiated with PHARMAC to the actual customers; and

(g) across the sector, there are a large number of actual and potential competitors.

[68] See *Brambles New Zealand Ltd v Commerce Commission* (2003) TCLR 868 (HC).

CONCLUSIONS ON COMPETITIVE ASSESSMENT

13.115 Actual competitive overlaps arise in respect of only four molecule areas. In none of these areas are the Parties' medicines clinically substitutable, meaning the Proposed Transaction does not alter the existing competitive landscape.

13.116 As regards the six molecules where the Parties overlap only as potential competitors, the Proposed Transaction will not substantially lessen competition. In those areas, the Parties either do not currently impose any competitive constraint on one another (for example, in epirubicin Pfizer has not been active for many years and its theoretical status as a potential competitor arises only because its Medsafe registration has not lapsed), or there are a sufficient number of potential competitors that the Proposed Transaction will not alter the competitive landscape.

13.117 For the reasons outlined above, coordinated effects are not likely to arise out of the Proposed Transaction.

13.118 For all medicines covered in this application for clearance, PHARMAC has significant countervailing power and, like all monopsonists, is able to act as a price maker.

13.119 Finally, as outlined in sections 12.1 and 7.14, the Proposed Transaction does not give rise to competitive overlaps in biopharmaceuticals or medical devices.

FURTHER DOCUMENTATION/INFORMATION

13.120 Notwithstanding that the Proposed Transaction does not adversely affect competition in any of these markets, the following further information is supplied for molecules where the Parties have actual competitive overlaps namely: gentamicin, heparin, morphine and phenytoin.

Names and contact details of industry associations

13.121 Pfizer is a member of Medicines New Zealand, an association of research-based pharmaceutical companies. Its principal focus is on patented medications and not the genericised pharmaceuticals that are the subject of this application. Contact details of Medicines New Zealand are:

PO Box 10-447
The Terrace
Wellington 6143
Telephone: +64 4 499 4277
Facsimile: +64 4 499 4276
Email: info@medicinesnz.co.nz

http://www.medicinesnz.co.nz/

Key competitors

13.122 See Appendix 5 (where contact details for all of the Parties' key competitors in the medicines considered in this application are listed).

Copies of most recent financial statements

13.123 Links to the Parties' most recent annual reports (including audited accounts) are provided at Appendix 6.

Key customers

13.124 See Confidential Appendix 7.

PART D: CONFIDENTIALITY

14. Reasons for seeking confidentiality

14.1 Confidentiality is sought in respect of the information in this application that is contained in square brackets and highlighted. Confidentiality is sought for the purposes of section 9(2)(b) of the Official Information Act 1982 on the grounds that:

(a) the information is commercially sensitive and valuable information which is confidential to the participants; and

(b) disclosure would be likely unreasonably to prejudice the commercial position of the participants, as the parties providing the information.

14.3 Pfizer requests that it be notified of any request made to the Commission under the Official Information Act 1982 for release of the confidential information. Pfizer also requests that the Commission seek and consider Pfizer's views as to whether the information remains confidential and commercially sensitive at the time responses to such requests are being considered.

14.4 The foregoing equally applies in respect of any additional information provided to the Commission that is expressed to be confidential.

14.6 A confidential version and a public version have been provided.

14.2 In the confidential version of the application, confidential information is contained in square brackets and highlighted.

PART E: DECLARATION

I, Marc Brotman, have prepared, or supervised the preparation, of this notice seeking clearance.

To the best of my knowledge, I confirm that:

- all the information specified by the Commission has been supplied;
- if the information has not been supplied, reasons have been included as to why the information has not been supplied;
- all information known to me that is relevant to the consideration of this notice has been supplied; and
- all information supplied is correct as at the date of this notice.

I undertake to advise the Commission immediately of any material change in circumstances relating to the notice.

I understand that it is an offence under the Commerce Act to attempt to deceive or knowingly mislead the Commission in respect of any matter before the Commission, including in these documents.

I am a director/officer of the company and am duly authorised to submit this notice.

Marc Brotman, Vice President and Assistant General Counsel, Pfizer Inc.

Signature **Date: 24 April 2015**

APPENDIX 1: Prima facie overlaps captured by applying an ATC3 level filter

1. INTRODUCTION

1.1 As noted in 13.28, Pfizer has also assessed the potential for overlaps to arise at ATC3 level (solely because Pfizer recognises that in earlier cases involving other types of medicines that has formed the Commission's starting point). As indicated below, this additional filtering has only confirmed Pfizer's view that, consistent with the EC's approach, the appropriate level for the assessment of overlaps is at the molecule level (even if the ultimate product market is defined more narrowly).

2. ALKYLATING AGENTS (ATC3 LEVEL L1A)

2.1 Although the 2014 IMS market share data indicates that the Parties' overlap in this ATC3 class, there is, in fact, no overlap in respect of alkylating agents. **[ ]**[69]

2.2 For this reason, alkylating agents will not be considered further in this application.

3. LABOUR INDUCERS (ATC3 LEVEL G2A)

3.1 'Labour inducers' is the name given to the group of pharmaceuticals that can be used to induce labour by facilitating uterine contractions, or to prevent postpartum (after childbirth) haemorrhage and post-abortion haemorrhage.

3.2 Pfizer currently supplies, or has Medsafe registrations for:

(a) Prostin 15M, containing the API carboprost. Prostin 15M is an injection used to stop excessive bleeding in women who have just given birth.[70] The API carboprost is listed on the Hospital Schedule, but no brand or price is listed.

(b) Prostin F2 Alpha, containing the API dinoprost. Prostin F2 Alpha is an injection used for term induction of labour, evacuation of third trimester foetal death *in utero*, and for aborting a pregnancy.[71] The API dinoprost is not listed at all on the Hospital Schedule as Pfizer has withdrawn from the New Zealand market.

(c) Prostin E2, containing the API dinoprostone. Prostin E2 is a gel that induces labour in term or near term women.[72] Pfizer is currently listed on the Hospital Schedule for 2 gel formulations. A different form of administration (pessaries) is also listed, with no brand or price.

3.3 Hospira currently supplies, or has Medsafe registrations for:

(a) DBL Ergometrine Injection, containing the API ergometrine. It is an injection used as an ongoing agent to speed up a labour, and also to prevent postpartum and postabortion haemorrhage.[73] Hospira currently has the only dose listed on the Hospital Schedule, pursuant to a HSS expiring in 2017.

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[69] In any event, the combined 2014 shares of the Parties at ATC3 level is **[ ]**, and the aggregation is *de minimis*.
[70] http://www.medsafe.govt.nz/consumers/cmi/p/Prostin15M.pdf
[71] http://www.medsafe.govt.nz/profs/datasheet/p/ProstinF2alphainj.pdf
[72] http://www.medsafe.govt.nz/profs/datasheet/p/ProstinE2vaggel.pdf
[73] http://www.medsafe.govt.nz/profs/datasheet/d/DBLErgometrineinj.pdf

3.4 As is apparent from the above, the differing clinical indications of the different API based products mean the relevant market is defined by the molecule or API used in the products. In particular, Pfizer's Prostin group of products are used to induce labour, while Hospira's ergometrine injection is used as an ongoing agent to speed up a labour that has already begun. Thus the ATC3 level does not provide a basis for the appropriate product market, due to the lack of clinical substitution between the different API based products that fall within ATC3 class G2A.

3.5 The Parties do not overlap across any molecules.

4. OTHER INJECTION SOLUTIONS AND INFUSION ADDITIVES (ATC3 LEVEL K4D)

4.1 This ATC3 category includes solutions to be mixed with API powders to form injectable liquids, as well as additives to be used for parenteral infusion.[74] It thus encapsulates a diverse range of solutions, from pure water, to multivitamin blends. These solutions are, in turn, used across an equally wide range of applications.

4.2 Each Party offers one product in New Zealand:

(a) Pfizer offers **Water for Injections BP**, which is a single dose of sterile, pure water, intended to be used for the reconstitution and preparation of water-based injections.[75]

(b) Hospira's offers a **multivitamin infusion additive** containing ascorbic acid, biotin, cocarboxylase, colecalciferol, cyanocobalamin, dexpanthenol, flavin mononucleotide, folic acid, glycine, nicotinamide, pyridoxine, retinol, and vitamin E.

4.3 Pfizer submits that in this area ATC3 level does not provide a basis for the appropriate product market. This is because, as illustrated above, there is limited or no clinical substitution between the different API based products that fall within ATC3 class G2A. Rather, the differing clinical indications of the different API based products mean the relevant market is defined by the molecule or API used in the products.

4.4 The Parties do not overlap across any molecules.

5. CYTOSTATIC HORMONES (ATC3 LEVEL L2A)

5.1 Cytostatic hormones are hormones that have some obstructive effect on an aspect of cell growth or proliferation. Hormones can differ significantly in effect on the body and are found in differing concentrations in (and have different effects on) men and women. Broadly speaking, cytostatic hormones are used to treat cancer by preventing the cancerous cells from growing. They differ from cytotoxic drugs which kill the cells.

5.2 Pfizer currently supplies, or has Medsafe registrations for:

(a) Premia, containing the API medroxyprogesterone. Premia is a tablet form hormone replacement therapy ("**HRT**") pack, indicated to prevent or treat certain adverse consequences of menopause.[76] The API medroxyprogesterone is listed on the Hospital Schedule, but no brand or price is listed.

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[74] 'Parenteral' refers to a means of taking or administering a substance into the body other than by the digestive tract (ie, intravenously or intramuscularly).
[75] http://www.medsafe.govt.nz/profs/datasheet/w/WaterforInjectionPfizer.pdf
[76] http://www.medsafe.govt.nz/profs/datasheet/p/Premiatab.pdf

(b) Provera, containing the API medroxyprogesterone. Provera is a tablet used either in the diagnosis and treatment of certain conditions associated with menstruation or (in the case of high-dose tablets) in the treatment of certain kinds of endometrial or renal carcinoma, and in the treatment of hormonally-dependent and recurrent breast cancer in post-menopausal women.[77] Pfizer is currently listed on the Hospital Schedule pursuant to a HSS expiring in 2016.

(c) Depo-Provera, containing the API medroxyprogesterone. Depo-Provera is an injection for suppressing ovulation, and treating endometriosis, certain endometrial or renal carcinomas, and breast cancer in post-menopausal women.[78] Pfizer is currently listed on the Hospital Schedule pursuant to a HSS expiring in 2016.

5.3 Hospira currently supplies, or has Medsafe registrations for Eligard, containing the API leuprorelin. Eligard is an injection used in the palliative treatment of advanced prostate cancer.[79] Hospira is currently listed (with no HSS) on the Hospital Schedule in respect of four of seven dosages of leuprorelin. The other three dosages are listed by AbbVie.

5.4 The EC has considered market definition in the context of cytostatic hormone antagonists (L2B) (another type of cytostatic hormones) and considered the market ought to be defined at the molecule level due to the lack of substitutability between molecules in the same class.[80]

5.5 For the same reasons, in the present case Pfizer considers the market should instead be defined at the molecular level, because the ATC3 level encompasses a range of hormones that are entirely unsubstitutable from a demand perspective, with each API based drug having radically different effects on the body. Indeed, the specific products supplied by each of the Parties are exclusively indicated in respect of different genders: Pfizer's products are indicated for certain conditions associated with post-menopausal women, while Hospira's product is solely indicated for the palliative treatment of prostate cancer in men.

5.6 The Parties do not overlap across any molecules.

6. MUSCLE RELAXANTS, PERIPHERALLY ACTING (ATC3 LEVEL M3A)

6.1 These medicines relax muscles and are also used to prevent involuntary muscular contractions. Peripherally acting muscle relaxants are thought to interact with the biochemical pathway within contractile proteins that make up the muscle fibres, thereby preventing them from contracting. By contrast, centrally acting muscle relaxants inhibit reflexes within the spinal cord.

6.2 Pfizer currently supplies, or has Medsafe registrations for:

(a) Dantrium Capsules, containing the API dantrolene. These are capsules that are taken home and used for the long-term control of clinical spasticity (unusual tightness of muscles) resulting from serious chronic disorders such as spinal cord injury, stroke, cerebral palsy or multiple sclerosis.[81] Pfizer is currently listed on the Hospital Schedule in respect of dantrolene, with no HSS in place.

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[77] http://www.medsafe.govt.nz/profs/datasheet/p/Proveratab.pdf
[78] http://www.medsafe.govt.nz/profs/datasheet/d/Depoproverainj.pdf
[79] http://www.medsafe.govt.nz/profs/datasheet/e/Eligardinj.pdf
[80] EC, *Teva / Barr*.
[81] http://www.medsafe.govt.nz/profs/datasheet/d/Dantriumcap.pdf

(b) Dantrium IV, containing the API dantrolene. Dantrium IV is an injection used in the management of malignant hyperthermia crisis (a possible side-effect of general anaesthesia, which eventually leads to complete circulatory collapse).[82] This injectable version of dantrolene is listed on the Hospital Schedule, but no price or brand is listed.

6.3 Hospira currently supplies, or has Medsafe registrations for:

(a) DBL Rocuronium Bromide Injection, containing the API rocuronium bromide. It is an injection used to provide skeletal muscle relaxation during surgery. Hospira is currently listed on the Hospital Schedule pursuant to a HSS expiring in 2015.

6.4 The EC's approach has been to subdivide the ATC3 level M3B (Centrally Acting Muscle Relaxants) either according to the particular spasticity treated,[83] or by molecule.[84]

6.5 Consistent with the findings of the EC, in Pfizer's view the differing clinical indications of the different molecule based medicines means that the product market ought to be defined according to molecule. As set out above, the Parties' products do not clinically overlap: Hospira's DBL Rocuronium Bromide Injection is injected in hospital to induce skeletal muscle relaxation during surgery, while Pfizer's Dantrium Capsules are intended to be taken home and self-administered by the patient to control the symptoms of chronic disorders like cerebral palsy. And its Dantrium IV is injected in hospital to manage a rare condition called malignant hypothermia crisis.

6.6 The Parties do not overlap across any molecules.

7. ANAESTHETICS (ATC3 LEVEL N1A)

7.1 A general anaesthetic is a drug that is able to bring about a reversible complete loss of consciousness. This is in contrast to local anaesthesia, which generally only numbs the area upon which the procedure is being performed.

7.2 Pfizer currently supplies, or has Medsafe registrations for:

(a) Midazolam Injection, containing the API midazolam. It is an injection used in premedication before induction of anaesthesia, conscious sedation before surgeries carried out under local anaesthetic, long term sedation in intensive care units, and the induction and maintenance of anaesthesia.[85] Pfizer is listed jointly with Roche for two doses of midazolam injection, with no HSSs in place.

7.3 Hospira currently supplies, or has Medsafe registrations for:

(a) Precedex, containing the API dexmedetomidine. Dexmedetomidine is a sedative used for anxiety alleviation and pain modulation. Precedex is an injection used for sedating initially intubated patients during intensive care treatment, and for sedating non-intubated patients prior to and during surgical and other procedures.[86] Hospira is currently listed on the Hospital Schedule pursuant to a HSS expiring in 2017.

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[82] http://www.medsafe.govt.nz/profs/datasheet/d/DantriumIVinj.pdf
[83] Case IV/M, Ciba Geigy / Sandoz (1997).
[84] COMP/M.3354, Sanofi-Synthelabo / Aventis (26 April 2004).
[85] http://www.medsafe.govt.nz/profs/datasheet/m/MidazolaminjPfizer.pdf
[86] http://www.medsafe.govt.nz/profs/datasheet/p/Precedexinf.pdf

(b) DBL Fentanyl Injection, containing the API fentanyl. Fentanyl is a very potent analgesic (painkiller) used for major surgery. It is an injection used for its analgesic action during anaesthetic periods; as a narcotic analgesic supplement in anaesthesia; and as an anaesthetic premedication for the induction of anaesthesia. Six of the eight doses of injections listed on the Hospital Schedule are listed by either Boucher & Muir or Biomed. The remaining two doses are listed with no price or brand.

(c) Ketalar, containing the API ketamine. Ketamine is an anaesthetic agent with some analgesic effect. Ketalar is an injection used as the sole anaesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation, for inducing anaesthesia prior to the administration of other general anaesthetic agents, and to supplement low-potency agents like nitrous oxide.[87]

7.4 As set out above, the molecules captured at the ATC3 level are not substitutable from a clinical perspective. They have significantly different therapeutic purposes, ranging from sedation to analgesia to anaesthesia. In Pfizer's view, these differing clinical indications between molecules mean that the product market ought to be defined according to molecule.

7.5 The Parties do not overlap across any molecules.

[87] http://www.medsafe.govt.nz/profs/datasheet/k/ketalar100mginj.pdf

CONFIDENTIAL APPENDIX 2: Corporate structure chart of Pfizer

Note: The below structure chart is a simplified version of Pfizer's overall corporate structure, designed to capture the structure as relevant to Pfizer's New Zealand subsidiary.

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CONFIDENTIAL APPENDIX 3: Corporate structure chart of Hospira

Note: The below structure chart is a simplified version of Hospira's overall corporate structure, designed to capture the structure as relevant to Hospira's New Zealand subsidiary.

[ ]

CONFIDENTIAL APPENDIX 4: Copy of Merger Agreement

APPENDIX 5: Table of competitors present in New Zealand

Competitor	Description	Contact Details
abbvie	**AbbVie Inc.** is an American multinational biopharmaceutical company created as a dedicated research-based unit following the separation of Abbot Laboratories into two companies in 2013 (the medical products company retained the Abbott name). AbbVie is responsible for the discovery, development and commercialisation of drugs addressing, inter alia, immunology, kidney disease, liver disease, neuroscience, oncology and women's health. Its discovery and development efforts are focused on a core set of therapeutic areas: hepatitis C (HCV), neuroscience, immunology, oncology, renal disease and women's health. AbbVie's pharmaceutical products are available to patients in more than 170 countries worldwide. AbbVie Limited operates in New Zealand as a subsidiary of AbbVie Inc.	PO Box 11437 Manners Street Wellington Phone: 04 802 2987 Fax: 04 802 2981 Email:CustomerServiceANZ@abbvie.com http://www.abbvie.co.nz/
Actavis	**Actavis PLC** is an Irish-based specialty pharmaceutical company. Actavis produces true generic, branded generic, branded and over-the-counter drugs. Actavis primarily focuses on developing innovative drugs for patients suffering from diseases in the central nervous system, gastroenterology, women's health, urology, cardiovascular, respiratory and anti-infective therapeutic categories. Actavis markets approximately 1000 generic, branded generic, established brands and over-the-counter pharmaceutical products globally. Actavis is an industry leader in product research and development, with one of the broadest brand development orientations in the pharmaceutical industry. Actavis has commercial operations in more than 60 countries and operates more than 30 manufacturing and distribution facilities around the world.	PO Box 128244 Remuera Auckland 1541 Phone: 09 630 4488 Fax: 09 630 4490 Email: enquiries@actavis.co.nz http://www.actavis.co.nz/
AFT pharmaceuticals Working to improve your health	**AFT Pharmaceuticals Pty Ltd** is a privately-owned pharmaceuticals company with operations in both Australia and New Zealand. AFT focuses on the Pharmaceutical Rx (prescription drug) and OTC (over the counter) market sectors where it holds considerable expertise. It offers fever and pain relief liquids for infants and children; aged care, wound care, and baby care products; eye ointments; and skin care products. It serves pharmacies and hospitals in Australia, New Zealand, and internationally. In addition, AFT undertakes drug development activities including clinical trials and has a growing portfolio of patented and niche pharmaceuticals. It began operations in New Zealand in 1998.	PO Box 33-203 Takapuna, Auckland, 0740 Phone: 09 4880232 Fax: 09 4880234 Email:customer.service@aftpharm.com http://www.aftpharm.com/nz/
AstraZeneca	**AstraZeneca PLC** is a British-Swedish multinational pharmaceutical company. It is one of few biopharmaceutical companies to span the entire value chain of a medicine from discovery, early and late stage development to manufacturing and distribution, and the global commercialisation of primary care, specialty care-led and specialty care medicines. Its primary focus areas are Cardiovascular and metabolic disease (CVMD); Oncology; and Respiratory, Inflammation and Autoimmunity (RIA). It is also involved with Infection, Neuroscience and Gastrointestinal (ING) disease areas. In research, focus areas are cancer, cardiovascular/metabolic disease and respiratory, inflammatory and autoimmune disease. In 2014 AstraZeneca acquired Almirall which significantly bolstered its respiratory portfolio. In New Zealand, AstraZeneca operates through its subsidiary AstraZeneca Limited.	303 Manukau Road, Epsom, Auckland,1023 Phone: 09-623 6300 http://www.astrazeneca.com.au/

Baxter	**Baxter International Inc.** is an American company founded in 1931 as the first manufacturer of commercially prepared intravenous (IV) solutions. Through its subsidiaries, Baxter develops, manufactures and markets products for haemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. Baxter is a global, diversified company that has invested heavily in New Zealand and Australia for over 50 years. New Zealand operations commenced in 1980 and include warehouse and distribution and aseptic compounding pharmacies. Aseptic compounding is the process by which a particular pharmaceutical product is created using tools to fit the unique need of a patient. The compounding products in New Zealand include chemotherapy, antibiotics, analgesics for pain relief and intravenous nutrition. The manufactured products include proteins to treat haemophilia, plasma-based therapies, and many renal products such as PD solutions and PD cyclers. Baxter also manufactures medication delivery products such as intravenous solutions and administration sets.	PO Box 14062 Panmure Auckland, 1741 Phone: 0800 229 837 Fax: 0800 229 329 http://baxter.co.nz/index.html
BIOMED PHARMACEUTICALS	**Biomed Limited** was incorporated as Mcgow Biomed in 1995 and changed its name to Biomed Ltd in 1999. The company is based in Auckland and it focused on the manufacture of intravenous injections for hospitals across New Zealand and Australia. Biomed supply stocked products through the normal hospital pharmacy supply chain as well as a critical care service of aseptically manufactured injections for patients in hospital. The classes of medicine it manufactures include antibiotics and preparations of antibiotics, sterile preparations, preparations that have a dose of 5mg or less per unit, antineoplastic agents and immunosuppressive agents other than steroid preparations. Biomed Ltd is a former subsidiary of Health Support Ltd, a service provider of medical products and hospital supplies.	16 Main Street Upper Hutt Phone : 04 5298 453 Email : support@biomed.co.nz http://www.biomed.net.nz/
Boehringer Ingelheim	**Boehringer Ingelheim** is one of the world's leading pharmaceutical companies. It was founded in 1885 and has remained a company committed to researching, developing, manufacturing and marketing novel medications of high therapeutic value for human and veterinary medicine. Boehringer Ingelheim's pharmaceutical business includes prescription medicines, consumer health care, and biopharmaceuticals. The product portfolio mainly covers diabetes, CNS, hypertension, myocardial infarction, oncology, respiratory, stroke prevention in AF, venous thromboembolism, and virology. Headquartered in Ingelheim, Germany, it operates globally with 142 affiliates and more than 47,400 employees.	PO Box 76216 Manukau City 2241 Phone: 09 274 8664 Fax: 09 2710629 Email:frontdesk.au@.boehringer-ingelheim.com http://www.boehringer-ingelheim.com.au/
CSL	**CSL** is a multinational pharmaceuticals company incorporated in Australia in 1991. Its areas of expertise are in the development and manufacture of vaccines and plasma protein biotherapies. CSL is involved with the development of human plasma life-saving products from the collection and testing of donated plasma, through to the production of a range of plasma-derived products. It manufactures and provides influenza vaccines globally and, in New Zealand, CSL also markets a comprehensive range of vaccines and antivenoms. CSL is also focused on new product development of protein-based medicines for treating a range of serious diseases. In 2013 CSL in New Zealand was renamed as bioCSL (NZ) Ltd.	P O Box 62 590 Greenlane Auckland 1546 Phone: 09 579 8105 Fax: 09 579 8106 Email: nzadmin@biocsl.co.nz http://www.biocsl.co.nz/home
douglas	**Douglas Pharmaceuticals** is a New Zealand based pharmaceuticals company involved in research, development, and manufacturing. Douglas Manufacturing has been manufacturing and distributing prescription medicines since 1967. It produces both solid oral dose formulations (tablets and capsules) and a variety of liquid, oral and topical formulations (soft gel capsules, solutions, suspension, creams, lotions and gels).	PO Box 45 234 Auckland 0651 Phone: 09 835 0685 Fax: 09 835 0689 mikes@douglas.co.nz http://www.douglas.co.nz/

FRESENIUS	**Fresenius** is a global health care group consisting of Fresenius Medical Care, Fresenius-Kabi, Fresenius Helios and Fresenius Vamed. Fresenius was founded in 1982 and provides a wide range of medicines and medical devices to over 70 countries. Fresenius-Kabi, the division of Fresenius mentioned in this application, specialises in intravenous generic drugs, infusion therapies and clinical nutrition products. One of its chief areas of focus is in the field of oncology products, where its product range spans injectables, tablets and capsules	PO Box 13071 Onehunga Auckland Phone: 09 9252700 Fax: 09 2551431 http://www.fmc-au.com/
gsk	**GlaxoSmithKline PLC** is a multinational science-led healthcare company that research and develop a range of innovative products in Pharmaceuticals, Vaccines and Consumer Healthcare. It manufactures and markets prescription and OTC medicines in major disease areas such as asthma, cancer, infections, diabetes, digestive and mental health conditions. It is also responsible for Stiefel dermatology products and Viiv Healthcare, an independent specialist HIV company. It operates in over 180 markets around the world, including in New Zealand through its subsidiary GlaxoSmithKline New Zealand Ltd.	Level 11, Zurich House, 21 Queen Street, Auckland 1010 Phone: 09 367 2900 Fax: 09 367 2910 https://gsk.co.nz/index.html
Johnson & Johnson	**Johnson & Johnson** is an American pharmaceutical company that manufactures healthcare products and provides related services for the consumer, pharmaceutical and medical devices and diagnostics markets. It manufactures and distributes acetaminophen products, pharmaceuticals, diagnostic equipment, and surgical equipment in countries located around the world. The pharmaceutical segment of the company is driven by the Janssen Pharmaceutical Companies of Johnson & Johnson, which is involved in the manufacture, marketing and sale of branded and generic drugs targeted at the areas of oncology, immunology, neuroscience, infectious disease and cardiovascular and metabolic diseases. In New Zealand, Johnson & Johnson operates through its subsidiary Johnson & Johnson (New Zealand) Ltd which has serviced the New Zealand market since 1945.	13 Gabador Place, Mount Wellington Auckland 1060 Phone: 09 574 1783 https://www.jnjnz.co.nz/home
MERCK Be well	**Merck & Co** (Merck Sharp & Dohme; MSD outside the US and Canada) is an American multinational pharmaceutical company that manufactures prescription medicines, consumer healthcare products, oncology products, vaccines, biologic therapies and animal health products, which it markets directly and through its joint ventures. In prescription medicines its main areas are cardiovascular disease, respiratory disease, oncology, neuroscience, infectious disease, immunology and women's health. It undertakes research and development and clinical trials to discover innovative ways to treat and prevent disease. Merck actively seeks strategic partnerships in order to complement and enhance its original research and product portfolio. Merck and ScheringPlough merged in 2009 to create MSD, supplying the New Zealand market through its subsidiary MSD (NZ) Ltd.	PO Box 99-851 Newmarket Auckland 1149 Phone: 09 523 6000 Fax: 09 523 6001 Email:msdnz_inquiries@merck.com www.msd-newzealand.com
Mylan Seeing is believing	**Mylan** is a multinational American-based company which manufactures and markets generics and specialty pharmaceuticals to over 140 countries. It provides retail, wholesale, government and institutional customers. Mylan is one of the world's biggest pharmaceuticals companies and maintains one of the industry's broadest and most high quality product portfolios. Mylan's over-the-counter products include Alanase, Butacort, Flucazole, Micreme, and Xergic. Mylan Specialty (formerly known as Dey) is operated as a fully integrated specialty pharmaceutical business which innovates medicinal therapies, including EpiPen Auto-Injector. Through its subsidiary Mylan Laboratories Limited, Mylan has access to one of the world's largest API manufacturers. Mylan Laboratories is also a leading producer of generic antiretroviral therapies for the treatment of HIV/AIDs. Mylan New Zealand is part of the international Mylan group and promotes a wide range of Mylan prescription and over-the-counter medicines.	PO Box 11183 Ellerslie, 1542 Auckland Phone: 09 579 2792 Fax: 09 579 7072 Email: info@mylan.co.nz http://www.mylan.co.nz/

	**Novartis** is a Swiss-based multinational company which manufactures branded and generic pharmaceuticals for cardiovascular, respiratory and infectious diseases, oncology, neuroscience, transplantation, dermatology, gastrointestinal and urinary conditions, arthritis, ophthalmology, hypertension, metabolism, vaccines and diagnostics. Novartis has supplied the New Zealand market through its Australian subsidiaries for over 50 years. Sandoz is a Novartis company and global leader in production of generic medicines. In New Zealand, Sandoz provides products that cover a large range of therapeutic classes from oral solids to complex biosimilars and essential anti-infective medicines, predominantly antibiotics.	Private Bag 65904 Mairangi Bay Auckland Phone: 09 361 8100 http://www.novartis.com/
	**Rex Medical** is an American based pharmaceuticals company which specialises in the development, manufacturing and marketing of innovative, minimally invasive medical devices targeted towards the cardiovascular, venous access, endosurgery and oncology markets to address unmet clinical needs and deliver high quality care. Its New Zealand subsidiary, Rex Medical Ltd, commenced operations in 1996.	67L Elizabeth Knox Pl Auckland 1072 Phone: 09 5746060 Fax: 09 5746070 http://www.rexmedical.com/
	**Roche Holding AG** is a Swiss global pharmaceutical and diagnostics company that researches, develops, and markets drugs. Its main areas of involvement are oncology, inflammation, metabolic disorders and central nervous system. Roche also manufactures products targeted at infectious diseases, immunology and cardiovascular and metabolism. Its pharmaceutical brands include Valium, Fuzeon, MIRCERA, Lariam and Anaprox. Its diagnostics include Accu-Check, AmpliChip, Elecsy and iScan. Roche is the leading provider of oncology medicines in New Zealand, as well as providing innovative medicines in the treatment of renal anaemia, hepatitis and rheumatoid arthritis.	98 Carlton Gore Road Newmarket Auckland 1023 Phone: 09 523 9400 Fax: 09 523 9465 http://www.roche.co.nz/
	**Sanofi S.A.** is a French multinational pharmaceutical company that researches, develops, manufactures and markets prescription medicines, vaccines, consumer healthcare products and animal health products. Its products are targeted at diabetes, oncology, rare diseases and multiple sclerosis. Sanofi ANZ is a horizontally integrated healthcare provider in New Zealand, with products ranging from complementary medicines through to patented medicines, generics, OTC medicines, nutraceutical products and vaccines. This is achieved through four distinct divisions: Pharmaceuticals, Consumer Healthcare, Vaccines, and Rare Diseases. Its pharmaceutical brands in New Zealand include Actonel, Amaryl, Apidra, Clexane, Clomid, Cordarone, Ditropan, Flagyl, Multaq, Panadeine Forte, Panamax, Primacor, Rilutek and Stilnox.	PO Box 12851 Penrose, Auckland Phone: 09 580 1810 http://www.sanofi.com.au/
	**UCB** is a global biopharmaceutical company focused on severe diseases. UCB have expertise across large and small molecules and are leaders in epilepsy. It has long-established antibody research which they are using to address complex biological pathways and interconnectedness of different disease types. Its further focus is on central nervous system diseases and immunology. The diseases targeted are Parkinson's disease, Restless legs syndrome, Ankylosing spondylitis, Axial spondyloarthritis, Psoriatic arthritis and Crohn's disease. Its products exist in two categories: central nervous system and immunology. These include Vimpat, Keppra, Neupro, and Cimzia. UCB operates in over 40 countries including in New Zealand.	PO Box 158 Malvern VIC 3144 Australia Tel: +61 3 9828 1800 Fax: +61 3 9828 1860 Email: cs.australia@ucb.com http://www.ucb.com/worldwide/australia-new-zealand

APPENDIX 6: Copies of annual reports and financial statements

A copy of Pfizer's 2014 annual report is available online at:

http://www.pfizer.com/system/files/presentation/Annual_Review_2014.pdf

A copy of Pfizer's 2014 audited financial statements is available online at:

http://www.pfizer.com/system/files/presentation/2014_Pfizer_Financial_Report.pdf

A copy of Hospira's 2014 audited financial statements is found inside its 2014 Annual Report, which is available online at:

http://www.hospirainvestor.com/phoenix.zhtml?c=175550&p=irol-reportsannual

CONFIDENTIAL APPENDIX 7: Contact details for key customers referred to in the application

Note: All values set out below are provided in New Zealand dollars.

Contact details for key Pfizer customers

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Contact details for key Hospira customers

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