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LAWYERS

Commerce Act 1986: Business Acquisition

Section 66 Notice seeking clearance

8 October 2014

The Registrar
Mergers and Authorisations
Commerce Commission
PO Box 2351
WELLINGTON

Pursuant to section 66(1) of the *Commerce Act 1986*, notice is hereby given seeking clearance of a proposed business acquisition.

PUBLIC VERSION

Contents

Executive summary

Proposed Transaction

On 14 July 2014, Mylan Inc. (**Mylan**) announced that it had entered into a transaction to acquire the Established Pharmaceuticals Division of Abbott Laboratories, Inc. (**Abbott**) (together, the **Parties**) in developed markets outside the US (**Abbott EPD-DM**). As consideration for the sale of these assets, Abbott, through its subsidiaries, will receive shares on closing representing approximately 21% in a new Mylan group registered in the Netherlands (**New Mylan**) (**Proposed Transaction**). This shareholding will be subject to limitations to prevent Abbott having any ability to influence New Mylan.

As part of the Proposed Transaction, Mylan will merge with a subsidiary of New Mylan so that New Mylan will become the parent company of Mylan. New Mylan will be led by the current Mylan leadership team and based in Canonsburg, Pennsylvania, United States.

Abbott will retain its Established Pharmaceuticals Division in emerging markets.

Description of the Parties

Mylan Inc

Mylan is a US-based global pharmaceutical company that develops, licenses, manufactures, markets and distributes generic, branded generic and specialty pharmaceuticals.

Mylan operates in New Zealand through its wholly owned subsidiary, Mylan NZ Ltd (**Mylan NZ**). Its product portfolio in New Zealand specialises in off-patent medicines and also includes a wide range of prescription and over-the-counter (**OTC**) medicines. Mylan NZ distributes **[ ]**.

Mylan NZ's products include anti-biotics, anti-infectives, cardiovascular drugs, anti-virals, sedatives, anti-epileptics and central nervous system (**CNS**) drugs.

Abbott Laboratories

Abbott is a global healthcare company that is involved in the discovery, development, manufacture and sale of a broad and diversified line of healthcare products. Abbott has four main segments: Established Pharmaceutical Products, Diagnostic Products, Nutritional Products and Vascular Products.

Abbot EPD-DM operates in Europe, Japan, Canada, Australia and New Zealand. It includes more than 100 specialty and branded generic pharmaceutical products in five major therapeutic areas – cardio / metabolic, gastrointestinal, anti-infective / respiratory, CNS / pain and women's and men's health, and includes several patent protected and novel products with continued growth potential.

Abbott Laboratories operates in New Zealand through its wholly owned subsidiary, Abbott Laboratories NZ Ltd (**Abbott NZ**), which is primarily involved in marketing and distribution activities from Auckland. Abbott NZ does not have any manufacturing facilities in New Zealand.

Key industry dynamics

Competition in the pharmaceutical industry in New Zealand reflects the following key dynamics:

(a) *There are a large number of strong, existing pharmaceutical companies in the market*. Many of the companies are part of large global pharmaceutical companies. The last five years has also seen the growth of third party, contract manufacturers.

(b) *Ease of generic entry.* The abridged approval process for bringing a generic product to market means the time taken to bring a generic drug to market is short and the cost of entry of a generic product is very low. Low barriers to entry are indicated by the fact that once a patent expires, generics very quickly and successfully enter the market, and this often results in the innovator product quickly losing market share, and in some cases, eventually ceasing to be supplied in the market altogether.

(c) *Increase in generic substitution*. There has been a trend over a number of years of integration between types of manufacturers with branded companies supplying more generic products and vice versa. Additionally, the use of generic drugs has been steadily increasing internationally as a result of economic pressure on drug budgets. In New Zealand, generic medicines are widely used and increasingly becoming so. The increasing use and promotion of generic substitution increases competition between bioequivalent medicines and limits the ability of pharmaceutical manufacturers or sponsors to price their products above the generics.

(d) *Entry is possible without local manufacturing facilities*. Many pharmaceutical companies active in New Zealand do not have local manufacturing facilities. Competitors without local manufacturing facilities are able to sell products in New Zealand through distributors. Distribution services are readily available through companies such as Healthcare Logistics, Pharmaco and DHL. This means that a new entrant, provided it can satisfy regulatory requirements regarding security of supply, is easily able to distribute its products through existing wholesalers and distributors.

(e) *High degree of regulation in the industry*. All pharmaceutical competitors are constrained by the high degree of regulation present in the industry with the role performed by PHARMAC and the District Health Boards exerting a high level of countervailing power. The use of reference pricing imposes a ceiling on the level of subsidisation for pharmaceuticals that have the same or similar therapeutic effect and tender processes continue to promote a high level of competition amongst pharmaceutical companies, particularly generic pharmaceutical suppliers. Furthermore, through the operation of PHARMAC, the New Zealand Government effectively acts as a monopsony buyer with substantial power over the prices it pays to pharmaceutical manufacturers or sponsors.

Relevant markets

The Parties' businesses are largely complementary, with a limited number of overlaps resulting in combined shares of relevant markets that generally remain low or result in *de minimis* increases.

In line with the Commerce Commission's approach, the Parties have defined the relevant market by reference to the substitutability of products for the same therapeutic purpose, having regard to the relevant treatment profile, mechanism of action and a range of other factors.

Finally, consistent with the Commerce Commission's previous approach, the Parties have considered the geographic dimension of the relevant markets to be national, but have considered the effect of potential global entry in their analysis.

The Parties overlap in the following markets:

(a) OTC laxatives (with a combined share of **[ ]** and a *de minimis* increase of **[ ]** on a volume basis and a combined share of **[ ]** and a *de minimis* increase of **[ ]** on a value basis);

(b) antiarrhythmics (with a combined share of **[ ]** and a *de minimis* increase of **[ ]** on a volume basis and a combined share of **[ ]** and a *de minimis* increase of **[ ]** on a value basis);

(c) antihypertensives (with a combined share of **[ ]** and a *de minimis* increase of **[ ]** on a volume basis and a combined share of **[ ]** and a *de minimis* increase of **[ ]** on a value basis);

(d) macrolides (with a combined share of **[ ]** and a *de minimis* increase of **[ ]** on a volume basis and a combined share of **[ ]** and an increase of **[ ]** on a value basis); and

(e) non-steroidal anti-rheumatics -- prescription only (with a combined share of **[ ]** and an increase of **[ ]** on a volume basis and a combined share of **[ ]** and an increase of **[ ]** on a value basis).

Competition assessment

Given the industry dynamics set out above, the Proposed Transaction is unlikely to substantially lessen competition in any relevant market:

(a) In relation to **OTC laxatives**: The Proposed Transaction will result in a *de minimis* increase in share and falls below the Commerce Commission's concentration indicators. In any event, the Parties' products will continue to be constrained by a large number of multinational companies, including Aspen, Douglas, Norgine, AFT Pharmaceuticals and Proctor & Gamble, within a highly fragmented and competitive market.

(b) In relation to **antiarrhythmics**: The Proposed Transaction will result in a *de minimis* increase in share and falls below the Commerce Commission's concentration indicators. In any event, the Parties' products will continue to be constrained by a large number of multinational companies, including Valeant

Pharma and Sanofi within a highly fragmented and competitive market.

(c) In relation to **antihypertensives**: The Proposed Transaction will result in a *de minimis* increase in share and there will be no change to competitive dynamics in relation to supply of antihypertensives after the Proposed Transaction. In any case, the market is highly fragmented and the Parties' products will continue to be constrained by a large number of multinational companies, including Apotex, Actavis and Astrazeneca.

(d) In relation to **macrolides**: The Proposed Transaction will result in a *de minimis* increase on a volume basis (**[ ]**) and a small increase on a value basis (**[ ]**). There will be no change in the competitive dynamics in any relevant market for the supply of macrolides and a number of large pharmaceutical manufacturers such as Apotex, Actavis, ABM Pharma and Pfizer will continue to compete vigorously with New Mylan in the market after the Proposed Transaction.

(e) In relation to **non-steroidal anti-rheumatics**: Actavis and Douglas will maintain a strong position in the market whilst a wide range of global pharmaceutical companies including Roche, Valeant Pharma, Astrazeneca, Sanofi and Novartis will continue to operate in the market. Additionally, OTC products such as Voltaren Rapid will continue to impose a significant competitive constraint on prescription-only products.

Conclusion

For the reasons set out above and in detail in this submission, the Proposed Transaction is not likely to result in a substantial lessening of competition in any relevant market.

We attach a glossary at Attachment D to assist the Commerce Commission in reading this application.

Part A TRANSACTION DETAILS

1 Party details

1.1 The Acquirer

This notice is given by Mylan, represented in New Zealand by its related company, Mylan NZ.

Details for Mylan NZ are:

Postal address:	Mylan New Zealand Ltd P.O.Box 11183, Ellerslie 1542 Auckland , New Zealand
Physical address:	2B George Bourke Drive Mt Wellington

	Auckland , New Zealand
Telephone number:	+64 9 5792792
Website:	www.mylan.co.nz
Contact person:	Lloyd Price lloyd.price@mylan.co.nz, +64 9 2592060 Managing Director
Relevant related entities:	None

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

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Level 37, 2 Park Street
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Sydney NSW 2000
T +61 2 9263 4362
E EAvery@gtlaw.com.au

1.2 Other merger party

The other party is Abbott, represented in New Zealand by its related company, Abbott NZ.

Details for Abbott NZ are:

Postal address:	Abbott Laboratories NZ – Pharmaceuticals PO Box 22-801 Otahuhu, Auckland 1640
Physical address:	Ground Floor, Building D 4 Pacific Rise Mount Wellington, Auckland 1060
Telephone number:	+64 9 573 6030
Website:	www.abbottaustralasia.com.au
Contact person:	Sylvain Vigneault sylvain.vigneault@abbott.com +61 2 9384 9766 General Manager Australia & New Zealand Established Pharmaceuticals

Please direct enquiries regarding Abbott NZ in the first instance to:

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Partner
Baker & McKenzie
Level 27, 50 Bridge Street
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E georgina.foster@bakermckenzie.com

2 About the Parties

2.1 Mylan

(a) *Corporate overview*

Mylan is a US-based global pharmaceutical company that develops, licenses, manufactures, markets and distributes generic, branded generic and specialty pharmaceuticals. It has a broad and high quality product portfolio, offering approximately 1,300 separate products in approximately 140 countries and territories, with more than 35 manufacturing facilities globally. Mylan is headquartered in Canonsburg, Pennsylvania, United States, and has a global workforce of more than 20,000 employees and external contractors.

Mylan's operations include a generic pharmaceutical business conducted primarily in North America, Europe, the Middle East, Africa, India, Australia, Japan, New Zealand and Brazil, an active pharmaceutical ingredients (**API**) business, and also a specialty business, conducted through Mylan Specialty, that is focused on respiratory and allergy therapies. Mylan Specialty engages mainly in the manufacture and sale of branded specialty injectable and nebulised products.

Mylan is listed on the NASDAQ (MYL). In 2013, Mylan had approximately US$6.9 billion in revenue (approximately NZ$8.4 billion[1]).

(b) *New Zealand operations*

Mylan operates in New Zealand through its wholly owned subsidiary, Mylan NZ.

Mylan NZ is a well-established supplier of generic medicines in New Zealand, with sales, marketing and distribution operations from a facility located in Auckland that employs 49 staff. Its product portfolio in New Zealand specialises in off-patent medicines and also includes a wide range of prescription and OTC medicines. Mylan does not have any manufacturing facilities in New Zealand.

Mylan NZ distributes a total of **[** **]**. Mylan NZ's products include anti-biotics, anti-infectives, cardiovascular drugs, anti-virals, sedatives, anti-epileptics and CNS drugs.

[1] Based on the Reserve Bank of New Zealand published exchange rate as at 31 December 2013: NZ$1 = US$0.8202.

In FY2013 (ending 31 December), **[**

].

2.2 Abbott

(a) *Corporate overview*

Abbott is a global healthcare company that is involved in the discovery, development, manufacture and sale of a broad and diversified line of healthcare products. Abbott has four main segments: Established Pharmaceutical Products, Diagnostic Products, Nutritional Products and Vascular Products.

- **Established Pharmaceutical Products** (23% of Abbott's 2013 global sales) – these products include a broad line of branded generic (as well as some on-patent) pharmaceuticals manufactured worldwide and marketed and sold outside the United States in both developed and emerging countries, some of which are co-marketed or co-promoted with other companies. It includes gastroenterology products, women's health products, cardiovascular and metabolic products, pain and CNS products and respiratory drugs and vaccines. Further detail is included in section (b) below. As explained below, the Proposed Transaction only concerns this segment in developed markets.

- **Diagnostic Products** (31% of Abbott's 2013 global sales) – these products include a broad line of diagnostic systems including immunoassay and clinical chemistry systems, haematology systems and reagents, DNA and RNA testing instruments, genomic based tests and informatics and automation solutions for laboratories.

- **Nutritional products** (21% of Abbott's 2013 global sales) – this portfolio includes a line of paediatric and adult nutritional products including prepared infant formula and follow-on formula and nutritional products used in enteral feeding.

- **Vascular products** (25% of Abbott's 2013 global sales) – this portfolio includes a range of coronary, endovascular, vessel closure and structure heart devices for the treatment of vascular disease, including coronary stent systems, coronary bioresorbable vascular scaffold, coronary balloon dilation products and percutaneous mitral valve repair systems.

The principal products in Abbott's other businesses include blood glucose and continuous glucose monitoring systems, test strips, data management software and accessories for people with diabetes and medical devices for the eye (including cataract and LASIK surgery and contact lens care products).

On 1 January 2013, Abbott completed the separation of its research-based proprietary pharmaceuticals business, AbbVie Inc, which is now an independent public company. Abbott continues to own over 500 branded generic pharmaceuticals in developed and emerging countries through its Established Pharmaceutical Products Business.

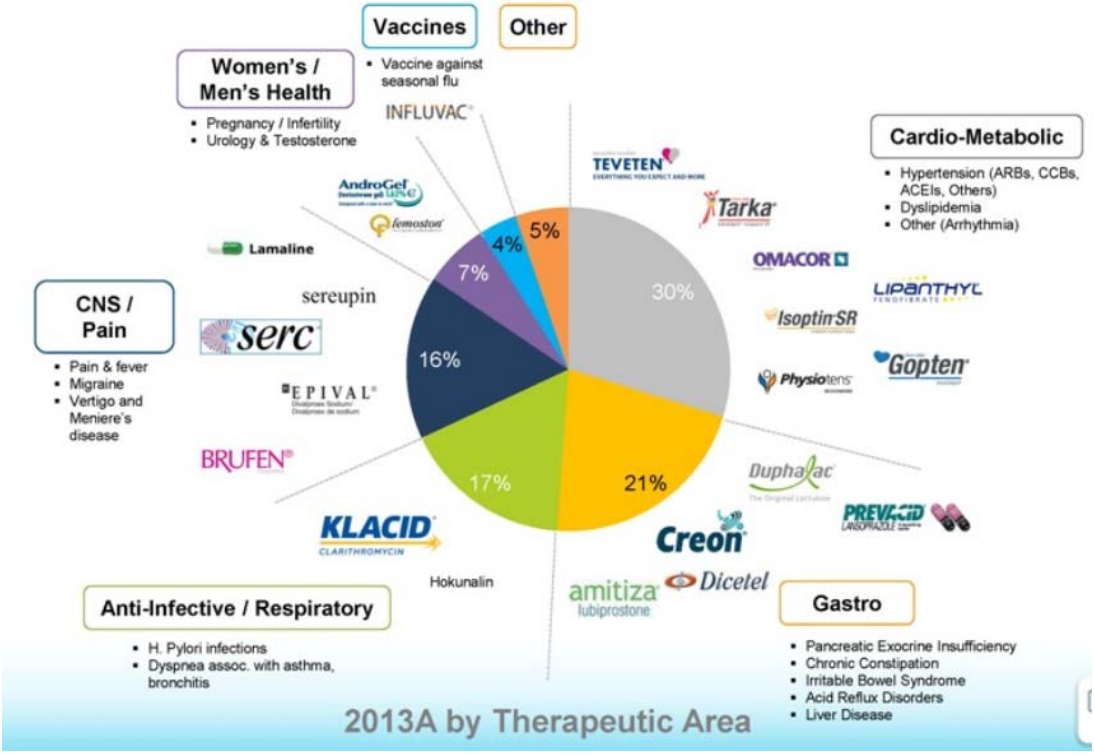
Abbott employs approximately 69,000 people globally, has 44 principal plants and over 150 third party manufacturer partners at over 200 sites worldwide. Abbott operates in over 130 countries.

Abbott Laboratories is listed on the New York Stock Exchange (NYSE: ABT). In 2013, Abbott had approximately US$21.8 billion in revenue (approximately NZ$26.6 billion[2]).

(b) *Established Pharmaceutical Products*

Abbott's Established Pharmaceutical Division (**Abbott EPD**) is headquartered in Abbott Park, Illinois, USA. Abbott EPD is focused on producing and marketing high-quality, trusted branded generics, which together with some on-patent products comprise approximately 90% of its products, the remaining 10% of which are OTC products. Abbott EPD-DM (the subject of the Proposed Transaction) operates in Europe, Japan, Canada, Australia and New Zealand. It includes more than 100 specialty and branded generic pharmaceutical products in five major therapeutic areas – cardio / metabolic, gastrointestinal, anti-infective / respiratory, CNS / pain and women's and men's health, and includes several patent protected and novel products with continued growth potential.

Figure 1: Breakdown of Abbott EPD-DM by segment including key brands



Abbott EPD-DM includes an active sales organisation of over 2,000 employees in more than 40 non-US markets, as well as a number of high-quality manufacturing facilities, including one in Chatillon, France and one in Katsuyama, Japan which form part of the Proposed Transaction.

In 2013, Abbott EPD-DM generated US$2.1 billion (approximately NZ$2.6 billion[3]) in sales worldwide.

[2] Based on the Reserve Bank of New Zealand published exchange rate as at 31 December 2013: NZ$1 = US$0.8202.

[3] Based on the Reserve Bank of New Zealand published exchange rate as at 31 December 2013: NZ$1 = US$0.8202.

(c) *New Zealand operations*

Abbott Laboratories operates in New Zealand through its wholly owned subsidiary, Abbott NZ, which is primarily involved in marketing and distribution activities from Mount Wellington, Auckland. Abbott NZ does not have any manufacturing facilities in New Zealand. Abbott NZ has a total of **[ ]** employees in New Zealand.

Abbott NZ's sales for 2013 were **[ ]** and Abbott EPD-DM's sales in New Zealand for 2013 were **[ ]** (approximately **[ ]**[4]).

3 The Proposed Transaction

On 14 July 2014, Mylan and Abbott announced that Mylan had entered into a transaction to acquire Abbott EPD-DM.

Under the Proposed Transaction, Abbott will carve out the relevant Abbott EPD-DM assets from Abbott and transfer them to a new public company, New Mylan**,** organized in the Netherlands. Immediately following the transfer, Mylan will merge with a wholly-owned subsidiary of New Mylan and New Mylan will become the parent company of Mylan. The new public company is expected to be known as Mylan N.V. and will be led by the current Mylan leadership team and based in Canonsburg, Pennsylvania.

Under the Proposed Transaction, by way of consideration, Abbott, through its subsidiaries, will receive 105 million shares in New Mylan upon closing, resulting in former Mylan shareholders owning approximately 79% of New Mylan and Abbott companies (**Abbott Shareholders**) owning approximately 21% of New Mylan in the short term.[5]

Abbott will retain its Established Pharmaceuticals Division in emerging markets.

Completion of the Proposed Transaction is not intended to take place until all relevant approvals have been obtained. Merger filings have been made in Canada, Japan, United States, Brazil, India and Australia, and a merger filing will be made in Europe. [6]

The Business Transfer Agreement and Plan of Merger (**BTA**), and its Schedules and Exhibits, is provided in Attachment B to this application.

3.1 Structure of ownership and control

The Proposed Transaction will occur in the following steps:

(a) Prior to completion, Abbott will carve out its specialty and branded generics business in non-US developed markets (ie Europe, Canada, Japan, Australia and New Zealand), which it will transfer to a new public company organised in the Netherlands.

(b) Mylan will then merge with a wholly-owned subsidiary of New Mylan and New Mylan will become the parent company of Mylan. The new public company is

[4] Based on the Reserve Bank of New Zealand published exchange rate as at 31 December 2013: NZ$1 = US$0.8202.

[5] See Mylan's press release announcing the transaction: http://www.mylan.com/news/press-releases/item?id=123238.

[6] The first draft of the Finished Dosage Products chapter of the Form CO has been submitted to the European Commission.

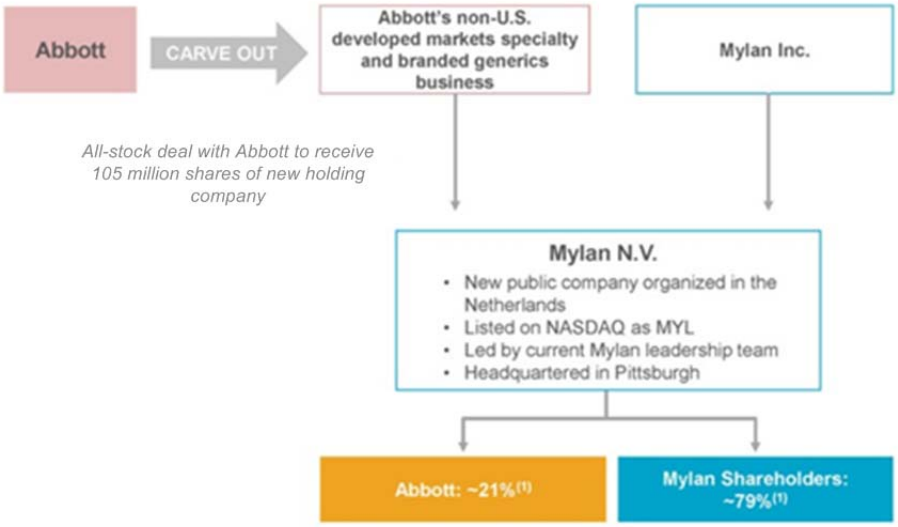
expected to be known as Mylan N.V. and will be led by the current Mylan leadership team and headquartered in Canonsburg, Pennsylvania.

It is expected that Mylan shares will continue to be listed on the NASDAQ under Mylan's existing ticker symbol. In addition to complying with certain Dutch law reporting requirements, the new holding company will continue to report financials consistent with Mylan's past practice.

Under the terms of the BTA, by way of consideration, Abbott will receive 105 million shares of New Mylan upon completion, resulting in former Mylan shareholders owning approximately 79% of New Mylan and Abbott Shareholders owning approximately 21% of New Mylan.

This transaction structure is represented as follows:

Figure 2: Mylan / Abbott EPD Transaction Structure



(1) Pro-forma shares outstanding

Abbott does not expect to be a long term shareholder in Mylan and plans ultimately to capitalise the proceeds from the Proposed Transaction.[7] Under the BTA, the Parties agree to enter into a shareholder agreement which will impose certain restrictions on Abbott's shareholding. These restrictions extend to the Abbott Shareholders' ability to vote, acquire new shares in New Mylan, call a meeting of shareholders, and initiate a shareholder proposal, among other actions. Abbott will be prevented from proposing candidates for nomination to the board of directors of New Mylan, and for so long as the total shareholding of the Abbott Shareholders is greater than 5%, they must vote only in accordance with the recommendations of the New Mylan board of directors (with the exception of certain decisions that relate to a merger/takeover involving New Mylan or the sale of all or substantially all of New Mylan's assets). The Abbott Shareholders are also limited as to whom they can dispose of their New Mylan shares.

[7] Abbott Laboratories Investor Call Script, *Abbott Laboratories announces sale of non-US developed markets specialty and generics business to Mylan Inc*, 14 July 2014.

As the Proposed Transaction involves the sale of Abbott's developed markets pharmaceutical business, with Abbott retaining its business in various emerging markets, there will be certain drugs that New Mylan will supply to Abbott for the emerging markets and Abbott will supply to New Mylan for the developed markets. Manufacturing and supply arrangements, as well as cross licensing of IP, are therefore required for this continued supply to occur. Further information is provided in section 3.3.

3.2 Rationale for the Proposed Transaction

(a) *Abbott*

The Proposed Transaction allows Abbott to focus its branded generics pharmaceutical business on emerging markets where demographic changes and increasing access to healthcare are expected to drive sustainable growth. Abbott expects to redeploy the net proceeds – following the expected sale of its share in New Mylan – from the Proposed Transaction to opportunities that would be accretive to earnings over time.

(b) *Mylan*

The Proposed Transaction will instantly diversify Mylan's business and strengthen its commercial platform outside of the US, building new opportunities for growth and additional sales channels in the acquired markets. Abbott EPD-DM will add a differentiated business with a complementary portfolio of attractive specialty and branded products to Mylan's existing business outside of the US, and will also provide entry into the OTC market in a number of key geographies.

The Proposed Transaction will strengthen Mylan's presence in Europe, Canada and Japan, provide Mylan with a meaningful presence in the specialty and branded generics market in Central and Eastern Europe, and will build on Mylan's business in New Zealand and Australia.

Further, the Proposed Transaction will significantly expand Mylan's commercial capabilities, adding a strong sales force in key developed markets and enhancing Mylan's reach with physicians and patients, complementing Mylan's existing strength in pharmacies. The Proposed Transaction will provide Mylan with the enhanced infrastructure and expertise to more effectively execute on the growth drivers that require access to the physician channel, such as the global expansion of a key Mylan product, the EpiPen® Auto-Injector, and the launch of biologics and respiratory products. In turn, this will allow Mylan to further effectively compete with large global pharmaceutical companies that combine an originator profile with a strong and developed generics division, such as Sanofi/Zentiva, Novartis/Sandoz and Watson/Actavis.

3.3 Relevant ancillary agreements

As noted above, the Parties intend to enter into ancillary agreements related to manufacture and supply of certain products, transitional services and shared intellectual property. In particular, the Proposed Transaction only includes the transfer of two of Abbott's manufacturing facilities.[8] The manufacturing operations retained by Abbott include the facilities in Olst and Weesp, Netherlands and Victoriaville, Canada. Mylan will acquire facilities in Chatillon, France and Katsuyama, Japan under the Proposed Transaction.

[8] Abbott has a number of other facilities which will continue to manufacture finished dosage products for Abbott's emerging markets business, including Baddie, India, Karachi, Pakistan, Neustadt, Germany, Rio de Janeiro, Brazil and Tlalpan, Mexico.

Therefore, as part of the Proposed Transaction, Mylan and Abbott intend to enter into Manufacturing and Supply Agreements (each a **Proposed MSA**) which provide for the supply between them of certain finished dosage form products in the EPD portfolio for a certain period, depending on the product and the facility. The terms of the supply arrangements under the Proposed MSAs will vary from 3 years to 10 years, depending on the products being supplied and the facility from which they are supplied.

As part of the Proposed MSAs, the Parties will also enter into a planning agreement which will set out the best practice and general standard of conduct with regard to implementing the Proposed MSAs, including details on manufacturing campaigns, minimum order quantities and order to supply lead times. As noted above, the Parties also intend to enter into certain other ancillary agreements relating to transitional services and shared intellectual property.

4 Other competition authorities being notified

The Proposed Transaction is an international transaction that has been, or will be, notified to the competition agencies in a number of jurisdictions.

The Parties have notified the competition agencies in Europe, Canada, Japan, Australia, United States, Brazil and India of the Proposed Transaction. Merger filings were made in Japan,[9] the United States and Brazil on 8 August 2014, in India on 12 August 2014, in Canada on 13 August 2014 and in Australia on 7 October 2014. A filing will also be made in Europe.[10] The Proposed Transaction received clearance in Brazil on 2 September 2014. The applicable waiting period under the United States HSR Process expired without the issuance of a second request on 8 September, and the Canadian Competition Bureau issued a no action letter on 22 September 2014.

Part B INDUSTRY BACKGROUND

5 The pharmaceutical industry

5.1 Pharmaceuticals in New Zealand

The pharmaceutical industry in New Zealand is a highly regulated industry, comprised of companies that research, develop, manufacture and distribute originator or innovator medicines as well as generic medicines. Originator or innovator pharmaceuticals are those that are generally initially protected by patent.[11] There is also an increasing number of companies that manufacture and distribute generic medicines, which are identical bioequivalent versions of off-patent innovator products.

Generic companies, like Mylan NZ, differ from originator companies, like Abbott NZ, in that they do not research, develop and manufacture originator pharmaceutical products (although Mylan does conduct "proprietary" R&D as well), but instead focus on the production and supply of generic (bioequivalent) versions of originator pharmaceuticals

[9] We note that the JFTC requested that the parties refile in order to give them time to evaluate additional information requested post-filing. The parties have now refiled their submission with the JFTC.

[10] The first draft of the Finished Dosage Products chapter of the Form CO has been submitted to the European Commission.

[11] In New Zealand, patents grant exclusive rights over a new discovery, including pharmaceutical products, for a maximum term of 20 years.

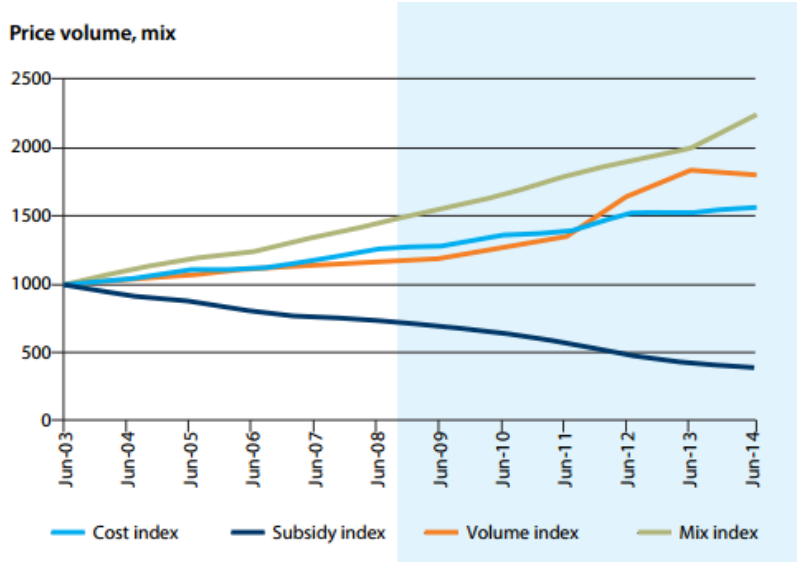
once the patent over those pharmaceuticals expires. Generic companies may also challenge the validity of patents.

Pharmaceutical products are generally divided into two categories: prescription and OTC. Most prescription pharmaceuticals in New Zealand are subsidised by the New Zealand Government. Prescription-only pharmaceuticals can be supplied by retail pharmacies only to persons holding a prescription from an authorised medical practitioner. On the other hand, many OTC pharmaceuticals can be sold directly to customers without the need for a prescription by retail pharmacies, supermarkets and some consumer goods stores. Some OTC pharmaceuticals are classified as "pharmacy only", requiring them to be sold only by retailers holding a pharmacist's license. Most OTC products in New Zealand are not subsidised.

In FY2013, the total combined pharmaceutical expenditure in New Zealand was NZ$783.6 million.[12]

The pharmaceutical industry in New Zealand has grown substantially, with increasing numbers of medicines coming off patent, consolidation and growth of multinational companies and the increasing sophistication of pharmaceutical regulation. The price, volume and mix of medicines over the past 10 years have grown as follows:[13]

Figure 3: PHARMAC analysis of price, volume and mix of medicines in New Zealand



It is an industry that is both dynamic and highly competitive for the reasons described in more detail below.

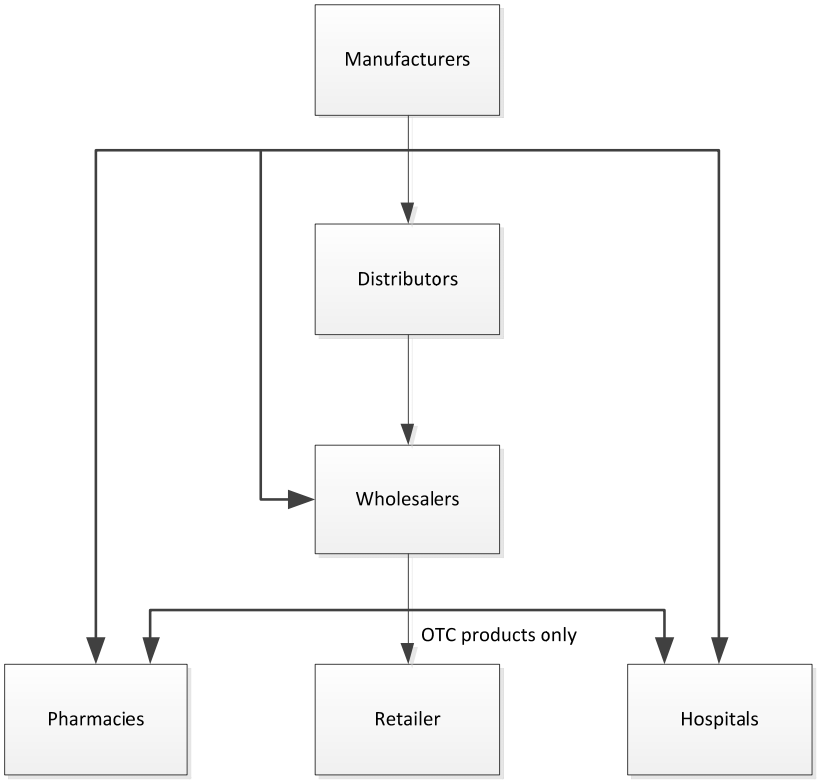
5.2 Industry participants

(a) *Overview*

The pharmaceutical supply chain in New Zealand operates as follows.

[12] PHARMAC, *Annual Review 2013*, p3.
[13] PHARMAC, *Annual Review 2013*, p3.

Figure 4: Industry overview



(b) *Manufacturers*

Global pharmaceutical groups have a strong presence in New Zealand. In the past, many global pharmaceutical companies manufactured products in New Zealand. However, only Douglas Pharmaceuticals and API Consumer Health currently have manufacturing plants in the country. No active pharmaceutical ingredients (**APIs**) are manufactured in New Zealand – APIs are imported and converted into a finished form that can be easily given to a patient.[14]

A large number of global pharmaceutical companies supply their products in New Zealand, either through distributors, wholesalers or directly to hospitals. In addition to Douglas Pharmaceuticals and API Consumer Health, global pharmaceutical companies that supply innovator/branded pharmaceutical products in New Zealand include Pfizer, AstraZeneca, Sanofi-Aventis, Bayer AG, Roche Holding AG, GlaxoSmithKline plc, Novartis AG, H. and Merck & Co.

In addition, a wide range of suppliers of generic pharmaceuticals operate in New Zealand including the following: Mylan, Aspen Pharmacare, Apotex Pty Ltd, Actavis, AFT Pharmaceuticals, API Consumer Brands, Douglas Pharmaceuticals, Dr. Reddy's NZ, Hospira, Multichem Laboratories, Perrigo and Rex Medical.

Across all product areas where the Parties overlap, there are a large number of well-resourced, multinational competitors that currently supply in New Zealand or regularly compete for tenders to supply in New Zealand, as well as strong global competitors that

[14] http://nzic.org.nz/ChemProcesses/biotech/12F.pdf

could enter New Zealand. These entities will continue to exert a strong competitive constraint on New Mylan. There are many leading generic companies that compete strongly against Mylan, as well as many significant branded companies that compete against Mylan and other generic manufacturers, which often supply both the originator brand in addition to a cloned generic. Branded companies can also elect to cross-licence the clone to a generic company to market and enhance the product lifecycle through to its maturity stage.

Attachment C provides a more extensive list and description of the competitors globally and in New Zealand.

(c) *Pharmaceutical distributors*

Pharmaceutical distributors provide an interface between manufacturers and wholesalers. Unlike wholesalers, distributors merely provide logistical services, rather than purchase and resell products, as is the case with wholesalers. Some pharmaceutical companies will provide their own distribution services, such as Douglas Pharmaceuticals. Others will rely on a distribution specialist, such as EBOS Group. Distribution services are readily available through companies such as Health Care Logistics, Pharmaco and DHL.

(d) *Pharmaceutical wholesalers*

Pharmaceutical wholesalers are involved in the procurement, distribution and sale of a range of pharmaceutical and medicinal products including prescription medicines, pharmacy-only medicines, OTC medicines and other healthcare products. Pharmaceutical wholesalers obtain products from upstream manufacturers, either directly or via a distributor, and sell those products to OTC retailers, pharmacies and hospitals.

The leading pharmaceutical wholesaler in New Zealand is the EBOS Group. It is also the leading pharmaceutical distributor to hospitals.[15] Other significant companies providing wholesale services include ProPharma (owned by EBOS), CDC Pharmaceuticals, Pharmacy Wholesalers BOP, Pharmacy Wholesalers Central and Onelink.

(i) Mylan's New Zealand distribution arrangements

[ ] These are the major pharmaceutical wholesalers in New Zealand and account for approximately **[ ]** of Mylan NZ's sales. The remaining **[ ]** is split across hundreds of retail pharmacies and a selection of hospital and general practitioners, each of which account for less than **[ ]** of Mylan's NZ sales.

(ii) Abbott EPD-DM's New Zealand distribution arrangements

Abbott EPD-DM currently supplies **[ ]** in New Zealand.

(e) *Pharmacies*

As at June 2014, the number of practising pharmacists in New Zealand was 3,406.[16] According to the Pharmacy Council of New Zealand, there are over 900 community

[15] http://www.ebosgroup.com/company-profile.php

[16] http://www.pharmacycouncil.org.nz/cms_show_download.php?id=491

pharmacies.[17] Despite declining numbers in recent years, community pharmacies remain an essential aspect of the pharmaceutical industry, dispensing a large number of the 50 million plus prescriptions dispensed each year in New Zealand.[18]

(f) *Hospitals*

Hospitals source the majority of their pharmaceuticals direct from pharmaceutical companies, or from specialist logistics companies, such as Onelink, EBOS' hospital division. Some hospitals purchase smaller quantities of pharmaceuticals from pharmaceutical wholesalers. **[**

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(g) *Other retailers*

Supermarkets and other retailers may provide OTC medicine in New Zealand. In relation to a number of common therapeutic good such as paracetamol and ibuprofen, this channel to market is very important. Retailers often have their own private label products for these common and popular drugs.

5.3 Overview of the regulatory environment

The New Zealand pharmaceutical industry is closely regulated by a number of agencies, schemes and guidelines. The various regulatory bodies include:

- the Ministry of Health, including the regulatory team, Medicines Control, that oversees the local distribution of medicines and controlled drugs within New Zealand;
- the New Zealand Medicines and Medical Devices Safety Authority (Medsafe), which is responsible for the regulation of medicines and medical devices in New Zealand, ensuring that they are acceptably safe for supply and use;
- District Health Boards, which are responsible for providing or funding the provision of health services in their district; and
- the Pharmaceutical Management Agency (**PHARMAC**), which is the New Zealand Crown agency that decides, on behalf of the District Health Boards, which medicines and related products will be subsidised for use in the community and public hospitals.

5.4 Initial approval - regulation on supply and marketing

Before a new medicine can be advertised, sold or distributed in New Zealand, the approval of the Minister of Health must be obtained under the *Medicines Act 1981*.[19]

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[17] http://www.pharmacycouncil.org.nz/yourpharmacist

[18] http://www.pharmacycouncil.org.nz/yourpharmacist

Medsafe operates as a business unit within the Ministry of Health, and is responsible for administering most aspects of the *Medicines Act 1981* and associated regulations, including the approval of new and/or changed medicines, approval of clinical trials of new medicines, classification of medicines and surveillance and monitoring of the industry. In order to advertise, sell or distribute a medicine in New Zealand, an application must be made to Medsafe including information about how the medicine meets recognised standards for quality, safety and efficacy, following which Medsafe will make a recommendation to the Minister as to whether the medicine is approved or otherwise.[20] Before Medsafe makes a recommendation, it considers the benefits and risks of the medicine to ensure that the safety profile is acceptable.

The distribution chain of medicines and controlled drugs in New Zealand is also regulated, with licenses for supply by pharmacies, wholesalers, hawkers (entities that act as a kind of travelling salesperson, "hawking" medicines to wholesale purchasers or pharmacies) and retailers being required to be obtained from Medicines Control, a team within the Ministry of Health.[21]

Post-marketing approval, Medsafe also undertakes surveillance of marketed medicines (for example, by monitoring adverse reactions in New Zealand).

5.5 Funding of medicines in New Zealand

The District Health Boards hold the funding for most health services provided by the Government, including the Community Pharmaceutical Budget, and are responsible for providing these services in their particular district.[22] There are 20 District Health Boards in New Zealand.[23] While District Health Boards hold the funds to purchase medicines, PHARMAC manages the spending on medicines on their behalf.

PHARMAC was created in 1993 in response to increasing medicines prices in New Zealand during the 1980s, with the aim of actively managing Government spending on medicines.[24] PHARMAC's objective was to *"introduce price competition to a market where it had not previously existed"*.[25]

PHARMAC's role within the New Zealand medicines system is to negotiate prices for community pharmaceutical medicines, set subsidy levels and conditions, and ensure spending stays within budgets. These Government-subsidised community medicines are managed through the Pharmaceutical Schedule. PHARMAC has negotiated prices and other supply terms also for certain hospital medicines on behalf of District Health Boards since 2011, and since 2010, has had an expanded role to assess and negotiate

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[19] Ministry of Health, *Medicines Act 1981*, http://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-act-1981.

[20] Medsafe, *Medsafe's Evaluation and Approval Process,* http://www.medsafe.govt.nz/consumers/Safety-of-Medicines/Medsafe-Evaluation-Process.asp.

[21] Ministry of Health, *Medicines Act 1981*, http://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-act-1981.

[22] Services funded include primary care, hospital services, public health services, aged care services and services provided by other non-government health providers included Maori and Pacific providers.

[23] Ministry of Health, *District Health Boards*, http://www.health.govt.nz/new-zealand-health-system/key-health-sector-organisations-and-people/district-health-boards.

[24] PHARMAC, *Information Sheet: Introduction to PHARMAC*, http://www.pharmac.health.nz/assets/infosheet-01-intro-2013.pdf.

[25] PHARMAC, *Information Sheet: PHARMAC's history*, http://www.pharmac.health.nz/assets/infosheet-02-history-2013.pdf .

nationwide supply terms for all hospital medicines, to avoid "postcode prescribing" (where medicines are funded in some District Health Board areas but not others).[26]

5.6 The Pharmaceutical Schedule

The New Zealand Pharmaceutical Schedule is a list of the approximately 2,000 medicines and therapeutic products subsidised by the New Zealand Government. As noted above, PHARMAC manages the Pharmaceutical Schedule, including determining which products to list, negotiating the prices and setting the subsidy levels for those products on the list.

(a) *The listing process*

Pharmaceutical suppliers, health professionals and consumer groups may apply to PHARMAC to have a medicine listed on the Pharmaceutical Schedule for subsidy. In determining the listing of medicines, PHARMAC is principally advised by the Pharmacology and Therapeutics Advisory Committee (**PTAC**) as well as specialist subcommittees.[27]

Decisions as to which medicines should be funded are determined according to clinical, economic and commercial considerations. These criteria include the availability and substitutability of existing medicines, the budgetary impact of any changes to the Pharmaceutical Schedule and direct cost to health service users.[28]

Following evaluation of an application for funding, the PTAC can make a recommendation as to whether to fund the medicine and what priority level it should be given by PHARMAC. A proposal regarding the application is produced by PTAC to the PHARMAC board, which then accepts the proposal, in which case the health sector is notified and the Pharmaceutical Schedule is updated.

(b) *Pharmaceutical pricing*

PHARMAC determines subsidy levels and negotiates prices for those medicines that appear on the Pharmaceutical Schedule. In order to maximise the amount of medicines that New Zealand can subsidize, PHARMAC encourages competition between pharmaceutical companies and applies a range of pricing strategies, from reference pricing, to tendering to multi-product agreements.

Reference pricing

In setting subsidy levels, PHARMAC may apply its policy of reference pricing, which is where pharmaceuticals which have the same or similar therapeutic effect are subsidised at the level of the lowest price pharmaceutical in that sub-group. This strategy of reference pricing was one of the first strategies adopted by PHARMAC in achieving lower prices.

Where a supplier sets its price above the reference price subsidy, the medicine is only partly subsidised so that the patient will have to pay the difference. PHARMAC aims to have at least one fully subsidised medicine in each therapeutic subgroup.

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[26] PHARMAC, *Information Sheet: Our place in the medicine system*, http://www.pharmac.health.nz/assets/infosheet-03-our-place-2013.pdf .

[27] PHARMAC, *Information sheet: Making funding decisions*, http://www.pharmac.health.nz/assets/infosheet-04-funding-decisions-2013.pdf .

[28] PHARMAC, *Information sheet: Making funding decisions*, http://www.pharmac.health.nz/assets/infosheet-04-funding-decisions-2013.pdf .

Negotiation, tendering and proposals

PHARMAC has since adopted a number of other purchasing strategies to promote competition:[29]

- **Negotiation** – This normally occurs for the funding and supply of patented medicines, as it can increase the degree of competition between suppliers competing for funding from a fixed budget. This competition allows PHARMAC to balance the monopoly held by companies that supply patented products.

- **Tendering** – This is usually used when medicines are no longer under patent and suppliers are seeking to sell generic versions. This allows for competition for the exclusive supply contract, often between a number of suppliers, which can lead to significant price reductions (in some cases, greater than 90%).[30]

  PHARMAC will issue a tender document to pharmaceutical suppliers, inviting bids for a set list of pharmaceuticals on a molecular basis. The successful bidder is granted sole subsidised supply of the medicine for a fixed term (usually three years), the security of which gives the supplier the maximum incentive to offer the best price. Tenders have been run every year since 1997, are used extensively and apply to nearly half of all subsidised medicines by volume. This dynamic results in the winning company having significant share for the duration of the contract, but by reason of the tender dynamic, may overstate a company's competitive position which quickly may be lost at the next tender.

  PHARMAC regularly awards sole supply tenders, which may be awarded to new suppliers so that the incumbent supplier's market share will move from 100% to 0% whilst the inverse will be true for the new supplier. By way of example, PHARMAC, as part of its 2013/14 tender decision process awarded sole supply of the molecule losartan, an antihypertensive drug, to Actavis. Consequently, Mylan NZ lost the exclusive supply contract and its share of supply for this molecule will change from 100% to 0%.

- **Alternative Commercial Proposals / Multi-product agreements** – PHARMAC uses this strategy to invite suppliers to submit a proposal for the supply of multiple products, which PHARMAC will then consider in determining whether a better outcome might be achieved compared to separate tenders for the products. Pharmaceutical companies can often supply portfolios of products and offer price reductions on older medicines in return for a new medicine being subsidised, which allows PHARMAC to subsidise new medicines that would otherwise not be affordable.

- **Expenditure caps** – Expenditure caps are another strategy employed by PHARMAC in managing spending on pharmaceuticals. In negotiating the purchasing of medicines on behalf of District Health Boards, PHARMAC may negotiate for the inclusion of expenditure caps in pharmaceutical supply contracts. Where annual spending exceeds the agreed cap, the balance (or portion of it) is refunded to the District Health Board. This is an effective way of sharing risk particularly where there is uncertainty and potential risk around the likely uptake of the medicine.

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[29] PHARMAC, *Information Sheet: Purchasing Medicines*, http://www.pharmac.health.nz/assets/infosheet-05-purchasing-medicines-2013.pdf .

[30] PHARMAC, *Information Sheet: Purchasing Medicines*, http://www.pharmac.health.nz/assets/infosheet-05-purchasing-medicines-2013.pdf.

(c) *Subsidisation of medicines and retail pricing*

Once a medicine has been listed on the Pharmaceutical Schedule, there are still a number of limited payments that a consumer may be required to make to purchase the medicine. The price of the medicine payable by a consumer depends on whether the medicine is fully or partially subsidised and the type of health card (if any) held by the consumer.

The regulated supply price paid by the Government for fully subsidised medicines is made up of the following components:[31]

- the manufacturer's / supplier's selling price, which is generally equal to the subsidies the District Health Boards provides for pharmaceuticals listed in the Pharmaceutical Schedule. This subsidy is determined by negotiation between PHARMAC and the manufacturer;
- a margin on PHARMAC's subsidy, which covers stock holding and procurement costs. This margin is paid by the District Health Boards to the retail pharmacy and is a mark-up of the subsidised portion of pharmaceutical costs; and
- a dispensing fee to cover the cost of dispensing the medicine to patients with associated advisory services which is reimbursed to retail pharmacies.

The price for partially subsidised medicines is different only in that the cost of the medicine (i.e. the manufacturers' / supplier's selling price) is determined only in part by negotiations between PHARMAC and the manufacturer, and includes a surcharge or premium borne by the patient, plus a pharmacy mark-up.

As such, the only difference in the regulated supply price for partially subsidised as compared to fully subsidised medicines is the premium on the medicine, which in turn affects the price charged to the customer.[32]

Given the price ex-supplier is determined by the policies of PHARMAC and the reimbursement to the retail pharmacies is set under contract, the only scope available for a wholesaler to affect wholesale price is in terms of its margin, however even this is limited. The wholesale margin is usually derived from a base margin, which is then discounted back for prompt payment, and for the volume of business undertaken.

By contrast, the wholesale pricing of most OTC pharmaceuticals is not subject to these regulatory constraints, but is influenced by competitive forces including the availability of many OTC products from retail pharmacies, supermarkets and department stores.[33]

5.7 Planned harmonisation between New Zealand and Australia

In September 2003, the Government of New Zealand and the Government of Australia signed a Treaty agreeing to establish a joint scheme for the regulation of therapeutic products in New Zealand and Australia. The creation of a joint regulatory scheme across both countries is designed to safeguard public health and safety, while encouraging economic integration and benefitting industry in both countries. Over time, the joint arrangements will be administered by a single regulatory agency, the Australia New

[31] Commerce Commission, *The Pharmacy Guild of New Zealand (Inc) – Draft Determination*, 26 April 2002, [61].
[32] Commerce Commission, *The Pharmacy Guild of New Zealand (Inc) – Draft Determination*, 26 April 2002, [70].
[33] Commerce Commission, Decision No. 417 – *Zuellig Pharma Limited and Sigma NZ Limited*, 2 February 2001, [55]-[56].

Zealand Therapeutic Products Agency (**ANZTPA**), which will absorb the current regulators - New Zealand's Medsafe and Australia's Therapeutic Goods Administration.

The project was suspended in 2007 and then recommenced in June 2011 with the signing of a statement of intent to implement a three-staged approach over a period of up to 5 years to progressively achieve this goal of harmonisation.[34]

The two countries' regulators, Medsafe and TGA, have already begun a program of work-sharing and increased joint operations. This enables the separate regulatory systems of each country to be enhanced by sharing of data and information, training, and establishing centres of expertise in each country. Building on this, a single entry point for the industry will be established and a common trans-Tasman regulatory framework will be agreed. During these two preliminary phases, each country will retain its own regulator and continue to make its own regulatory decisions, but business will be subject to only one set of requirements to operate in two countries. As business operations become increasingly integrated and following a review of progress, the single regulator will be established.

In February 2014, the first harmonisation activity was completed, with harmonisation of paediatric dosages for paracetamol and ibuprofen.[35]

This planned harmonisation will make it easier for competitors currently in Australia to enter New Zealand and vice versa. Competitiveness of the industry is only set to increase as a result.

5.8 Therapeutic categorisation

Drugs can be classified in different ways according to different criteria, such as their mode of action, their indications, or their chemical structure.

There are two main categorisation systems used in drug utilisation research worldwide – The Anatomical Therapeutic classification developed jointly by Pharmaceutical Business Intelligence & Research Group (**PBIRG**) and the European Pharmaceutical Marketing Research Association (**EphMRA**), and the Anatomical Therapeutic Chemical (**ATC**) classification developed by Norwegian researchers and used by the WHO Collaborating Centre for International Drug Monitoring in Sweden.

The EphMRA ATC classification system is a generally adopted method of grouping certain pharmaceutical products used worldwide and adopted by the industry and by IMS Health (**IMS**) for providing market research statistics to the pharmaceutical industry. There are some technical differences between the EphMRA classification and the ATC classification which means that the systems are not directly comparable for some drugs. Despite this, generally, codes should not be substantially different at the third level of classification, given the work on harmonisation of the two systems that has taken place.

Under the EphMRA classification system, there are 16 general categories of drugs which are then broken down into a series of four levels (ATC1 to ATC4). The ATC1 level identifies the anatomical main group. The ATC2 level identifies the therapeutic main group. The ATC3 category then groups drugs by their therapeutic indications, i.e. their intended use. This level can describe a chemical structure, indication or a method of action. The ATC4 level is a further subdivision which may be based on therapeutic, or

[34] http://www.anztpa.org/about/faqs.htm

[35] http://www.anztpa.org/projects/harmonisation-med-safety-pd-paracetamol-ibuprofen.htm

more frequently, pharmacological criteria such as molecule class, formulation or mode of action. This level gives detail about the formulation, chemical description and mode of action.[36]

Additionally, a "plain" product contains one or more active ingredients of a similar type. When another active ingredient is added of a different type, the product becomes a "combination" product. Only the active ingredients are taken into consideration when determining whether a product is a plain product or a combination. Non-therapeutic ingredients are ignored.

Part C COMPETITIVE ASSESSMENT

6 Overview of the competitive landscape

There are a number of competitive dynamics in the pharmaceutical sector that impose significant constraints on the conduct of manufacturers, distributors and retailers. The high degree of government regulation has a particular influence on conduct, and there are several other aspects that would constrain competitors in relation to the pricing of medicines. These factors will continue to provide strong constraints following the Proposed Transaction.

6.1 Existing competitors

There are a large number of strong, existing pharmaceutical competitors in New Zealand, many of which are part of large global pharmaceutical companies, as mentioned above, and as set out in further detail in Attachment C.

The key competitor expansion in New Zealand over the past 5 years has been the growth in supply via third party, contract manufacturers. Suppliers like Intas Pharmaceuticals Ltd and Ipca Laboratories in particular have grown in prominence as well as a range of Indian manufacturers such as Ranbaxy, Wockhardt and Torrent, with multinational domestic suppliers losing business to these fiercely competitive companies.

A wide range of domestic generic companies are increasingly collaborating with third party, contract manufacturers to provide lower cost offers in tenders. For example, Actavis sources nine of its top ten selling medicines from third party suppliers (with eight being sourced from Indian manufacturers). Another leading example is Douglas Pharmaceuticals, with each of its six top selling medicines in New Zealand sourced from overseas manufacturers either as finished products imported into New Zealand or imported in bulk form and repacked in New Zealand.

6.2 Potential competition

(a) *Ease of generic entry*

In order to market a generic product in New Zealand, a pharmaceutical company need only go through an abridged approval process. Originator drugs are authorised and marketed on the basis of a full application dossier which may include chemical, biological,

[36] EphMRA / PBIRG Classification Committee, *Who we are; What we do; 2014*, p 6-7, http://www.ephmra.org/user_uploads/ephmra%202014%20who%20we%20are%20booklet%20final.pdf

pharmaceutical, pharmacological-toxicological and clinical data. The abridged application for generic medicines only requires information on the safety, quality and efficacy of the new medicine. Therefore, where the clinical data provided with the originator product are not protected by patent, Medsafe will accept applications to register generic products without clinical data on the basis of data that demonstrates that the generic and originator products are bioequivalent, or a justification that bioequivalence data is not required.

This means the time to bring a generic drug to market is relatively short, and the cost of entry of a generic product is very low. If a full new medicine application process is undertaken for a generic drug, the process typically takes between 15 and 18 months. However, if a company's dossier has been approved by a recognised health authority (which includes authorities in the EU, Australia and Canada) within the last 3-5 years, the registration process may be reduced to between 9 and 12 months.

(b) *Increase in generic substitution*

There has been a trend over a number of years of integration between different types of manufacturers, with branded companies supplying more generic products and vice versa. This means that all products compete against each other and there is less of a distinction (and price premium) with branded products, and prices for drugs on the whole have been decreasing. However, for a number of manufacturers of innovator drugs, it is hard to compete at this level with the generic companies so they persist in charging a brand price premium in order to capture that small proportion of the market that has brand loyalty to a product. This segment is slowly being eroded with the increase in generic substitution as innovator drugs' patents expire.

The use of generic drugs has been steadily increasing internationally as the result of economic pressure on drug budgets. In New Zealand, generic medicines are widely used and increasingly becoming so. As outlined in section 5.6(b), PHARMAC applies its policy of reference pricing to ensure that pharmaceuticals that have the same or similar therapeutic effect are subsidised at the level of the lowest price pharmaceutical in that sub-group. This is used in conjunction with tenders to ensure that, in most cases, at least one product is fully subsidised in each therapeutic subgroup and that subsidy occurs for the product with the lowest price.

The increasing use of and promotion of generic substitution increases competition between bioequivalent medicines and limits the ability of pharmaceutical manufacturers or sponsors to price their products above the generics.

(c) *Entry possible without local manufacturing facilities*

Many pharmaceutical companies active in New Zealand do not have local manufacturing facilities. A number of the multi-national pharmaceutical companies, including Mylan, have manufacturing facilities in Australia and import products into New Zealand.

Competitors without local manufacturing facilities are able to sell products in New Zealand through distributors. Distribution services are readily available through companies such as Healthcare Logistics, Pharmaco and DHL. These distributors then supply products direct to the customer or to other wholesalers, such as Propharma and CDC (as described above in section 5.2).

Therefore, a new entrant would be easily able to distribute its products through existing wholesalers and distributors provided it is able to satisfy regulatory requirements regarding security of supply.

6.3 Countervailing power of buyers and the effect of government regulation

All pharmaceutical competitors are constrained by the high degree of regulation present in the industry. The role of PHARMAC and the District Health Boards in regulating price through negotiations with pharmaceutical suppliers (as described above in section 5.3) exerts a high level of countervailing power.

(a) *Reference pricing*

The use of reference pricing imposes a ceiling on the level of subsidisation for pharmaceuticals that have the same or similar therapeutic effect. In turn, this severely restricts the ability of companies to place upward pressure on prices for generic pharmaceuticals.

(b) *Tender process*

Furthermore, the purchasing strategies implemented by PHARMAC promote a high level of competition amongst pharmaceutical companies, particularly generic pharmaceutical suppliers. The tendering process, whereby the successful bidder is granted sole subsidised supply of a medicine for a period up to three years, relies on market dynamics to place downward pressure on prices. If a supplier is unsuccessful in their bid, their product will be sold without a subsidy for an extensive period of time. This incentivises each pharmaceutical company participating in the tender process to compete with other participating pharmaceutical companies on price.

For example, in the April 2014 tender announcement for amoxicillin, GlaxoSmithKline reduced the price of its product by 22% to take sole supply from Sandoz, a significant generic competitor, for the next 3 years.

The Proposed Transaction will not substantially alter these dynamics as a number of large global and national pharmaceutical companies will remain active in the bidding process.

(c) *The New Zealand Government effectively acts as a monopsony buyer*

For the majority of pharmaceutical products, listing on the Pharmaceutical Schedule is critical in order to have meaningful sales in New Zealand. Although the Government does not purchase pharmaceuticals itself and therefore is not strictly a monopsony buyer, this is essentially the effect of its subsidisation of the industry.

In many cases, commercial dynamics will be introduced into the process, for example, through the tendering process utilised in most cases of generic pharmaceuticals subsidisation. The tender process creates competitive tension between bidders, however, it is simply a mechanism used to determine which product or products will ultimately be subsidised by the New Zealand Government; the price at which the drug is supplied to the New Zealand Government is constrained not only by the presence of competitors, but by the fact that there is effectively only one buyer in New Zealand.

PHARMAC's role as an effective monopsonist is well recognised both by statute and in a number of cases. PHARMAC's high degree of power is acknowledged by a statutory exemption to Part 2 of the Commerce Act, set out in section 53 of the *New Zealand Public Health* and *Disability Act 2000*, which prevents PHARAMC's pharmaceutical buying practices from amounting to contraventions of the *Commerce Act*.

The Court of Appeal has also discussed PHARMAC's role as a monopsonist in *Astrazeneca Limited v Commerce Commission*:[37]

> *Pharmac determines which pharmaceuticals should be listed, which subsidies are payable for each and negotiates the terms upon which the subsidised pharmaceuticals are supplied. In short, Pharmac has a substantial degree of power in the markets for the supply of subsidised pharmaceuticals in New Zealand. As a monopsonist, Pharmac has the ability to control the entry of different pharmaceuticals onto the pharmaceutical schedule.*

District Health Boards also exercise substantial countervailing power as they purchase a substantial quantity of pharmaceuticals for use in hospitals. Where pharmaceutical products required by public hospitals are not subsidised by PHARMAC, the hospitals will either purchase these at the supplier's list price or at prices negotiated by PHARMAC.

Section H of the Pharmaceutical Schedule includes pharmaceuticals that can be purchased at a national price by District Health Boards for use in hospitals. These are known as National Contract Pharmaceuticals.

7 Relevant markets

7.1 Introduction

Mylan is active in the supply of a variety of generic, branded generic and specialty pharmaceutical products. Abbott EPD-DM is active in the supply of innovator, specialty and branded generic products. Their businesses are largely complementary. The addition of Abbott EPD-DM to Mylan's existing pharmaceutical portfolio will add complementary generics and branded business and access to a range of non-US markets in which Mylan currently does not focus.

7.2 Market definition overview

(a) *The Commerce Commission's approach in previous decisions*

The Commerce Commission, in line with the European Commission (**EC**), has consistently applied the ATC classification system (used by EphMRA and IMS)[38] as a starting point for market definition,[39] with a focus on therapeutic purpose, requiring a broader or narrower market definition depending on the particular context.[40] The Commerce Commission has indicated that it may be necessary to analyse pharmaceutical products at a broader, narrower or mixed level of ATC classification in order to arrive at an accurate assessment of the product market definition depending upon the particular circumstances of the pharmaceuticals and the conditions requiring treatment. For example, a mixed level of ATC classifications may be appropriate where certain products from different ATC classes are substitutes for the treatment of specific illness or disease.

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[37] [2008] NZCA 479, paragraph 19.

[38] We note that there is also a World Health Organisation (**WHO**) version of the ATC classification that differs slightly of the EphMRA version. See further section 5.8 above.

[39] See for example, COMP/M.2922 – Pfizer/Pharmica, [15].

[40] First adopted in Decision No. 398, *Glaxo Wellcome Plc and SmithKline Beecham Plc*, 1 September 2000, [48]-[52], subsequently followed in many decisions including for example, Decision No. 621, *Schering-Plough Corporation and Organon Biosciences N.V.*, 4 October 2007, [94]-[97], and Decision No. 692, *Novartis AG and Alcon Inc*, 6 May 2010, [15].

The Commerce Commission has previously considered OTC and prescription pharmaceuticals as falling within the same market on the basis that there are no distinguishing characteristics in terms of wholesaling[41] but more recently considered them to fall within different markets on the basis that there are some differentiating characteristics, being:

- severity – prescription medicines generally treat more severe conditions;
- clinical risk – prescription medicines generally have a higher clinical risk (eg contraindications, side effects); and
- regulation – prescription medicines are significantly more highly regulated than OTC products.[42]

The Parties consider that, irrespective of the scope of the relevant market, OTC and prescription drugs for the same therapeutic purpose provide a strong competitive constraint on each other.

(b) *The Parties' approach*

In line with the Commerce Commission's approach, the Parties have defined the relevant market by reference to therapeutic purpose, having regard to the relevant treatment profile, mechanism of action and a range of other factors.

Finally, as is consistent with the Commerce Commission's previous approach, the Parties have considered the national market is the relevant geographic market, but have considered the effect of potential global entry in their analysis.

7.3 Specific product overlaps between the Parties

The Parties' overlap in New Zealand in relation to the supply of a number of products to New Zealand customers, as set out below in Table 1.

Table 1: Overlap between the Parties (by volume and value (USD), MAT to December 2013; IMS data)

Product category	Total market value (USD)	Mylan (% based on volume)	Abbott EPD-DM (% based on volume)	Combined share (% based on volume)	Mylan (% based on value)	Abbott EPD-DM (% based on value)	Combined share (% based on value)
Alimentary Tract and Metabolism							
OTC Laxatives (A6A)	[						

[41] Decision No. 417, *Zuellig Pharma Limited and Sigma NZ Limited*, 2 February 2001, [64]-[65].

[42] Decision No. 594, *Johnson & Johnson and Pfizer Consumer Health Care*, 8 December 2006, applied again most recently in December No 692, *Novartis AG and Alcon Inc*, 6 May 2010, [20].

Product category	Total market value (USD)	Mylan (% based on volume)	Abbott EPD-DM (% based on volume)	Combined share (% based on volume)	Mylan (% based on value)	Abbott EPD-DM (% based on value)	Combined share (% based on value)
Cardiovascular drugs							
Antiarrhythmics (C1B)							
Antihypertensives[43]							
General systemic anti-infectives							
Macrolides (J1F)							
Musculo-skeletal system							
Non-steroidal anti-rheumatics (M1A)							]

As can be seen based on the 2013 data presented, in most of the product categories, the increase in Mylan's share resulting from the Proposed Transaction is insignificant.

Each of these relevant markets is described further below.

8 OTC Laxatives

Laxatives may be grouped by mechanism of action. For example, saline cathartics (such as magnesium hydroxide, epsom salts and others) act by attracting and holding water in the intestinal lumen. Stimulant and irritant laxatives (such as castor oil and Dulcolax, containing the molecule Bisacodyl) increase the peristaltic movement in the intestine. Bulk-producing laxatives (such as psyllium-based products like Metamucil and methylcellulose) act to increase the volume of the stool, and both softens the stool and stimulates intestinal motility. Colace (containing the molecule docusate), the only representative example in this type of stool softener class, holds water within the fecal mass, providing a larger, softer stool. Emollient laxatives, like mineral oil, act by retarding intestinal absorption of fecal water, thereby softening the stool. Hyperosmotic laxatives (like glycerine and lactulose) act by holding water within the intestine, and may also increase the peristaltic action of the intestine.

Laxatives may also differ in use based on whether they are safe for use while pregnant, and depending on the symptoms, severity and issue being treated.

[43] This includes a range of antihypertensives which fall in the following ATC3 classes: C2A, C8A, C9A, C9B, C9C and C9D.

Given the high demand side substitutability, the Parties consider that there is a national market for the manufacture and supply of all laxatives in the ATC3 category A6A. Most laxatives in New Zealand are sold OTC, but some may be prescription. As the Parties provide OTC products only (which includes pharmacy only products), prescription laxatives have been excluded from the market definition and competitive effects considerations below, but without reaching any conclusion as to whether the market should include both OTC and prescription drugs.

8.1 The Parties' products

(a) *Mylan*

Mylan supplies the product, Konsyl, a natural psyllium fibre supplement, which increases the bulk and amount of water in the stool, making it softer and easier to pass. It is an OTC product sold in powdered form, and available from a range of retailers and pharmacies.

(b) *Abbott EPD-DM*

Abbott EPD-DM supplies the product Duphalac, the originator brand based on the lactulose molecule, in New Zealand. Duphalac is an OTC osmotic laxative used in the treatment of constipation. It works as a hydrating agent, drawing more water into the intestine.

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8.2 Overlap in relation to laxatives sold OTC

Table 2 sets out the Parties' shares and the shares of their competitors in respect of all laxatives sold OTC by volume and by value, respectively.

Table 2 Share of supply of OTC laxatives (A6A) by volume and value (USD), MAT to Dec 2013; IMS data

Supplier	Products (molecule)	Total volume	Share (vol)	Total value	Share (value)
Abbott EPD-DM	**Duphalac** (lactulose)	**[**			
Mylan	**Konsyl** (plantago ovata)^				
New Mylan					
Aspen	**Coloxyl** (docusate)***** **Coloxyl C Senna; Laxsol** (docusate / sennosides A&B)*****				
Douglas[44]	**Laevolac** (lactulose)^				
Norgine	**Movicol** (macrogol) **Normacol** (foeniculum volgare / frangula alnus / plantago psyllium / phamnus				

[44] Douglas also previously supplied Clin Fibrecare (containing vegetable fibre) up to 2010 and Mucilax (containing plantago psyllium) up to 2012, but currently does not supply either product.

Supplier	Products (molecule)	Total volume	Share (vol)	Total value	Share (value)
	catharticus / senns / sterculia gum)°				
Procter & Gamble	**Metamucil** (plantago ovata)				
Reckitt Benckiser	**Senokot** (sennosides A&B)°				
AFT Pharmaceutical	**AFT Lax-Sachets** (macrogols / potassium / sodium) ^ **AFT Lax-Tabs** (bisacodyl)* **AFT Micolette** (citric acid / laurylsulfonic acid / sorbitol)^				
Red Seal	**Nuclense** (foeniculum volgare / ilex paraguariensis / rhamnus catharticus / senna / sennosides A&B)				
Actavis	**Arrow-Lacdol** (lactulose) **Arrow-Laxofast** (docusate) ^				
Vital Food Proces	**Phloe** (actinida chinensis)				
Good Health	**MG Lax** (aloe barbadensis / ascorbic acid / foeniculum vulgare / magnesium / potassium / pyridoxine / sodium)				
API	**Glycerol** (glycerol)^				
Johnson & Johnson	**Microlax** (citric acid / dodecyl sulfoacetic acid)				
Blackmores	**Peritone Herb Laxative** (alow africana / elettaria cardomommum / mentha piperita / phamnus purshiana / zingiber officinale)				
Novartis	**Benefiber** (dextrin, guar gum)				
Fleet[45]	**Fleet Mineral Oil** (paraffin oil) **Fleet Phosphate** (phosphoric acid)*				
Orchard Manuf	**Nu-Lax** (purgative / laxative)				
Go Healthy NZ	**G/H Kiwi-Lax** (actinidia chinensis)				
Biomed (NZ)	**Biomed Carboxymeth** (carmellose)				

[45] Fleet also previously supplied Fleet Bisacodyl (containing bisacodyl) up to 2010, but currently does not supply this product.

Supplier	Products (molecule)	Total volume	Share (vol)	Total value	Share (value)
Health World	**E/N Laxeze** (mentha piperita / phamnus paliurus / rumex crispus / taraxacum officinale / zingiber officinale)				
Perrigo	**Sorbitol** (sorbitol)				]

º indicates partial subsidy

** indicates full subsidy*

^ indicates sole supply

As the above shows, the Proposed Transaction will result in a very small increase in Mylan's share – only **[ ]** by volume and **[ ]** by value – and falls below the Commerce Commission's concentration indicators.[46] The market is highly fragmented and New Mylan will continue to be constrained by a large number of multinational companies. In particular, Aspen and Douglas will maintain a strong position in the market each having greater than **[ ]** by volume and **[ ]** by revenue in the market. AFT Pharmaceuticals, Norgine, and Proctor & Gamble will continue to provide vigorous competition with their respective products.

Furthermore, as the IMS data only captures sales made through the pharmacy channel, it does not reflect the sale of OTC products through the supermarket and other retailer channel. Therefore, it is likely to significantly under-represent the share of, and competitive constraint provided by, OTC products that are not pharmacy only, including Coloxyl, Movicol and Metamucil, among others.

In any case, as an OTC category of products, the market is highly fragmented and competitive. Any increase in price, reduction in supply or innovation would rapidly be rejected by the large range of alternatives. Therefore the Proposed Transaction will not result in any substantial lessening of competition.

9 Antiarrhythmics

Antiarrhythmics are drugs which are used to suppress abnormal rhythms of the heart and include all products recommended for use in arrhythmia, disorders of cardiac rhythm and tachycardia.

There are many antiarrhythmic agents that have multiple modes of action for the treatment of the same indication. As such, there is significant therapeutic interchangeability between them and it is difficult to further classify antiarrhythmic agents into separate product markets.

The ATC classification system does not in fact contain any ATC4 levels for anti-arrhythmics for this reason.

All classes of antiarrhythmics are indicated for the treatment of cardiac dysrhythmias, and as such, the ATC3 category C1B has been considered as the relevant market in which the Parties overlap.

[46] Commerce Commission, *Mergers and Acquisitions Guidelines*, July 2013, [3.51].

9.1 The Parties' products

Mylan and Abbott EPD-DM supply different types of antiarrhythmics.

(a) *Mylan*

Mylan supplies the product Aratac, which contains amiodarone, indicated in the treatment of both acute life-threatening arrhythmias as well as chronic suppression of arrhythmias.[47]

(b) *Abbott EPD-DM*

Abbott EPD-DM alternatively supplies the product Rytmonom, containing propafenone. Propafenone is a type of anti-arrhythmic that works by slowing the influx of sodium ions into the cardiac muscle cells, causing a decrease in excitability of the cells.

9.2 Overlaps between the Parties

Table 3 below sets out the shares and products of the Parties and each of their competitors based on volume and by revenue.

Table 3 Share of supply of antiarrhythmics (C1B) by volume and value (USD), MAT to Dec 2013; IMS data

Supplier	Products (molecule)	Volume	Share (volume)	Value	Share (value)
Abbott EPD-DM	**Rhytmonorm** (propafenone)	**[**			
Mylan	**Aratac** (amiodarone)*****				
New Mylan					
Valeant Pharma	**Tambocor** (flecainide)*****				
Sanofi	**Adenocor** (adenosine) **Cordarone X** (amiodarone)**^**[48] **Rythmodan** (disopyramide)*****[49]				
Integria Healthcare	**T/S Garlic Perles** (allium sativum)				
Link Pharmaceutics	**Mexiletine** (mexiletine)*****				

[47] **[**

]

[48] Only for injections; * for tabs.

[49] Only for 150mg cap; º for 100 mg caps.

Supplier	Products (molecule)	Volume	Share (volume)	Value	Share (value)
Bristol-Myers SQB	**Pronestyl** (procainamide)				]

º indicates partial subsidy

** indicates full subsidy*

^ indicates sole supply

As the above share data shows, the Parties' share following the Proposed Transaction will be small, with a *de minimis* increase in share – only **[ ]** by volume and **[ ]** by value. Abbott's sales of Rhythmonorm are small and in fact **[**

] In any case, there will be other significant multinational companies with significant shares which will continue to constrain New Mylan. In particular, Valeant Pharma will remain the market leader with a significant share (**[ ]** by volume and **[ ]** by value), followed by Sanofi, with three anti-arrhythmic products (one of which has sole subsidised supply on the PHARMAC schedule) and a substantial share of the market (**[ ]** by volume and **[ ]** by revenue). These shares are also below the Commerce Commission's concentration indicators.

Therefore, the Proposed Transaction is unlikely to raise any competition concerns in relation to the supply of antiarrhythmic products in New Zealand.

10 Antihypertensives

10.1 Overview

Antihypertensives are drugs used to treat high blood pressure and the complications of such an indication, including stroke and myocardial infarction. Hypertension treatments act to lower blood pressure and do so by different means. The most widely used types of antihypertensives include Angiotensin Converting Enzyme inhibitors (**ACE inhibitors**), calcium antagonists, beta blockers, angiotensin II receptor antagonists and other plain, centrally acting antihypertensives (for example, thiazide diuretics). Some of the mechanisms of action differ in these classes of drugs, as well as in side effect profiles and cost.

There have been several studies and much discussion about the type of medication to use initially for hypertension that has resulted in various guidelines in different countries being produced. For example, the UK's National Institute for Health and Care Excellence (NICE) recommends ACE inhibitors or low-cost angiotensin II receptor blockers as first line treatments for most people under 55 years old,[50] whereas in the US, the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure recommends first line treatment of a thiazide diuretic if another medication is not indicated.[51] In New Zealand, the current guidelines indicate that the conventional antihypertensive medications used (thiazide diuretics, beta-blockers, ACE inhibitors or A2 receptor blockers and calcium channel blockers) have similar efficacy in lowering blood

[50] NICE, *Hypertension: Clinical management of primarily hypertension in adults (NICE clinical guideline 127)*, Issued: August 2011, http://www.nice.org.uk/guidance/cg127/resources/guidance-hypertension-pdf (accessed 31 July 2014).

[51] National Heart, Lung and Blood Institute, *Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure*, 2004, http://www.ncbi.nlm.nih.gov/books/NBK9630/ (accessed 31 July 2014)

pressure, with beta blockers being reserved for those with specific indications or when the other three main classes have proved inadequate in achieving blood pressure control.[52] Despite the differences in approach, what is clear is that there is high demand side substitutability between a range of major hypertension treatments.

Given this, the Parties consider that this market should include all antihypertensives.[53]

Irrespective of the precise scope of the market definition, there is no substantial lessening of competition as a result of the Proposed Transaction as is set out in more detail below.

10.2 The Parties' products

Mylan and Abbott EPD-DM supply a range of antihypertensives as follows:

Type	Mylan's products (molecule)	Abbott EPD-DM's products (molecule)
Plain antihypertensives	**Prodopa** (methyldopa)	N/A
Calcium antagonists	**Felo** (felodipine) **Adefin** (nifedipine) **Verpamil** (verapamil)	**Isoptin** (verapamil)
ACE inhibitors	**Zapril** (cilazapril) **Acetec** (enalapril)	**Gopten** (trandolapril)
Angioten II Antagonists	**Candestar** (candesartan cilexetil) **Lostaar** (losartan)	N/A

As this table shows, the Parties both supply a range of hypertensive products, and both supply calcium antagonist products with the active ingredient verapamil. Verapamil is also a calcium channel blocker derived from phylalkylamine. It modulates the influx of ionic calcium across the cell membrane of arterial smooth muscle, as well as in myocardial cells, and exerts antihypertensive effects by decreasing systemic vascular resistance. Verapamil is also used in the treatment of angina, as it dilates the main coronary arteries and coronary arterioles, is indicated for the control of tachyarrhythmia and is a potent inhibitor of coronary arterial spasm. There are two types of verapamil products sold in New Zealand – immediate release (being the most conventional oral drug products formulated to release the active drug after oral administration) and modified release (products that have altered timing and/or rate of release of the drug, for example through particular coatings).

[52] Ministry of Health, *New Zealand Primary Care Handbook 2012*, pg 37, http://www.heartfoundation.org.nz/uploads/nz-primary-care-handbook-2012(2).pdf.

[53] This includes all antihypertensives in the category C2A (plain antihypertensives), C8A (calcium antagonists), C9A (plain ACE inhibitors), C9B (combination ACE inhibitors), C9C (plain angiotension II antagonists) and C9D (combination angiotensin II antagonists)

10.3 Overlap in relation to antihypertensives

Table 4 below sets out the shares of the Parties and their competitors by volume and by revenue.

Table 4 Share of supply of antihypertensives by volume and value (USD), MAT to Dec 2013; IMS data

Supplier	Products (molecule)	Total volume	Share (volume)	Total value	Share (value)
Abbott EPD-DM	**Gopten** (trandolapril)**º** **Isoptin** (verapamil)*****	**[**			
Mylan	**Prodopa** (methyldopa)***** **Felo** (felodipine) **Adefin** (nifedipine)***** **Verpamil** (verapamil)***** **Zapril** (cilazapril)**^** **Acetec** (enalapril)***** **Candestar** (candesartan cilexetil)**^** **Lostaar** (losartan)*****				
New Mylan					
Apotex[54]	**APO-Amlodipine** (amlodipine)***** **APO-Catopril** (catopril) **APO-Cilazapril/Hyd** (cilazapril / hydrochlorothiazide)**^** [55] **APO-Diltiazem** (diltiazem)***** **APO-Doxazosin** (doxazosin)***** **APO-Perindopril** (perindopril)***** **APO-Prazo** (prazosin)*****				
Actavis	**Arrow Enalapril** (enalapril) **Arrow Lisinopril** (lisinopril)**^** **Arrow-Losartan** (losartan / hydrochlorothiazide)***** **Arrow-Nifedipine** (nifedipine)***** **Arrow-Quinapril** (quinapril)**^** **Arrow-Terazosin** (terazosin)**^**				
Astrazeneca	**Atacand** (candesartan cilexetil)				

[54] Apotex also previously sold APO-Terazosin (containing the active ingredient terazosin) up to 2012 in New Zealand, but no longer sells this product.

[55] But * for BSF APO-Cilazapril/Hydrochlorothiazide.

Supplier	Products (molecule)	Total volume	Share (volume)	Total value	Share (value)
	Plendil ER (felodipine)^				
Roche	**Inhibace** (cilazapril) **Inhibace Plus** (cilazapril / hydrochlorothiazide)				
Pfizer	**Accupril** (quinapril) **Accuretic** (quinaparil / hydrochlorothiazide)^ **Loniten** (minoxidil)* **Norvasc** (amlodipine)				
Multichem	**Ethics Enalapril; M-Enalapril** (enalapril)* **M-Captopril** (captopril)				
Mercury Pharma	**Clonidine** (clonidine)^				
Douglas	**Calvasc** (amlodipine) **Dilzem** (diltiazem)^ **Nyefax** (nifedipine)* [56]				
Boehringer Ingelheim	**Catapres; Catapres TTS** (clonidine)^				
Merck & Co	**Renitic** (enalapril) **Co-Renitec** (enalapril / hydrochlorothiazide) **Cozaar** (losartan) **Hyzaar** (losartan / hydrochlorothiazide)*				
Sanofi	**Cardizem CD** (diltiazem)* **Karvea** (irbesartan) **Karveide** (irbesartan / hydrochlorothiazide)				
Bayer	**Adalat** (nifedipine)* [57]				
Aspen	**Captoten** (captopril) **Pexsig** (perhexiline)*				
Novartis	**Dynacirc** (isradipine)* [58]				
Servier	**Coversyl** (perindopril)º				
AFT Pharmaceutical	**AFT Apresoline** (hydralazine)*				
Hospira	**Diazoxide** (diazoxide) **Sodi Nitroprusside** (nitroprusside)				

[56] Only for Nyefax Retard.
[57] But º for Adelat Oros.
[58] Only for Dynacirc-SRO.

Supplier	Products (molecule)	Total volume	Share (volume)	Total value	Share (value)
Link Pharmaceutics	**Hydralazine** (hydralazine)*****				**]**

º indicates partial subsidy

** indicates full subsidy*

^ indicates sole supply

As the share data above shows, New Mylan's increase in share as a result of the Proposed Transaction will be *de minimis* – only **[ ]** by volume and **[ ]** by revenue, and there will be no change to competitive dynamics or market structure in relation to supply of antihypertensives after the Proposed Transaction. The market is highly fragmented, and there are numerous other strong multinational companies which will continue to constrain New Mylan post-Transaction. In particular, Apotex, Actavis and Astrazeneca will be very strong competitors with **[ ]**, **[ ]** and **[ ]** share by volume respectively.

Further, the antihypertensives market in New Zealand is one that has experienced increasing penetration of generic drugs. This is evident in the fact that Actavis' share, for example, has grown dramatically from **[ ]** in 2010 to **[ ]** in 2013 (by volume). This has corresponded with the decline in shares of innovator companies, like Abbott, whose share has continued to decrease from **[ ]** in 2010 to **[ ]** in 2013.

As noted above, the Parties' only overlapping hypertensives are in relation to products containing verapamil. Abbott EPD-DM and Mylan are the only two companies who have maintained their registrations in this category and have done so since 2006. Other companies, for example, Douglas Pharmaceuticals, Knoll Australia Pty Limited, Sanofi-Aventis, Hexal New Zealand Pty Limited (which ceased trading in 2006), Novartis New Zealand and Origen Pharmaceuticals, previously supplied products containing verapamil but have ceased to do so at this time. However, a company could seek to reactivate its registration to commence resupply in New Zealand. This would involve the submission of a new medicine application with Medsafe and provided no additional scientific data is required to support the application, the process is likely to take between 15 and 18 months.

Verapamil is in any case an old medicine of this class and is substitutable for other, newer, forms of antihypertensives, for example, felodipine and quinapril, that are currently supplied in New Zealand by large pharmaceutical companies including Astrazeneca, Actavis and Pfizer (as evidenced by falling sales and market share).

PHARMAC's tender process with respect to the granting of sole supplier status will also impact Mylan's share in the short-term. Mylan is currently a fully subsidised supplier of plain losartan products via its Lostaar product. However, following PHARMAC's recent tender decision with respect to the molecule, from November 2014, Actavis will be the sole supplier with its Arrow-Losartan product. On the other hand, Mylan will have sole supply for its nifedipine product Adefin, taking over from Actavis from July 2014.

In light of these factors and the competitive dynamics of the market as described in section 6 above, the Proposed Transaction therefore does not give rise to any competition concerns.

11 Macrolide antibiotics

11.1 Overview

Macrolides are a class of safe and well tolerable antibiotics which are used in the treatment of infections. Macrolides are commonly used for a range of indications, including lower and upper respiratory tract infections, infections of skin and soft tissue, severe acne, and certain sexually transmitted diseases. In New Zealand, there are a range of different macrolides available including clindamycin, azithromycin, roxithromycin, erythromycin, clarithromycin, clindamycin and lincomycin. There are also other macrolides which are available globally, but not yet available in New Zealand, for example, dirithromycin and telithromycin.

All macrolides operate in a very similar manner. Azithromycin, clarithromycin and roxithromycin are semi-synthetic macrolides which have a very similar structure to erythromycin, the first macrolide, with minor modifications in structure which result in better gastrointestinal tolerability and tissue penetration, as well as a decreased risk of interaction with other drugs and an increased half-life. The newer macrolides also have advantages over erythromycin in dosing regimen, requiring less frequent ingestion.

We note that the European Commission has considered that the most appropriate market definition is at the ATC3 level of all macrolides, because the class was sufficiently homogenous, having both respiratory and dental indications and being promoted amongst both GPs and dentists.[59]

In line with the Commerce Commission's approach to market definition, the Parties consider the relevant market to be at the ATC3 level of all macrolides. Therapeutic interchangeability is clear between the molecules as indicated below:

Table 5 Macrolide molecules indication matrix

	Upper respiratory infections	Lower respiratory infections	Skin and structure infections	Uncomplicated urethritis and/or cervicitis	Serious infections
Azithromycin	✓	✓	✓	✓	✗
Roxithromycin	✓	✓	✓	✓	✗
Clarithromycin	✗	✓	✓	✗	✗
Erythromycin	✓	✓	✓	✓	✗
Clindamycin	✓	✓	✓	✗	✓

[59] Case No COMP/M.2922 – Pfizer / Pharmica, at [52]; Case No IV/M.1378 – Hoeschst / Rhone-Poulenc, at [17].

	Upper respiratory infections	Lower respiratory infections	Skin and structure infections	Uncomplicated urethritis and/or cervicitis	Serious infections
Lincomycin	✓	✓	✓	✘	✓

11.2 The Parties' products

(a) *Mylan*

Mylan supplies one generic macrolide in New Zealand:

- E-Mycin (erythromycin) – indicated for treatment of mild to moderately severe upper and lower respiratory tract infections, and skin and skin structure infections. Clinical studies have also shown erithromycin to be effective in treating non-gonococcal urethritis.

Mylan previously supplied Klamycin (clarithromycin). However, upon losing the tender for this product, Mylan ceased supply.

(b) *Abbott EPD-DM*

Abbott EPD-DM supplies the following macrolides in New Zealand:

- ERA Erythrocin (erithromycin) – indicated for the same treatments as described for E-Mycin above.
- Klacid (clarithromycin) – Klacid is the originator brand and is indicated for respiratory tract infections, skin and skin structure infections, and disseminated or localized mycobacterial infections.

11.3 Overlap between the Parties

The table below sets out the shares of the Parties and their competitors in relation to supply of macrolides on both a volume and a value basis.

Table 6: Shares of supply of all macrolides by volume and value (USD), MAT to Dec 2013; IMS data

Supplier	Products (molecule)	Total volume	Share (volume)	Total value	Share (value)
Abbot EPD-DM	**Klacid** (clarithromycin)***** **ERA Erythrocin** (erythromycin)***** [60]	**[**			
Mylan	**E-Mycin** (erythromycin)*****				
New Mylan					

[60] Only for Erythrocin IV, º if ERA.

Supplier	Products (molecule)	Total volume	Share (volume)	Total value	Share (value)
Actavis	**Arrow-Roxithromycin** (roxithromycin)**^** **Arrow-Azithromycin** (azithromycin)				
ABM Pharma Ltd	**Clindamycin ABM** (clindamycin)**^**				
Apotex	**APO-Clarithromycin** (clarithromycin)***** **APO- Azithromycin** (azithromycin)**^**				
Baxter International	**Clindamycin** (clindamycin) **Clindamycin Plus** (clindamycin)				
AFT Pharmaceutical	**AFT ERA** (erythromycin)**º**				
Pfizer	**Dalacin-C** (clindamycin)**^** **Zithromax** (azithromycin)***** **Lincocin** (lincocin)				**]**

º indicates partial subsidy

** indicates full subsidy*

^ indicates sole supply

The table above shows that whilst Mylan has the largest share of the macrolide market, Abbott EPD-DM's share is very small, both on a value basis and especially on a volume basis. Furthermore, over the past four years, Abbott EPD-DM's share has steadily decreased from **[ ]** in 2010 to **[ ]** in 2013 on a volume basis and **[ ]** in 2010 to **[ ]** now on a value basis. This is in line with the increasing growth of generics and the usual trend of brand erosion that occurs with originator drugs after they come off patent. As such, the increase in New Mylan's share following the Proposed Transaction will be very small and there will be no change in the competitive dynamics in any relevant market for the supply of macrolides.

A number of large pharmaceutical manufacturers such as Apotex, Actavis, ABM Pharma and Pfizer will remain in the market after the Proposed Transaction and will provide vigorous competition to New Mylan.

The absence of patent protection and the increasing genericisation is also indicative of low barriers to entry in this market. This was exemplified by the entry of Apotex into the New Zealand macrolide market with its clarithromycin products in 2011 and its azithromycin product in 2012. Its growth from no presence to over a **[ ]** share (volume basis) and over a **[ ]** share (value basis) in under 3 years is indicative of low barriers to entry and the constraints that will continue to exist with respect to New Mylan after the Proposed Transaction.

International developments also suggest that competitive constraints will remain in the market after the Proposed Transaction. In Australia, there have been a number of recent

registrations of clarithromycin products on the Australian Register of Therapeutic Goods. These include Mythrine (sponsored by Eris Pharmaceuticals[61]) in November 2012, Clarant (sponsored by Actavis) in June 2012 and Clarithromycin AN (sponsored by Amneal Pharma Australia) also in June 2012. Particularly with the planned harmonisation between the regulatory regimes, the ease of entry into New Zealand of these products provides further competitive constraint.

Moreover, further developments in other macrolides that provide additional alternatives to clarithromycin, include also:

- Solithromycin (developed by Cempra) is the next-generation oral and intravenous fluorketolide, which is now in Phase II clinical trials.[62] It has particularly been successful against most macrolide-resistant strains.

- There have been recent developments in a subclass of macrolides called bicyclolides, developed by Enanta Pharmaceuticals[63] which have shown to possess a significantly improved target product profile to existing macrolides. Phase 1 clinical trials are planned to start in 2014.

There are many other antibiotics that have recently been FDA approved for the same indications as clarithromycin and macrolides more generally:

- Dalvance (dalbavancin), manufactured by Durata Therapeutics, was approved by the FDA in May 2014.[64] It is used in the treatment of acute bacterial skin and skin structure infections (**ABSSSI**).

- Sivextro (tedizolid phosphate), manufactured by Cubist Pharmaceuticals, received FDA approval in June 2014.[65] It is also indicated for the treatment of ABSSSI.

- Teflaro (ceftarolone fosamil), manufactured by Actavis/Forest Laboratories, which is indicated for the treatment of community-acquired bacterial pneumonia and for ABSSSI. It received FDA approval in October 2010.[66]

Finally, as has been detailed above, government regulation and subsidisation of the pharmaceutical industry will continue to impact upon the competitive dynamics of the pharmaceutical industry and prevent New Mylan from attempting to increase prices in the macrolide market.

Irrespective of how the market is defined, the Proposed Transaction will therefore not be likely to substantially lessen competition in relation to macrolides.

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[61] An Australian private pharmaceutical company located in Melbourne and founded in 2009, with a business strategy of aggressive penetrated in targeted markets

[62] Sempra, *Solithromycin*, http://www.cempra.com/products/Solithromycin-cem-101/.

[63] Enanta Pharmaceuticals, *Antibiotics*, http://www.enanta.com/research/antibiotics/.

[64] Durata Therapeutics, *FDA approves Durata Therapeutics' DALVANCE™ for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible gram-positive bacteria, including MRSA, in adults*, 23 May 2014 http://www.duratatherapeutics.com/news-media/press-releases/detail/774/fda-approves-durata-therapeutics-dalvancetm-for-the .

[65] Cubist Pharmaceuticals, *Sivestro™ (Tedizolid phosphate)*, http://www.cubist.com/products/sivextro (accessed 31 July 2014).

[66] Forest Laboratories, *Forest announces FDA approval of Teflaro™ (ceftaroline fosamil) for the treatment of community-acquired bacterial pneumonia and acute bacterial skin and skin structure infection,*29 October 2010, http://investor.frx.com/press-release/product-news/forest-announces-fda-approval-teflaro-ceftaroline-fosamil-treatment-commu.

12 Non-steroidal anti-rheumatics

Non-steroidal anti-rheumatic drugs are anti-inflammatory drugs used primarily for the treatment of a range of arthritis, including rheumatoid arthritis. Rheumatoid arthritis is an auto-immune disease that affects the joints and surrounding tissues.

Non-steroidal anti-rheumatics inhibit the generation of prostaglandins by blocking cyclooxygenase enzymes. Prostaglandins are mediators of inflammation and pain but also have important roles in maintenance of normal body functions including protection from stomach acid, maintenance of kidney blood flow, and contributing to platelet stickiness and vascular function.[67]

Non-steroidal anti-rheumatics have a short onset of action and mild to moderate analgesic properties independent of their anti-inflammatory effect. These drugs alone, unlike disease modifying anti-rheumatic drugs, do not change the course of the disease of rheumatoid arthritis or prevent joint destruction.

Non-steroidal anti-rheumatics are based on a range of different molecules: diclofenac, ibuprofen, naproxen, meloxicam, tenoxicam, ketoprofen, sulindac, tiaprofenic acid, indometacin and piroxicam.

12.1 The Parties' products

(a) *Mylan*

Mylan supplies the following non-steroidal anti-rheumatics in New Zealand:[68]

- Noflam (naproxen) – Noflam is an anti-inflammatory drug with analgesic action used to treat a range of types of arthritis, acute gout, acute musculoskeletal disorders and post-operative pain.
- Aclin (sulindac) – Aclin provides prompt symptomatic relief of inflammation, pain and tenderness, and promotes early restoration of joint mobility. It is used to treat a range of types of arthritis, acute gout, acute musculoskeletal disorders and low back pain.

(b) *Abbott EPD-DM*

Abbott EPD-DM only supplies Brufen (ibuprofen) in New Zealand. It is an anti-inflammatory drug with analgesic and antipyretic activities used to treat a range of types of arthritis, pyrexia and acute/chronic pain states in which there is an inflammatory component. Brufen is the originator drug, but is no longer patent protected.

12.2 Overlap between the Parties

The table below sets out the shares of the Parties and their competitors in relation to supply of prescription non-steroidal anti-rheumatics on both a volume and a value basis.

[67] http://www.hopkinsarthritis.org/arthritis-info/rheumatoid-arthritis/ra-treatment/.
[68] [

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Table 7: Shares of supply of prescription non-steroidal anti-rheumatics by volume and value (USD), MAT to Dec 2013; IMS data

Supplier	Products (molecule)	Total volume	Share (volume)	Total value	Share (value)
Abbott EPD-DM	**Brufen** (ibuprofen)* [69]	[			
Mylan	**Noflam** (naproxen)^ **Aclin** (sulindac)*				
New Mylan					
Actavis	**Arrowcare Ibuprof** (ibuprofen)* **Arrow-Meloxicam** (meloxicam)*				
Douglas	**Diclax** (diclofenac)^ [70] **Melorex** (meloxicam)				
Apotex	**APO-DICLO** (diclofenac)^				
Roche	**Naprosyn** (naproxen)* [71] **Synflex** (naproxen)				
Valeant Pharma	**Tilcotil** (tenoxicam)*				
Novartis	**Voltaren** (diclofenac)* [72]				
Sanofi	**Oruvail** (tetoprofen)* **Surgam** (tiaprofenic acid)				
Boehringer Ingelheim	**Mobic** (meloxicam)				
Astrazeneca	**Vimovo** (naproxen/esomeprazole)				
Rex Medical Ltd	**Meloxicam** (meloxicam)				]

º indicates partial subsidy

** indicates full subsidy*

^ indicates sole supply

[69] Only for Brufen SR; º for other Brufen products.

[70] Only for Diclax SR.

[71] Only for Naprosyn SR.

[72] But º for Voltaren D.

The table above indicates that the Parties' shares are low on a volume basis (Abbott EPD-DM **[ ]**, Mylan **[ ]**, New Mylan **[ ]**). On a value basis, Abbott EPD-DM's Brufen product has a **[ ]** share of the market whilst Mylan has a **[ ]**, resulting in a New Mylan share of **[ ]** on a value basis.

On a volume basis, Actavis has the highest share with over **[ ]** of the market. Douglas, with almost **[ ]** share will also enjoy a larger share than New Mylan. Apotex, a large global generic pharmaceutical manufacturer will have over **[ ]** share and a number of other large global pharmaceutical companies will continue to operate in the market, including Roche, Valeant Pharma, Astrazeneca, Sanofi and Novartis.

Whilst New Mylan's share on a value basis will be larger than its share on a volume basis (accounted for by the brand premium associated with the fact that Brufen is the originator drug), the non-steroidal anti-rheumatics market will remain highly fragmented after the Proposed Transaction. Both Douglas and Actavis will have a significant share of the market (**[ ]** and **[ ]** respectively) and Roche, Novartis and Valeant Pharma will all have shares greater than **[ ]**). Astrazeneca and Sanofi will remain in the market, albeit with small shares.

Abbott EPD-DM's current share of only **[ ]** is reflective of the fact that they have recently been awarded the tender from PHARMAC for their Brufen product. Prior to the tender, Abbott's sales were approximately a third of their current value. This shows the significance of PHARMAC's tendering decisions and their impact on the market, particularly a market like this where there are such a large number of other suppliers with viable prescription non-steroidal anti-rheumatics products as described above.

Furthermore, the shares above are based only on prescription drugs, in accordance with previous decisions by the NZCC. However, OTC non-steroidal anti-rheumatics will continue to impose a competitive restraint on prescription-only non-steroidal anti-rheumatics. In particular, Novartis' Voltaren Rapid products, which are available OTC, are popular products that sell in large quantities. In 2013, almost 8 million Voltaren Rapid standard units were sold OTC. Voltaren Rapid is used for the short-term treatment of pain and inflammation. 25mg dosage strengths are available on a restricted basis OTC in blister packs containing between 10 and 30 capsules. On the other hand, the enteric coated tablet Voltaren product that is prescription only is used to treat chronic or long-term pain and inflammation associated with degenerative forms of rheumatism. The prescription only product also has a dosage strength of 25mg and is available in 50 and 100 tablet plastic bottles. Whilst the products are not exact equivalents, the dosage strength and similarity of indications that they treat suggests a degree of interchangeability. This means that Voltaren Rapid products and other OTC non-steroidal anti-rheumatics such as Multichem's Sonaflem will continue to act as a constraint on the market after the Proposed Transaction.

In addition to OTC non-steroidal anti-rheumatics, non-narcotic analgesics such as Nurofen, Panadol and Advil will constrain New Mylan after the Proposed Transaction. Non-narcotic analgesics are class of drugs used to relieve mild to moderate pain and inflammation. Many products in the non-narcotic analgesics category are based on the active pharmaceutical ingredient ibuprofen, the same active pharmaceutical ingredient that Brufen and a number of other non-steroidal anti-rheumatics are based on.

Given the high degree of constraint, both potential and actual, that will continue, the Proposed Transaction therefore does not give rise to any competition concerns.

13 Abbott's minority interest in New Mylan will not give rise to coordinated effects

As outlined in section 3 above, under the Proposed Transaction, the Abbott Shareholders will execute a shareholder agreement that will limit their capacity to influence the actions taken by New Mylan. In particular, for so long as the total shareholding of the Abbott Shareholders is greater than 5%, they must vote only in accordance with the recommendations of the New Mylan board of directors (with the exception of certain decisions that relate to a merger/takeover involving New Mylan or the sale of all or substantially all of New Mylan's assets). Abbott Shareholders are expressly precluded from nominating directors to the Board of New Mylan. Additionally, the shareholder agreement imposes strict confidentiality obligations on New Mylan and the Abbott Shareholders with respect to each party's confidential information. Additionally, as stated in section 3.1, Abbott does not expect to be a long term shareholder of New Mylan and plans ultimately to sell the shares it obtains under the Proposed Transaction. [73]

The limitations on the Abbott Shareholders and the confidentiality obligations in the shareholder agreement have the effect of preventing any chance of co-ordinated effects between New Mylan and Abbott after the Proposed Transaction.

14 Conclusion

For the reasons set out in this submission, the Proposed Transaction will not have the effect or likely effect of substantially lessening competition in any relevant market in breach of the *Commerce Act 1986*. In particular, in each case where there is an overlap between the Parties, New Mylan will continue to be constrained by a range of forces:

(a) **OTC laxatives**: The Proposed Transaction will result in a *de minimis* increase in share on both a volume and a value basis and falls below the Commerce Commission's concentration indicators. In any event, the Parties' products will continue to be constrained by a large number of multinational companies, including Aspen, Douglas, Norgine, AFT Pharmaceuticals, and Proctor & Gamble. New Mylan will continue to operate within a highly fragmented and competitive market.

(b) **Antiarrhythmics**: The Proposed Transaction will result in a *de minimis* increase in share on both a volume and a value basis and falls below the Commerce Commission's concentration indicators. In any event, the Parties' products will continue to be constrained by a large number of multinational companies, including Valeant Pharma and Sanofi within a highly fragmented and competitive market.

(c) **Antihypertensives**: The Proposed Transaction will result in a *de minimis* increase in share on both a volume and a value basis and there will be no change to competitive dynamics in relation to supply of antihypertensives after the Proposed Transaction. In any case, the market is highly fragmented and the Parties' products will continue to be constrained by a large number of multinational companies, including Apotex, Actavis and Astrazeneca.

(d) **Macrolides**: The Proposed Transaction will result in a *de minimis* increase on a volume basis (0.72%) and a small increase on a value basis (6.14%). There will be no change in the competitive dynamics in any relevant market for the supply of

[73] http://abbott.mediaroom.com/2014-07-14-Abbott-to-Sell-its-Developed-Markets-Branded-Generics-Pharmaceuticals-Business-to-Mylan.

macrolides and a number of large pharmaceutical manufacturers such as Apotex, Actavis, ABM Pharma and Pfizer will remain in the market after the Proposed Transaction.

(e) **Non-steroidal anti-rheumatics**: Actavis and Douglas will maintain a strong position in the market whilst a wide range of global pharmaceutical companies including Roche, Valeant Pharma, Astrazeneca, Sanofi and Novartis will continue to operate in the market. Additionally, OTC products such as Voltaren Rapid will continue to impose a competitive constraint on prescription only products.

In addition to the elements particular to each market outlined above, New Mylan will continue to be constrained by the following dynamics that operate across the entire pharmaceutical industry in New Zealand:

- there are a large number of strong pharmaceutical companies in the market, many of which are part of large global organisations;
- the abridged approval process for bringing a generic product to market means the time taken to bring a generic drug to market is short and the cost of entry of a generic product is very low;
- there has been a trend over a number of years of integration between types of manufacturers with branded companies supplying more generic products and vice versa;
- the prevalence of distribution services in New Zealand means that entry is possible without local manufacturing facilities; and
- all pharmaceutical competitors are constrained by the high degree of regulation present in the industry with the role performed by PHARMAC and the District Health Boards exerting a high level of countervailing power.

Part D Further information, confidentiality and declaration

15 Contact details

15.1 Parties' annual reports

A copy of Mylan Inc's 2013 10K SEC filing is found here. A copy of Mylan NZ's Annual Financial Report for the year ended 31 December 2013 is included as Attachment E.

A copy of Abbott's 2013 10K SEC filing is found here. A copy of Abbott NZ's Annual Financial Report for the year ended 31 December 2013 is included as Attachment F

15.2 Parties' main competitors

Name of company (legal and trading names)	Contact details	Relevant contact person
Mylan's main competitors		
Actavis	P.O Box 128244 Remuera , Auckland 1541 +64 9 6304488	Ron Van der Pluijm
AFT Pharmaceuticals	P.O. Box 33-203 Takapuna, Auckland 0740 +64 94880232	Hartley Atkinson
Douglas Pharmaceuticals	P.O. Box 45027, Auckland, 0651 + 64 98350660	Jeffery Douglas
Apotex	Private Bag 102995 North Shore City, Auckland 0745 +64 9 4442073	Colin Roberston
Hospira	C/o Hospira Australia + 61 3 87445200	Mark Crotty
Rex Medical	67 L Elizabeth Knox Place Auckland +64 95746060	John Hernon
Aspen Pharmacare	C/o Health Care Logistics +64 9 9185100	Wayne Smith

Name of company (legal and trading names)	Contact details	Relevant contact person
API Consumer Brands	P.O. Box 76401 Manukau City , Auckland + 64 9 2797979	Mitch Cuevas
Multichem Laboratories	Private bag 93527, Takupuna, Auckland 0740 +64 9 4880330	Clay Jones
Dr Reddys NZ	Level 6, AMI Building, 63 Albert Street, Auckland 1142 +64 9 3567000	Sheryl Williams
Abbott's main competitors		
AFT Pharmaceutical	P.O. Box 33-203 Takapuna, Auckland 0740 +64 9 4880232	Unknown
Apotex	Private Bag 102995 North Shore City, Auckland 0745 +64 9 4442073	Unknown
Actavis	P.O Box 128244 Remuera , Auckland 1541 +64 9 6304488	Unknown
AstraZeneca	15 Hopetoun Street Freemans Bay Auckland +64 9 3065650	Unknown
Douglas Pharmaceuticals	P.O. Box 45027, Auckland, 0651 + 64 98350660	Unknown
Inova Pharma	Valeant Australia Level 3, Suite 3.05 120 Bay Street Port Melbourne Victoria 3007 Australia	Unknown

Name of company (legal and trading names)	Contact details	Relevant contact person
	+61 3 96961800	
Novartis	Building G 5 Orbit Drive Rosedale Private Bag 65904 +64 9 3618100	Unknown
Pfizer	Level 1, Suite 1.4 Building B 8 Nugent Street Grafton Auckland 1023 +64 9 3543065	Unknown
Sanofi—Aventis	Part Level 8 56 Cawley Street Ellerslie Auckland + 64 9 5801810	Unknown

Note: Abbott does not have contact details for its competitors.

15.3 Trade associations

Mylan NZ is a member of the New Zealand Self Medication Industry Association (NZSMI).

Abbott NZ is not currently a member of and does not currently participate in any trade or industry associations in New Zealand.

15.4 Parties' key customers

(a) *Mylan*

Wholesaler Group	Wholesaler Branch	Address	Telephone	Revenue earned in last financial year (NZD)
[				

Wholesaler Group	Wholesaler Branch	Address	Telephone	Revenue earned in last financial year (NZD)
				]

(b) *Abbott EPD -DM*

Wholesaler	Address	Telephone	Revenue earned in last financial year (NZD)
[			]

16 Confidentiality

Confidentiality is not sought for the fact of the Proposed Transaction.

Confidentiality is sought in respect of all items indicated in bold and square brackets, and deleted from the public copy of this Notice (**confidential information**).

In respect of this confidential information, confidentiality is claimed under section 9(2)(b)(ii) of the *Official Information Act 1982*, on the grounds that the information is commercially sensitive and valuable information which is confidential to the participants, and disclosure of it is likely to give an unfair advantage to competitors of the participants and/or unreasonably prejudice the commercial position of the persons involved.

The Parties request that they be notified of any request made to the NZCC under the *Official Information Act* for release of their own confidential information, and that the NZCC seeks their views as to whether the information remains confidential and commercially sensitive at the time responses to such requests are being considered.

Attachment A Declaration

I, Lloyd Price have prepared, or supervised the preparation of this notice seeking clearance.

To the best of my knowledge, I confirm that:

(a) all information specified by the Commission has been supplied;

(b) if information has not been supplied, reasons have been included as to why the information has not been supplied;

(c) all information known to me that is relevant to the consideration of this notice has been supplied; and

(d) 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.

It 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.

Name and title of person authorised to sign:

Lloyd Price
Managing Director, Mylan New Zealand Limited

Signature:

Date: 8/10/14

Attachment B Transaction documents

[Confidential - provided separately.]

Attachment C Competitor profiles

Supplier	Description
Global and local pharmaceutical companies operating in New Zealand	
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 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. It also offers treatments for diseases including Multiple Sclerosis, Parkinson's, and Alzheimer's disease. AbbVie's pharmaceutical products are available to patients in more than 170 countries worldwide. Abbvie operates in New Zealand, though the date of commencement of operations is not clear. AbbVie Limited, (New Zealand) operates as a subsidiary of AbbVie Inc.
Actavis	**Actavis PLC** is an Irish-based global pharmaceutical manufacturer which makes true generic, branded generic, branded & over-the-counter drugs. Principally Actavis focuses on diseases affecting 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 through operations in more than 60 countries. Actavis' North American branded pharmaceutical business is an industry leader in women's health, maintaining a more than 90 percent share of voice in oral contraceptives based on IMS Audits. Additionally, with the acquisition of Warner Chilcott in October 2013, Actavis significantly bolstered its Urology business and established a platform for continued expansion into the gastroenterology and dermatology therapeutic categories. Actavis is a global, integrated specialty pharmaceutical company that supplies New Zealand through its subsidiary Actavis New Zealand Limited.
AFT pharmaceuticals Working to improve your health	**AFT Pharmaceuticals Pty Ltd** is a privately-owned pharmaceutical company with operations in both Australia and New Zealand. Its product offering includes moisturizers, calcium supplements, scalp ointments, eye drops, cracked heel creams, emulsifying ointments, iron and folic acid tablets, stomach ache and pain treatment products, constipation relief tablets, cold and flu relief tablets, sinus relief products, and persistent pain relief tablets; hayfever, urticaria (hives), and allergic rhinitis relief liquids; and replacement liquid solutions for iron deficiency and iron deficiency anemia. The company also offers fever and pain relief liquids for infants and children; aged care, wound care, and baby care products; eye ointments; and skin care products. In addition, it specializes in sourcing niche prescription pharmaceuticals; and engages in drug development activities, including clinical trials. The company serves pharmacies and hospitals in Australia, New Zealand and internationally. It was founded in 1997 and has additional offices in Malaysia and Singapore. It distributes pharmaceuticals for a number of overseas principals with a sales force visiting pharmacies and hospitals in both Australia and New Zealand. It began operations in New Zealand in 1998.
ALLERGAN Our pursuit. Life's potential.®	**Allergan, Inc.** is an American multinational pharmaceutical company focused on discovering, developing and commercialising innovative pharmaceuticals, biologics and medical devices in the areas of eye care, medical aesthetics, dermatology, neurosciences and urology. With the acquisition of Inamed Corporation in 2006, Allergan added breast aesthetics and dermal fillers to its business portfolio to create a medical-

Supplier	Description
	aesthetics franchise. Allergan has a presence in more than 100 countries. It operates in New Zealand through its subsidiary Allergan New Zealand Limited which commenced operations in 1981.
	**Apotex Inc.** is a Canadian-owned pharmaceutical company which develops, manufactures and distributes more than 260 generic pharmaceuticals in approximately 4000 dosages. The Apotex Pharmaceutical Group of Companies also researches, develops, manufactures and distributes fine chemicals, non-prescription and private label medicines, and disposable plastics for medical use. Research on new chemical entities is carried out by ApoPharma Inc., a subsidiary of Apotex, where its current focus is in the areas of hematology, neurodegenerative diseases and psoriasis. Apotex's first innovative drug, Ferriprox™, is approved in over 50 countries for treating iron overload in Thalassemia. Apotex has been servicing the New Zealand market through its subsidiary Apotex NZ Ltd since 1992. It aims to use their vertically integrated global company to provide high quality, low cost generic medicines to New Zealand.
	**Aspen Pharmacare Holdings Limited** is a South African-based supplier of branded and generic pharmaceuticals in more than 150 countries and of consumer and nutritional products in selected territories. Aspen is a leading generics manufacturer in the Southern hemisphere and is Africa's largest pharmaceutical manufacturer. Aspen has production capabilities for a wide variety of product types including tablets, capsules, eye drops, injectable products (including lyophilized vials), oral contraceptives, form-filled seals, suppositories, liquids, creams, ointments, infant nutritional products, and specialist active pharmaceutical ingredients. It operates in New Zealand through its subsidiary, Aspen Pharmacare Australia (established in 2001), which distributes products into the New Zealand market through its distributer Healthcare Logistics Auckland. Through this chain, Aspen Pharmacare Australia provides the New Zealand market branded prescriptions, generics and over-the-counter pharmaceuticals.
	**AstraZeneca PLC** is a British-Swedish multinational pharmaceutical company formed through the merger of Astra AB of Sweden and Zeneca Group PLC of the UK that spans 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. It primarily focuses on the manufacture of branded drugs targeted at cardiovascular and metabolic disease, oncology, respiratory, inflammation and autoimmunity, infection, neuroscience and gastrointestinal disease areas. Its research focus areas include cancer, cardiovascular/metabolic disease and respiratory, inflammatory and autoimmune disease. On 4 August 2014, it was announced that AstraZeneca would acquire Almirall, bolstering its respiratory portfolio. See Almirall profile below. It operates in New Zealand through its subsidiary AstraZeneca Limited.
	**Aurobindo Pharma Limited** is an Indian multinational pharmaceutical company that manufactures generic pharmaceutical drugs in therapeutic segments such as neurosciences, cardiovascular, anti-retrovirals, anti-diabetics, gastroenterology and cephalosporins. It has a product portfolio of over 300 formulations in various dosage forms and strengths and over 160 APIs(active pharmaceutical ingredients) including treatments for life-style diseases, anti-retrovirals (ARVs), anti-infectives and pain management with paediatric products and technologies. Its marketing partners include Pfizer and AstraZeneca. Its New Zealand subsidiary, Aurobindo Pharma NZ Ltd, manufactures products stocked by wholesalers.
	**Baxter International Inc**. is an American multinational company that, through its subsidiaries, develops, manufactures and markets drugs targeting haemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. It has expertise in medical devices, pharmaceuticals and biotechnology. It was responsible for the first commercially manufactured intravenous (IV) solutions, the first commercial kidney dialysis system and the first factor VIII concentrate to treat haemophilia. Baxter New Zealand

Supplier	Description
	commenced operations in 1960.
	**Bayer AG** is a German-based international, research-based group with major businesses in health care, nutrition and high-tech polymer materials. Its pharmaceutical and medical products arm, Bayer HealthCare, researches, develops, manufactures and markets branded prescription medicines relating to diseases in areas such as cardiology, oncology, ophthalmology, women's healthcare, diabetes, infections as well as over-the-counter multivitamins, energy supplements, pain relief and dermatological products. Its carries business in the markets for diagnostic imaging and animal health. Bayer commenced operations in New Zealand over 85 years ago.
	**Biomed Limited** is a manufacturer of a range of pharmaceutical products. The company was incorporated as Mcgow Biomed Ltd in 1995 and changed its name to Biomed Ltd in October 1999. The company is based in Auckland, New Zealand. Biomed Ltd is a former subsidiary of Health Support Ltd.
	**Boehringer Ingelheim Group** is one of the world's 20 leading pharmaceutical companies, headquartered in Germany and operating globally with 143 affiliates and more than 47,400 employees. It was founded in 1885 and has since been involved in the research, development, manufacturing and marketing of novel medications of high therapeutic value human and veterinary medicines. Boehringer's product portfolio includes medicines treating chronic obstructive pulmonary disease, diabetes, HIV/AIDS, hypertension, myocardial infarction, oncology, Parkinson's disease, restless legs syndrome, stroke prevention and venous thromboembolism. In New Zealand, Boeringher operates through a wholly owned subsidiary Boeringher (NZ) Ltd through its three divisions; prescription medicines, consumer health care and animal health.
	**Bristol-Myers Squibb** is an American multinational biopharmaceutical company that discovers, develops and markets medicines in areas such as oncology, virology, immunology, cardiovascular and diabetes. In February 2014, Bristol-Myers Squibb sold its global diabetes business to AstraZeneca (profiled above). The transaction included the rights to Bristol-Myers Squibb's global diabetes business that was part of its collaboration with AstraZeneca, the former Amylin manufacturing facility in West Chester, Ohio, and also covers the future purchase by AstraZeneca of Bristol-Myers Squibb's Mount Vernon, Indiana, manufacturing facility approximately 18 months following the close of the deal. It has operated in New Zealand as Bristol-Myers Squibb (NZ) Limited since being established in 1957.
	**Celltrion** is a Korea-based multinational company that researches, develops and manufactures biologics, specialising in the production of biosimilar antibody therapeutics and new biopharmaceuticals. It is known especially for its product RESIMA™ which is the world's first true biosimilar monoclonal antibody equivalent in terms of quality, safety, and efficacy to previously-licensed infliximab and approved by the European Medicines Agency for the treatment of rheumatoid arthritis, adult Crohn's disease, pediatric Crohn's disease, ulcerative colitis, pediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and psoriasis. It began distribution in New Zealand following a deal with Hospira (profiled below) in 2009.

Supplier	Description
	**Chugai Pharmaceutical Co Ltd** is a Japanese multinational biopharmaceutical company that manufactures and sells drugs targeted at therapeutic areas such as oncology, renal diseases, and bone and joint diseases. It is a subsidiary of Hoffman-La Roche (Roche Holding AG profiled below). Since forming a strategic alliance with Roche, Chugai Pharmaceutical has constructed a network related to exploratory research into low-molecular-weight drugs. It also conducts research studies on drugs with private and public medical research institutions. Chugai supplies various drugs into the New Zealand market such as Actemra .
	**Cipla Ltd** is an Indian global pharmaceutical company that manufactures generic prescription drugs, over-the-counter, personal care and veterinary products. Its key therapeutic areas include cardiovascular, children's health, dermatology and cosmetology, diabetes, HIV/AIDS, infectious diseases, malaria, neurosciences, oncology, ophthalmology, osteoporosis, respiratory, urology and women's health. It exports to and maintains partnerships/alliances for product development, technical support and marketing with over 170 countries, including New Zealand. It commenced its New Zealand operations in 2011 upon acquiring Meditab Specialities New Zealand Ltd.
	**Colocap Pharmaceuticals** is a health and lifestyle company focused on providing safe and effective solutions to common gastro-intestinal problems. Their Colocap Balance™ product is a revolutionary approach to the management of constipation. Colocap products are distributed across both Australian and New Zealand markets.
	**Douglas Pharmaceuticals** is a New Zealand based pharmaceuticals company involved across the industry in both the research and development and manufacturing areas. Douglas Manufacturing 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). The company has been manufacturing and distributing prescription medicines since its establishment in 1967.
	**Doxcon Pharmaceuticals Ltd** is a privately owned company based in West Auckland in New Zealand. Its product lines include mineral and herbal supplements, health products, vitamins as well as specialist products for market segments such as athletes, infants and older persons. The company was established in 2010.
	**Dr. Reddy's Laboratories Ltd** is an integrated global pharmaceutical company based in India that manufactures generic formulations, APIs, biosimilars and proprietary products. Its generic formulations target key therapeutic areas of gastrointestinal ailments, cardiovascular disease, pain management, oncology, anti-infective, pediatrics and dermatology. It also manufactures and exports molecules such as norfloxacin, ciprofloxacin, and varieties of semi-synthetic penicillin. It markets its products in India and around the world. It operates in New Zealand through its wholly-owned subsidiary, Dr. Reddy's Laboratories New Zealand Ltd which commenced operations in 2008 upon acquiring Affordable Healthcare Ltd. The basic activities of the company remained the same even after the acquisition which is gaining tenders from the New Zealand Government, Pharmac and supplying the pharmaceutical drugs for the prescription market.
	**Eisai Co. Ltd** is a Japanese multinational pharmaceutical company that manufactures and markets prescription pharmaceutical drugs, over-the-counter drugs and pharmaceuticals productions systems. Its focus areas include neuroscience and general medicine, oncology, antibodies and cell biology. It produces and sells diagnostic drugs through its subsidiary, Sanko Junyaku. Eisai is currently undergoing a transformation from a two brand structure built upon the anti-Alzheimer's agent Aricept® and the proton-pump inhibitor Pariet®/AcipHex® to a multi-brand

Supplier	Description
	structure established for the coordinated global launches for each of six new products, which form the basis of its next-generation product portfolio. Apart from its neurological drugs, it markets Halaven®, an anticancer agent. Eisai also provides treatments in the field of biologics through a licensing agreement with AbbVie GK. It distributes anticancer pharmaceuticals in Australia and New Zealand through its subsidiary, Eisai Australia Pty Ltd.
	**Eli Lilly & Co** is an American multinational pharmaceutical company that researches and develops drugs in the areas of oncology, cardiovascular, diabetes, critical care, neuroscience, endocrinology, anti-infectives, men's health and musculoskeletal fields, as well as animal health care. Its products are marketed in 125 countries. It operates research and development facilities and runs clinical trials. It is a pioneer behind breakthroughs against polio and mental illnesses. It is a strong advocate of the effective protection of intellectual property rights, including patent protection for pharmaceutical products. It operates in New Zealand through its subsidiary Eli Lilly & Co (NZ) Ltd.
	**Gilead Sciences** is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. Gilead's portfolio of products and pipeline of investigational drugs includes treatments for HIV/AIDS, liver diseases, cancer and inflammation, and serious respiratory and cardiovascular conditions. Gilead is based in the US but services the New Zealand market through its Australian subsidiary Gilead Sciences Pty Ltd.
	**GlaxoSmithKline PLC** is a British multinational research-based pharmaceutical company that develops, manufactures and markets vaccines and prescription and over-the-counter medicines for major disease areas such as asthma, cancer, infections, diabetes, digestive and mental health conditions. Its consumer healthcare product brands include Sensodyne, Panadol, Aquafresh and Nicorette/Niquitin. 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 New Zealand through its subsidiary GlaxoSmithKline New Zealand Ltd, with Glaxo having originally been founded in New Zealand in 1904.
	**Fleet Laboratories** is an American based pharmaceutical company founded in 1869 that focuses on the production of non-prescription drugs. The New Zealand market is supplied by the Fleet's Australian subsidiary C.B. Fleet Co (Aust) Pty Ltd which focuses on the supply of pharmaceuticals and toiletries to both Australia and New Zealand.
	**Go Health New Zealand** is a New Zealand based vitamin, mineral and supplement company that brings to the New Zealand market a wide range of personal health products. Specifically it has products relating to general health, women's health, men's health, joint health, healthy oils, the immune system, the nervous system, sleep, weight management, energy and children's health. Go Health services both the New Zealand vitamin, mineral and supplement market, as well exporting its products to markets internationally.

Supplier	Description
	**H. Lundbeck A/S** is a Danish-based multinational specialty pharmaceutical manufacturer of branded products specialising in brain disease. Through its products it targets depression and anxiety, psychotic disorders, epilepsy and Huntington's, Alzheimer's and Parkinson's diseases. Its most recently launched compounds targeted at brain diseases include: Brintellix® (depression), Cipralex/Lexapro® (depression), Abilify Maintena® (schizophrenia), Selincro® (alcohol dependence), Azilect® (Parkinson's disease), Xenazine® (chorea associated with Huntington's disease), Sabril® (epilepsy) and Onfi® (Lennox-Gastaut syndrome). It researches both in-house and in cooperation with research centres, employing more than 1,200 trained specialists in research and development. In 2013, 46% of its revenue derived from Europe, 17% from the USA and 27% from the International Markets region. It operates in New Zealand through its subsidiary Lundbeck New Zealand Ltd.
	**Health World Ltd** is a New Zealand based vitamin, mineral and supplement company formed in 1985 that supplies its products into the New Zealand market to both consumers and professionals. Health World Ltd has agreements with other Australasian personal health product companies such as Metagenics Australia and New Zealand and Sun Ten Ltd in order to produce and distribute a wider range of products.
	**Hospira, Inc.** is an American global pharmaceutical and medical device company that manufactures specialty pharmaceuticals, including generic acute-care and oncology injectables and intensive care proprietary pharmaceuticals. Its products and services portfolio includes IV sets and clinical integration, infusion pumps, clinical software, implementation services, clinical services and contract manufacturing. Its products are used by hospitals and alternate site providers, such as clinics, home healthcare providers and long-term care facilities. It was formerly the hospital products division of Abbott Laboratories. It operates in New Zealand through its subsidiary Hospira NZ Ltd.
	**Ipca Laboratories** is Ipca is a fully-integrated Indian pharmaceutical company manufacturing over 350 formulations and 80 APIs for various therapeutic segments. For more than 60 years, Ipca has been partnering healthcare globally in over 110 countries and in markets as diverse as Africa, Asia, Australia, Europe and the US. Our international client roster includes global pharmaceutical giants like AstraZeneca, GlaxoSmithKline, Merck, Roche and Sanofi Aventis; most of whom we have been partnering over the years.
	**Intas Pharmaceuticals** is a leading, vertically integrated global pharmaceutical formulation development, manufacturing and marketing company headquartered in India. Besides rapidly growing domestic prominence, Intas is also present in more than 70 countries worldwide with robust sales, marketing and distribution infrastructure in markets like North America, Europe, Central & Latin America, Africa, Australia, New Zealand, Asia – Pacific as well as CIS and MENA countries. Intas' global strategy includes alliances with leading Global Pharma Companies for development and distribution of products as well as direct product distribution. Intas has made a substantial commitment to its Biologics Business Unit in terms of creating R&D, manufacturing and marketing capabilities for its biotech portfolio. As on date, Intas commercialized 11 biologic products and continues its R&D efforts in chronic disease areas such as Oncology (Cancer), Rheumatology, Auto-Immune, Nephrology, Ophthalmology and Plasma derived product based therapies. Continual R & D initiatives have strengthened niche and complex product offerings in India and International markets. Commercialized in India, three pharmaceutical formulations are based on the novel lipid based drug delivery system with studies ongoing to extend these products to International markets.

Supplier	Description
	**Integria Healthcare** is an Australian based personal healthcare company that focuses on the research and development, manufacture and distribution of natural medicines. It offers a full range of natural healthcare products, including treatments and products relating to cardiovascular health, respiratory health, skin care, gastrointestinal support, immune support, weight management, musculoskeletal support, dietetics, endocrine and nervous system support and general wellbeing and ageing. Integria services the New Zealand market through its subsidiary Thompsons which was established in 1951.
	**Johnson & Johnson** is an American pharmaceutical that manufactures healthcare products and provides related services for the consumer, pharmaceutical and medical devices and diagnostics markets. It sells consumer healthcare products such as skin and hair care, baby care, wound care and topicals, oral healthcare, over-the-counter medicines, nutritionals and vision care products. In addition, it manufactures and distributes acetaminophen products, pharmaceuticals, diagnostic equipment, and surgical equipment in countries located around the world. Its medical devices and diagnostic products are geared towards orthopaedics, cardiovascular disease, coronary artery disease, peripheral vascular and obstructive disease, neurovascular disease, arrhythmias, diabetes care, self-measured blood glucose monitors, insulin delivery devices, urologic surgery, hernia surgery and aesthetics. 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. Johnson & Johnson operates in New Zealand through its subsidiary Johnson & Johnson (New Zealand) Ltd which has serviced the New Zealand market since 1945.
	**Link Healthcare** is a specialist pharmaceutical and medical technology business operating in Australia, New Zealand, Asia and Southern Africa, founded in 1997. Its pharmaceutical range consists of proprietary and in-licensed products. It operates in New Zealand through its subsidiary New Zealand Link Pharmaceuticals Limited.
	**Key Pharmaceuticals** is an Australian owned and operated private company established in 1901. It is involved in a full range of brand management activities from research and product development through to marketing, sales and export. Key Pharmaceuticals also retains exclusive license and distribution arrangements with companies in the USA, Europe, Asia as well as New Zealand. Some of its key brands include Blistex, Diareze, Gasbusters, Hamilton, Mintec, No-Doz, OsmoLax and Seda. Key provides products to New Zealand pharmacies, supermarkets, convenience stores, health food shops as well as specialised outlets such as hospitals.
	**Mallinckrodt Pharmaceuticals PLC** is an Irish multinational speciality pharmaceutical company that manufactures and distributes branded and generic specialty pharmaceutical products and diagnostic imaging agents in neurology. It specialises in the manufacture of pain management medications. It offers its products to major wholesalers and retail drug store chains around the world. It uses its active pharmaceutical ingredients (API) products in the manufacture of its generic pharmaceuticals and also sells them to other pharmaceutical companies. It markets its global medical imaging products primarily to physicians, technologists and purchasing administrators at hospitals, imaging centres, cardiology clinics and radiopharmacies. Mallinckrodt PLC was formerly a part of Covidien PLC. It has provided a variety of pharmaceutical products into the New Zealand market through its Australian subsidiary Mallinckrodt Australia Pty Ltd since 1974.

Supplier	Description
	**New Zealand Pharmaceuticals** since 1974 has manufactured pharmaceutical intermediates and diagnostic products for the world's pharmaceutical and biotechnology companies. The company's chemical and pharmaceutical related services include enzyme and chemical hydrolyses, large scale aqueous and organic solvent extractions, ion-exchange purification, distillation, ultrafiltration, filtration and centrifugation, spray drying, vacuum oven tray drying, freeze drying, crystallisation, milling (grinding) and recently chemical synthesis. In addition to supplying the global pharmaceutical industry with pure biochemicals, NZP also manufactures a range of biochemicals and natural extracts for the international health food, cosmetic, biotechnology and aquaculture industries.
	**PSM Healthcare Limited** operates as a manufacturer and exporter of pharmaceuticals. The company was founded in 1976 and is based in Auckland, New Zealand. As of October 1, 2002, PSM Healthcare Limited became a subsidiary of Australian Pharmaceutical Industries (see profile above).
	**The Menarini Group** is an Italian biopharmaceutical multinational company that develops, manufactures and commercialises medical devices, branded prescription drugs targeted at key therapeutic areas including dermatology, gastroenterology, antibiotics, diabetes, men's health, cardiovascular, allergy/respiratory drugs and diagnostics as well as over-the-counter consumer health products. It undertakes research and development through its biotechnology centre, Menarini Biotech, and the Menarini Research and Development Centre. Its current research and innovation interests include cancer (for solid tumours and blood cancer and for support therapies) gastro-intestinal, osteoarthritis, and analgesia. Menarini supplies the New Zealand market with a variety of pharmaceutical products through its subsidiary Menarini Australia which began operating following the acquisition of Invida Asia Pacific in 2011.
	**Merck & Co., Inc.** (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. Its prescription medicines target cardiovascular disease, respiratory disease, oncology, neuroscience, infectious disease, immunology and women's health. Its consumer health products include Claritin, Dr Scholl's and Oxytrol for Women. It undertakes research and development and clinical trials to discover innovative ways to treat and prevent disease. Moreover, it actively seeks strategic partnerships to complement and enhance its original research and product portfolio. Merck and Scherubg-Ploiugh merged in 2009 to create MSD, supplying the New Zealand market through its subsidiary MSD (NZ) Ltd.
	**Merck KgaA** (EMD Millipore in the US and Canada) is a German global chemical and pharmaceutical company that researches and manufactures consumer health over-the-counter pharmaceuticals, biopharmaceuticals and life science tools such lab solutions for pharmaceutical research and biotechnology. In the market for biopharmeceuticals, it focuses on specialized therapeutic areas such as neurodegenerative diseases, oncology, immuno-oncology, fertility, endocrinology and biosimilars. Its consumer health product brands include Bion Health Enhancer, Cebion, Femibion, Seven Seas, Kytta, Nasivin, Sangobion and Sedalmerck. It is also in the market for products for flat screens and the pharmaceutical, food, cosmetics, packaging, and coatings. Merck has been active in New Zealand since 1974.

Supplier	Description
	**Mercury Pharma Group Limited** is an international specialty Pharmaceutical company selling niche prescription pharmaceuticals and non-prescription medicines. The company markets its products in more than 50 countries across the globe with primary focus in UK and EU markets. Mercury Pharma has operational bases in the UK, Ireland and India, however distributes products to countries elsewhere through distributor agreements. The BNM Group is responsible for the distribution of Mercury Pharma products in Australia, New Zealand and the South Pacific Islands.
	**Multichem** is a privately owned New Zealand importer and distributor of pharmaceutical product founded in 1966. Multichem has supplier agreements with a wide number of large manufacturers from across the world. The company currently represents more than 600 product lines from at least 20 suppliers. The company's products include pharmaceuticals, biological products and medical consumables and equipment. Multichem Group operates Multichem NZ, Multichem Export and Oraltec.
	**Norgine** is an independent pan-European specialty pharmaceutical group established in 1906, with headquarters based in the Netherlands and global operations based out of the UK. Norgine has many sites and offices globally including in New Zealand. Its key products include Movicol, Xifaxan, and Normacol enema.
	**Novartis AG** is a Swiss-based multinational pharmaceutical company that 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. It also manufactures Alcon eye care products and consumer and animal health products. Its line of consumer health product brands include Theraflu, Otrivin, Sinecod, Voltaren, Benefiber, Excedrin and Nicotinell. Its animal healthcare brands include Atopica, Capstar, Deramxx and Milbemax. Novartis has supplied the New Zealand market through its Australian subsidiaries for over 50 years. The Australian arm of Novartis has several companies: Novartis Pharmaceuticals, Alcon (eye care company), Sandoz (generics), Vaccines & Diagnostics, and Novartis Consumer Health (OTC).
	**Novo Nordisk A/S** is a Danish pharmaceutical multinational company that develops, manufactures and markets pharmaceuticals targeted at diabetes (through insulin delivery systems). It also manufactures pharmaceuticals addressing haemastosis management, hormone replacement therapy, and growth therapy. It also provides educational and training support materials in respect of these medical conditions. In terms of treatment for diabetes patients, Novo Nordisk markets insulin pens and needles, including NovoPen® 4, FlexTouch® and NovoPen Echo® and NovoTwist®. For growth hormone therapy, it provides a range of branded injection devices, including FlexPro®, NordiFlex®, NordiPen® and NordiLet®. It operates in New Zealand through its subsidiary Novo Nordisk Pharmaceuticals Pty Ltd.

Supplier	Description
	**Omega Pharma NV** is a Belgian-based multinational specialty pharmaceutical company that specialises in delivering branded over-the-counter products. It produces cosmetics, vitamins, food supplements, dental equipment, consumable packages, and generic drugs, as well as distribution services and medical software. It offers its range of healthcare products and services to pharmacists, dentists, and other medical sectors. Its brands include BecoAllergy, etixx sports nutrition, Jungle Formula, TCP, Buttercup, Nytol, Solpadein, BecoNase, Dermalex and Wartner. It also provides training resources including training modules on weight loss, sleep, and hayfever. Omega Pharma operates in New Zealand through its wholly owned subsidiary Omega Pharma New Zealand Ltd.
	**Orion Corporation** is a global pharmaceuticals company based in Finland. It develops, manufactures and markets human and veterinary pharmaceuticals, APIs and diagnostic tests. Its R&D focusses on central nervous system drugs, oncology and critical care drugs. All of Orion's R&D and manufacturing facilities are based in Finland but its products are marketed in over 100 countries, including New Zealand through its subsidiary Orion Corporation Limited.
	**Otsuka** is a US pharmaceutical and medical device company with an emphasis on neuroscience, oncology, cardio-renal and medical device markets. It operates through a number of subsidiaries that alternatively focus on the North American operations, research and clinical development, and a research centre that investigates pharmacological compounds in oncology. In a joint venture with Diatranz in 2011 forming Diatranz Otsuka Ltd, Otsuka entered the New Zealand market for the supply of their diabetes treatment Diabecell.
	**Perrigo Co. PLC** is an Irish-based global pharmaceutical manufacturer that develops, manufactures and distributes generic over-the-counter and prescription pharmaceuticals, infant formulas, nutritional products, animal health, dietary supplements, active pharmaceutical ingredients, and medical diagnostic products. The company receives royalties from the Multiple Sclerosis drug Tysabri®. It is the world's largest manufacturer of over-the-counter pharmaceutical products for the store brand market and an industry leader in pharmaceutical technologies. Its over-the-counter products include store-brand alternatives to national brand products such as Claritin, Pepcid and Sudafed. It operates in the New Zealand market through its Australian subsidiary which was established in 2010. Additionally it formed an agreement with Aspen Global Inc for a basket of value-brand over-the-counter products in 2014 that it supplies to both the Australian and New Zealand market.
	**Pfizer Inc.** is an is an American research-based pharmaceutical multinational company that discovers, develops, manufactures and markets generic and branded prescription and over-the-counter drugs in immunology, oncology, cardiology, diabetology and neurology as well as animal healthcare products. Its over-the-counter brands include Advil®, Chapstick®, Centrum® and Dimetapp®. It operates in New Zealand through its wholly-owned subsidiary, Pfizer New Zealand Ltd. Its prescription brands include ZOLOFT®, VIAGRA® and LIPITOR®. Its current research areas include immunology and inflammation, CV and metabolic diseases, oncology, vaccines, neuroscience and pain, and rare diseases. For the past 50 years, Pfizer New Zealand Ltd has focused on providing branded prescription medicines and animal health, consumer and nutritional products.
	**Pharmaco (NZ) Ltd** is a New Zealand owned company that provides a range of sales and marketing services supported by warehousing, distribution, regulatory and administration services to international pharmaceutical, medical, diagnostic and scientific companies in New Zealand, Australia and the rest of the world. Pharmaco (NZ) Ltd commenced trading in New Zealand in 1967.

Supplier	Description
	**Pharmacor Limited** is an Australian pharmaceutical company established in 2007. It offers generic prescription and over-the-counter medicines to pharmacies and hospitals around Australia and New Zealand. It conducts its manufacturing operations in facilities in Asia and Europe. Its over-the-counter products are targeted at pain relief, hayfever, cold and flu, schedule 3 and digestive health. Its over-the-counter brands include Mydol 15, Trust Ibuprofen Plus Codeine, Gastrex and Cal-Care.
	**Priceline Pharmacy** is an Australian-based health and beauty retailer of cosmetics, skincare, haircare and healthcare products. It is involved in pharmaceutical retailing through the Priceline Pharmacy brand. Its over-the-counter consumer health products are targeted and skincare and pain relief. It has product manufacturing capabilities and it is a niche player in over-the-counter pharmaceuticals and toiletries, which have supplied the Australian and New Zealand markets since 1982. It is owned and operated by Australian Pharmaceutical Industries (API) since its purchase in 2004. (API is a pharmaceutical support company which provides wholesale distribution of pharmaceutical and related products to pharmacies, hospitals and doctors. It also provides various retail support services and financial services to pharmacies along with distributing dental and related products to dental practices.)
	**Procter & Gamble Co** is a multinational consumer goods company whose pharmaceutical arm manufactures, markets and distributes more than 68 drugs in the US. In 2011 Procter & Gamble formed an international joint venture with Teva Pharmaceutical Industries Ltd to form Healthcare LPP to service pharmaceutical markets globally. Healthcare LPP services more than 70 countries around the world including New Zealand with cough and cold products, and brands such as Vibovit, Ambrobene, Hylak, Novo-Passit, Gastal, and Metamucil. In 2013 Healthcare LLP and Australian company Swisse Wellness commenced a cross-licensing partnership arrangement to expand their collective range to over 100 over the counter vitamins, minerals and supplements.
	**Ranbaxy Laboratories** is an Indian research-based multinational pharmaceutical company that was incorporated in India in 1961 and is a member of the Daiichi Sankyo Group. It has operations in 43 countries and 21 manufacturing facilities spread across 8 countries. Ranbaxy is a vertically integrated company that develops, manufactures and markets generic, branded generic, value-added and OTC products, anti-retrovirals, active pharmaceutical ingredients and intermediates which covers a large portfolio across a range of therapies, including anti-infectives, cardiovascular, pain management, CNS, gastrointestinal, respiratory, dermatology, orthopaedics, nutritionals and urology.
	**The Reckitt Benckiser Group PLC** is a London-based multinational that manufactures and markets household, toiletry, pharmaceutical and food products. It also markets fabric treatments , disinfectant spray and cleaners, dishwashing detergent, personal care, food, and prescription drugs. Its brands include Strepsils, Mortein, Nurofen, Clearasil, durex, Dettol, Scholl, Veet, Harpic, finish, Lysol, Vanish, Aerogard and AirWick. It has an New Zealand subsidiary, Reckitt Benckiser (New Zealand) Ltd through which it supplies branded products to supermarkets and pharmacies.

Supplier	Description
red seal. live your best life	**Red Seal** is a New Zealand owned vitamin, mineral and supplement company that specialises in natural products. Founded in 1923, the company is best known for its range of supplements, vitamins and toothpastes. The company also markets soaps, molasses, sea salt, UMF honey and protein diet formula.
REX MEDICAL	**Rex Medical** is an American based pharmaceutical company that specializes 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. It services the New Zealand market through its subsidiary Rex Medical Ltd which commenced operations in 1996.
Roche	**Roche Holding AG** is a Swiss global pharmaceutical and diagnostics company that researches, develops and markets drugs in five main therapeutic areas: oncology, virology, inflammation, metabolic disorders and central nervous system. In addition, it manufactures products targeted at infectious diseases, immunology and cardiovascular and metabolism. Its current research areas include oncology, neuroscience, infectious diseases, immunology and cardiovascular and metabolism. Its pharmaceutical brands include Valium, Fuzeon, MIRCERA, Lariam and Anaprox. Its diagnostics include Accu-Chek, AmpliChip, Elecsy and iScan. Roche Diagnostics New Zealand Pty Ltd is part of the International F. Hoffmann-La Roche Group that was founded in 1896 in Basel, Switzerland. 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.
SANOFI	**Sanofi S.A**. is a Paris-based 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 scelrosis. In New Zealand, Sanofi ANZ is a horizontally integrated healthcare provider with products ranging from complementary medicines, through to patented medicines, generics, over-the-counter medicines, nutraceutical products and vaccines. It does this through its four divisions: Pharmaceuticals, Consumer Healthcare, Vaccines and Rare Diseases. Its key consumer healthcare products in New Zealand include Mersyndol® DayStrength, Phenergan® and Telfast®. It also distributes nutraceutical products including Betadine, Cenovis, MICROgenics and Nature's Own. Its pharmaceutical brands in the New Zealand market include Actonel, Amaryl, Apidra, Clexane, Clomid, Cordarone, Ditropan, Flagyl, Multaq, Panadein Forte, Panamax, Primacor, Rilutek and Stilnox.
SERVIER	**Servier** is French pharmaceutical company specialising in cardiology, diabetes, venous disease, menopause and depression. They are present in 140 countries with more than 21,000 countries. Servier operates in New Zealand through its wholly owned subisdiary, Servier Laboratories (NZ), with a clinical research and sales and marketing divisions. Some of their key products include Valdoxan, Coralan, Coveram, Coversyl, Protos, Diamicron, Natrilix, and Muphoran.

Supplier	Description
	**Spirit Pharmaceuticals**, founded in 2003, is a UK based industry leader of OTC and generic products. Its products include analgesics, laxatives, sleep aids, cough, cold and allergy medicines and nutritional supplements. Operating as a subsidiary to Actavis PLC, Spirit Pharmaceuticals NZ (Pty) Ltd supplies the New Zealand market with its full range of pharmaceutical products.
	**Shire PLC** is a Jersey-based Irish multinational specialty pharmaceutical company that manufactures, licences and markets biopharmaceuticals to provide treatments in neuroscience, rare diseases, gastrointestinal and internal medicine. Its research and development expertise is in developing medicines for patients treated by specialist physicians, and for discovering new therapies for rare, life-threatening genetic disease. It also runs Patient Assistance Programs, providing support to patients to help get them the Shire medicines that their physicians have prescribed. Shire PLC targets the New Zealand market with its products ELAPRASE and REPLAGAL.
	**Teva Pharmaceutical Industries Ltd** is an Israeli pharmaceutical multinational company that develops, produces and markets a wide range of specialty medicines, generic and over-the-counter products and active pharmaceutical ingredients. Its specialty products are targeted at the central nervous system, respiratory, oncology, women's health, pain and transplant. Its key pharmaceuticals include COPAXONE, ProAir HFA, Myocet®, SYNRIBO™, PARAGARD and FENTORA. In 2013, Teva embarked on a strategy to address unmet patient needs with New Therapeutic Entities (NTEs) – a program aimed at identifying and developing new specialty medicines that provide advances on existing therapies by formulating, delivering or using them in a novel way. Thus far, products from the NTE process include those that treat pain, schizophrenia, glaucoma and Crohn's disease. In New Zealand, it operates through its subsidiary Teva Pharmaceuticals NZ Ltd.
	**Torrent Pharmaceuticals** is the flagship company of the Torrent Group, based in India. It opeartes in more than 50 countries with other 1,000 product registrations globally. It has wholly owned subsidiaries in USA, UK, Germany, Brazil, Russia, Mexico, Philippines Australia and other major markets. The company's key areas of formulations, active pharmaceutical ingredients, drug discovery, marketing and sales of drugs. Torrent Pharmaceuticals considers itself to be a dominant player in the therapeutic areas of cardiovascular and CNS and has achieved significant presence in gastro-intestinal, diabetology, anti-infective and pain management segments.
	**Valeant Pharmaceuticals** is a diverse and decentralised pharmaceutical company with headquarters in Canada. It has a broad portfolio with a focus on branded pharmaceuticals, branded generics and OTC products, specialising in dermatology and eye health. Its product sales focus on North America, Europe and the Middle East, Latin America and Asia Pacific. It operates in the New Zealand market through its subsidiary Valeant Pharmaceuticals Australasian Pty Ltd.
	**Vital Foods** is a New Zealand based company producing digestive products with a focus on using natural ingredients. The company launched in Auckland in 1991 with a single product, however has since expanded its range of nutritional supplement products. The company focuses on its lines of products to aid digestion utilising the chemical Zyactinase.

Supplier	Description
	**Wockhardt** is a pharmaceutical and biotechnology company headquartered in Mumbai, India, with manufacturing plants in India, UK, Ireland, France and US, and subsidiaries in US, UK , Ireland and France. Its businesses range from manufacture and marketing of pharmaceuticals and biopharmaceutical formulations, to active pharmaceutical ingredients and vaccines.
Global pharmaceutical companies not currently operating in New Zealand	
	**Acs Dobfar** is a privately held Italian company founded in 1973. It is a fully integrated manufacturer of Cephalosporin, Carbapenem and Penicillin APIs as well as solid and injectable finished dosage formulations, offering generic sales to third parties, custom pharmaceutical services for innovators and contract manufacturing. Acs Dobfar exports its products to more than 100 countries around the world. In 2000, it acquired a high tech pharmaceutical facility in Chungbuk, South Korea.
	**Akorn** is a niche generic pharmaceutical company engaged in the development, manufacture and marketing of multi-source and branded pharmaceutical products in the areas of ophthalmology, antidotes, anti-infectives, and controlled substances for pain management and anesthesia in the United States and across the globe. It manufactures a range of injectables and opthalmics primarily in the United States and in India.
	**Almirall** researches, develops, manufactures and markets proprietary and licensed medicines worldwide. It is headquartered in Barcelona, Spain and has three manufacturing plants in Spain and Germany. Almirall products are available in over 70 counties around the world, through its affiliate and strategic partnership network. Its therapeutic focus is on respiratory diseases, dermatologic diseases, gastrointestinal diseases and pain. On 4 August 2014, it was announced that AstraZeneca would acquire Almirall in a deal worth US$875 million. Almirall licenses its cardiac drug Aclidinium to Invida for supply to Australian and New Zealand markets.
	**Amneal Pharmaceuticals** is a US based manufacturer of generic pharmaceuticals, operating research and development facilities in the US and India, manufacturing facilities in the US and a distribution centre based in Kentucky, US. Amneal operates in a range of therapeutic areas including analgesics, anti-anxiety, antibiotics, bronchodilator, diuretics, laxatives and urinary antiseptic.
	**Astellas Pharma Inc.** is a Japanese multinational pharmaceutical company that develops products focusing on cardiology, dermatology, immunology, infectious disease, oncology and urology. Its leading products in the global market include Prograf®, an immunosuppressant used to prevent rejection in organ transplants; Vesicare®, a treatment for overactive bladders; Protopic®, the world's first treatment for atopic dermatitis in the topical immunomodulator class; Harnal®, a blocking agent with great selectivity for prostatic and urethral smooth muscle, to treat the functional symptoms of benign prostatic hyperplasia (BPH); and Funguard®, a candin antifungal agent that operates to inhibit synthesis of the fungus cell wall. It recently began operations in Australia when it commenced business in July 2011.

Supplier	Description
	**Cadila Healthcare Ltd** is an Indian pharmaceutical multinational company that manufactures generic cardiovasculars, gastrointestinals, women's healthcare pharmaceuticals, respiratory, pain management and anti-infectives. In addition, it manufactures and markets healthcare solutions ranging from formulations, active pharmaceutical ingredients, vaccines, diagnostics, health and dietetic foods, animal healthcare to cosmeceuticals. Its products are available in tablets, capsules, injections, liquids, dry syrups, powders, granules, and ointments. In 1995, the group restructured its operations and Cadila Healthcare came into being under the aegis of the Zydus group. In December 2004, it entered the Australasian region, entering into a Memorandum of Understanding with the Mayne Group of Australia for setting up a joint venture company to explore business opportunities including the manufacture of cytotoxic (anti-cancer) finished products in Australia.
	**Cempra** is an American based clinical-stage pharmaceutical company focused on developing antibiotics to meet critical medical needs in the treatment of bacterial infectious diseases. Cempra has two antibiotic candidates, solithromycin (CEM-101) and TAKSTA™ (CEM-102, sodium fusidate), in clinical trials. Both target the growing problem of antimicrobial resistance. Cempra also has identified a number of promising lead candidates for treating anti-inflammatory diseases, such as chronic obstructive pulmonary disease (COPD), late stage asthma and psoriasis, endocrine diseases and gastrointestinal motility disorders.
	**Chiesi Farmaceutici SpA** is an Italian multinational pharmaceutical company that develops and produces specialty pharmaceuticals targeted specifically to respiratory diseases and rare diseases, and secondly to musculoskeletal and cardiovascular diseases. It also develops products targeted at the central nervous system, gastronutrition and neonatology. In terms of research and development, development in the respiratory therapeutic area represents 67% of total R&D spending.
	**CSPC Pharmaceutical** is a leading pharmaceutical company in China, listed on the Hong Kong Stock Exchange since June 1994. It supplies innovative, branded and generic drugs in China with its major products including the "NBP" series, "Oulaining" series and "Xuanning" series. CSPC's production facilities are located in Shijiazhuang City, Hebei Province, China.
	**Cubist Pharmaceuticals** is an acute care pharmaceutical company in the US. It markets a selective range of drugs in the US and Canada used for novel acute care therapies in hospitals and other acute care environments. The products include Cubicin, the first antibiotic in a class of anti-infectives called lipopeptides and Entereg – the first and only FDA-approved therapy to accelerate the time to upper and lower gastrointestinal recovery following surgeries that include partial bowel resection with primary anastomosis. Cubist is also in the process of making global regulatory applications for an oxazolidinone, for the potential treatment of certain Gram-positive infections, including MRSA.
	**Daiichi Sankyo Co Ltd** is a Japanese global pharmaceutical holding company established through merger of Sankyo and Daiichi pharmaceutical. It manufactures pharmaceuticals including vaccines, generics and over-the-counter drugs for human/veterinary use and medical tools and equipment. Its current priority areas include oncology and cardiovascular-metabolic therapies. It also researches and promotes products through related companies throughout the world. Moreover, it produces food, food additives, livestock feeds, and agrochemicals. In 2009 Daiichi Sankyo entered the Australasian market, entering into a deal with Australian biotech company Biota Holdings. Daiichi Sankyo received approval in Japan to manufacture and market a new treatment for influenza developed by Biota Holdings.

Supplier	Description
	**Durata Therapeutics** is a new US pharmaceutical company, established in 2009, focused on the development and commercialization of differentiated therapeutic solutions in relation to infectious disease and acute illnesses. Its major product is Dalvance, an injectable treatment for acute bacterial skin and skin structure infections in adults. Durata's goal is to create a substantial enterprise through targeted in-licensing or acquisition of clinical stage product candidates or approved products for the hospital and acute care markets, investing in high unmet need indications, streamlined development, and targeting highly specialized audiences for eventual commercialization.
	**Enanta Pharmaceuticals** is a research and development-focused biotechnology company discovering and developing novel inhibitors designed for use against the hepatitis C virus, or HCV. In particular, it is pursuing four fundamental and validated HCV targets: NS3 Protease Inhibitor, NS5A Inhibitor, Cyclophilin Inhibitor and Nucleotide Polymerase Inhibitor. Enanta is also focusses on a new class of antibiotics, called Bicyclolides, for the treatment of multi-drug-resistant bacteria, with a current focus on developing intravenous and oral treatments for hospital and community infections of methicillin-resistant Staphylococcus aureus bacteria, known as MRSA.
	**Endo** is an international pharmaceutical and medical device manufacturer with global headquarters in Dublin, Ireland and Malvern, United States. It supplies branded pharmaceuticals, generic and OTC drugs, innovative pharmaceutical products within Canada and high quality pharmaceutical products for key market segments in Mexico. Its therapeutic areas of focus include allergy immunotherapy, dermatology, pain, insomnia, infectious disease, urology and women's health.
	**Eris Lifesciences** is the fastest growing super specialty focused pharmaceutical company, which has key operations in cardiology, diabetology, endocrinology, gastroenterology, ENT, orthopaedics, paediatrics and gynaecology segments. It was established in 2007 with headquarters and presence throughout India, and is engaged in selling branded generics across the country.
	**Gedeon Richter** is a multinational pharmaceutical company headquartered in Budapest. Its products are distributed in more than 100 companies. Gedeon Richter is focused on innovation and research of original drug molecules in relation to the treatment of benign gynaecological conditions and diseases of the central nervous system. It operates in the UK under the name Medimpex UK with a particular focus on women's health.
	**Generic Health Pty Ltd** is a Melbourne-based pharmaceutical manufacturer of generic prescription and over-the-counter drugs. It was formerly known as Generix Pty. Ltd. and in September 2004 it changed its name to Generic Health Pty, Ltd. It offers medicines for oral antihistamine, hair regrowth treatment, cholesterol lowering, antihypertensive, antidepressant, hypnotic, diabetes, and antibiotic. It distributes its products through wholesalers. It supplies hospitals and pharmacies through four main product offerings: generic prescription tablets, 'Pharmacy Action' (OTC pharmacy only range), Goanna (therapeutic oils and rubs), hospital injectable products.
	**Glenmark Pharmaceutical** is a global, integrated pharmaceutical company with a focus on research and the discovery of new molecules. It also has a significant presence in branded generics markets across emerging economies including India. It has 14 manufacturing facilities across four countries in addition to six R&D centres. It has a truly global presence from central eastern Europe to Russia, Latin America, Africa and the Asia Pacific. Under a licensing agreement with Sanofi, Glenmark will develop and supply a novel monoclonal antibody for the treatment of Crohn's Disease to markets around the world including New Zealand.

Supplier	Description
	Guangzhou Baiyunshan Pharmaceutical is located in the Baiyun District of Guangzhou with a factory covering 240,000 square meters. It is a leading API manufacturer in China, including the API cephalosporin. It also engages in contract manufacturing.
	Guardian Drug Company, Inc is a New Jersey-based consumer healthcare organisation that develops, manufactures and distributes pharmaceutical over-the-counter and nutritional products through various distribution channels, including drug store chains, mass merchandisers, supermarkets and wholesalers. It is a pioneer in over-the-counter gastrointestinal products for the private-label marketplace but also sells cough/cold, allergy, analgesic, probiotics, antacids, antiflatulents, laxatives, antidiarrheals, and other stomach remedies products in solid, liquid, tablet, capsule, tube, and powder forms. It also provides liquids, softgels, and topicals.
	Hikma is a diverse pharmaceuticals business, headquartered in the middle east and listed on the London Stock Exchange. It has a branded pharmaceutical business focused on the middle east and north Africa, an oral generics business in the US and a global injectables business. It has 27 manufacturing facilities around the world, including the middle east, north Africa, Europe and the US.
Hisamitsu	**Hisamitsu** focuses on R&D for transdermal drug delivery system (TDDS) products in a wide range of the therapeutic fields. It has four major R&D centres, three in Japan and one in the US. It also manufactures high quality pharmaceutical products in two community-based manufacturing plants in Japan.
	Impax Laboratories technology-based specialty pharmaceutical company with a balanced business model consisting of; a successful generic business targeting high-value solid oral and alternative dosage form Abbreviated New Drug Applications (ANDA), and a branded business currently focused on internally developing Central Nervous System (CNS) products. Impax has production facilities in the US and Taiwan.
	Jazz Pharmaceuticals is a global pharmaceutical company based in the US, supplying products in ten core countries in Europe and more than 80 countries through a wide distribution network. It has product that relate to narcolepsy, oncology, pain and psychiatry.
	Kyowa Hakko Kirin is a research-based biotechnology company. Its pharmaceuticals division focuses on discovering new medicines in the therapeutic areas of oncology, necrology and immunology/allergy. It has a strong presence across Asia as well as a presence in the US and Europe.
	Lannett Company develops, manufactures and distributes generic prescription pharmaceutical products in tablet, capsule and oral liquid forms to customers throughout the US. Products cover a wide range of therapeutic areas. Lannett also manufactures APIs.

Supplier	Description
	**Lupin** is a multinational pharmaceutical company headquartered in Mumbai, India. It produces a wide range of high quality, affordable generic and branded pharmaceutical formulations and APIs for developed and developing markets around the world. Lupin's products are sold in over 100 countries around the world.
	**Meda AB** is a global pharmaceutical company based in Sweden. It offers a wide range of specialty products, branded generics and OTC products. Meda has manufacturing facilities in Germany, France and the US. Its product portfolio spans dermatology, respiratory, cardiology, pain and inflammation, CNS, gastroenterology and metabolism/vitamins.
	**Medis** is an Iceland-based pharmaceutical multinational company that manufactures generic pharmaceutical products for human use, mainly in the form of tablets, capsules and injections. Its portfolio includes specialist oncology products and product formulations including modified release, solid oral dosage, semi-solids, suspensions, transdermals, suppositories, creams, ointments, liquids and injectables. It also offers a portfolio of products and intellectual property to other pharmaceutical companies. Medis has established itself as a source of pharmaceutical intellectual property in the form of comprehensive registration dossiers, for instance by securing regulatory approval prior to patent expiry. Medis has obtained marketing authorisations in over 130 countries to date and exports to most European nations, as well as other regions of the world. Medis has been operating in Australia since the acquisition of Spirit Pharmaceuticals in 2013. Medis is a subsidiary of Actavis PLC (profiled above).
	**Mitsubishi Tanabe Pharma Co** is a research-driven pharmaceutical company. It manufactures products that treat autoimmune disease, diabetes and kidney disease, CNS disease, hypertension, allergies and also products used as vaccines. In addition to its prescription drugs business, it also manufactures a range of OTC drugs. Mitsubishi is headquartered in Japan with an overseas network operated from Shanghai. The company has licensed the rights to develop and market the glycemic drug Invokana in a number of countries around the world including New Zealand.
	**Pacira Pharmaceuticals** is an emerging speciality pharmaceutical company with a focus on pain management, in particular the development of non-opioid products for postsurgical pain control. Its major product is Exparel, delivered through DepoFoam, a multivesicular liposome technology that encapsulates drugs without altering their molecular structure and then releases them over a desired time period.
	**Petrus Pharmaceuticals** is a wholly Australian opened and operated company specialising in the research, development, marketing and distribution of pharmaceutical products since 1988. The company markets a broad range of prescription and OTC products to pharmacies, medical practitioners and hospitals throughout Australia, including Co-Senna, Centa-Vite, Fibre Health, Lubri-Gel, Oraplex and Sorbisol.
	**Pharmacy Life Pty Ltd** is an Australian-based private label company that markets and distributes a range of specialty and branded over the counter products to pharmacies, using the brand 'Your Pharmacy'. Its 'Your Pharmacy' branded over-the-counter products target skincare, arthritis, cough and cold, head lice and weight management. It also markets vitamin supplements, antiseptics, analgesic and anti-inflammatories and antihistamines as well as gastrointestinal and traditional pharmacy medicines. It distributes branded product and pack lines

Supplier	Description
	for Orion Laboratories, a manufacturing import and distribution company in Perth. Pharmacy Life is also partnered with Alphapharm (profile above) a company who supplies a range of product lines to the New Zealand market.
Piramal knowledge action care	**Piramal Enterprises** consists of a number of companies that operate in the pharmaceutical industry, including healthcare, life sciences and infrastructure investment. Piramal is one of the largest custom manufacturing companies in the world with a vast network of contract development and manufacturing facilities located in North America, Europe and Asia offering a multitude of services that cover the entire drug-cycle, from development and commercial manufacturing to off-patent supplies of Active Pharmaceutical Ingredients (APIs) and formulations. Piramal also focuses on the discovery and development of innovative small molecule medicines in relation to cancer, metabolic disorders and inflammatory conditions.
RECORDATI	**Recordati S.p.A** is a specialty pharmaceutical group dedicated to partnering, discovering and developing innovative, value-added products. Through its European field force promotes a wide range of innovative prescription and OTC products, including its flagship product Zanidip (lercanidipine) in a range of therapeutic areas. Recordati products are sold in 135 countries around the world.
SAGENT Pharmaceuticals	**Sagent Pharmaceuticals** manufactures and supplies specialty injectable products based in the US. Its latest products include Irinotecan, adenosine, Octreotide and Propofol.
Santen A Clear Vision For Life	**Santen Pharmaceutical Co** is focused on the research and development, production and marketing of pharmaceuticals and medical devices. It is headquartered in Japan with international operations conducted through the US and Finland. Santen's primary areas of operation are in the ophthalmic and rheumatic fields, particularly the development of eye drops for a variety of eye diseases, including glaucoma and dry eye.
FOSUNPHARMA 复星医药	**Shanghai Fosun Pharmaceutical (Group) Co., Ltd** is a Chinese specialty biopharmaceutical company that, through its subsidiaries, manufactures generic medicines, Chinese traditional medicines, diagnostic products, and medical instruments, provides technology, marketing, and advertising services, as well as invests in import and export trading. It operates through the following segments: pharmaceutical manufacturing, distribution, and retailing; healthcare services; medical diagnostic products; and medical devices. Its products consist of metabolism and alimentary tract drugs, anti-infection drugs, cardiovascular and blood system drugs, oncology drugs, central nervous system drugs, vaccines, crude drugs, and intermediates. It operates US pharmacy chains such as For Me Pharmacy and Golden Elephant Pharmacy. In May 2014, it expressed interest in acquiring private equity owned Australian hospital operator Healthscope.
SHIONOGI & CO., LTD.	**Shionogi & Co** is a Japanese company that manufactures and distributes pharmaceuticals, diagnostic reagents and medical devices. It also operates overseas offices in Taiwan and China. Its prescription business accounts for over 90% of its total net sales and Shionogi supplies these products in the US, Europe and Asia. Its core products are Crestor (cholesterol medication), Irbetan (anti-hypertension) and Cymbalta (depression).

Supplier	Description
	**Sihuan Pharmaceutical** is the largest cardio-cerebral vascular prescription drug company in China. Founded in 2001, it has experienced strong growth, attributed to a proven sales and marketing model, a diversified product portfolio including drugs relating to the cardio-cerebral vascular system, central nervous system, metabolism, oncology and anti-infectives. Sihuan's major products are Kelinao, Anjieli, Chuanqing, Qu'Ao GM1 and Oudimei. Whilst currently focused on China, it has ambitions to be a fully integrated global pharmaceutical company.
	**STADA-Arzneimittel AG** is a German multinational pharmaceutical company that produces generic over-the-counter drugs. Its core segments include generics (61% of Group sales) and branded over-the-counter products (35% of Group sales). Its major therapeutic areas for generics include stomach medicines, antihypertensive agents and anti-inflammatory agents. In the area of branded products, its key products include the cold medicine Grippostad®, the Parkinson's disease medication ApoGo® and the suncream Ladival®. It deliberately does not conduct any of its own research on, or marketing of new active pharmaceutical ingredients, but rather focuses on the development and marketing of products with active ingredients – generally active pharmaceutical ingredients – which are free from commercial property rights, particularly patents. In 2012 the company announced the creation of an Australian subsidiary STADA Pharmaceuticals Australia Pty Ltd.
	**Sumitomo Dainippon** is a Japanese pharmaceutical company that also has a manufacturing presence in the US and China. It focusses its marketing activities on cardiovascular/diabetes, psychiatry and neurology as well as specialty products. It is also enhancing its presence in oncology. One of Sumitomo's basic strategies is global development – to this end, it has R&D bases in the four regions of Japan, the US, China and the UK.
	**Sun Pharmaceutical** is a global pharmaceutical company with manufacturing facilities in the US, Europe, the middle east, South America and Asia. It markets brands and branded generics in the US, India and. Sun is the largest specialty pharmaceutical company in India with established brands across niche therapies such as psychiatry, neurology, cardiology, nephrology, gastroenterology, orthopedics and ophthalmology. In the US, Sun is an integrated generic drugs company. It also markets brands and branded generics in over 40 other markets around the world.
	**Synthon Holding BV** is a Dutch multinational pharmaceutical company that produces biopharmaceuticals and generic drugs, with a focus on specialty pharmaceuticals, including autoimmune/ neurodegenerative diseases – particularly multiple sclerosis (MS) and oncology. Its generic product portfolio targets allergies, infections, cardiovascular disease, neurological illnesses, oncology, skeletal disease and urology. Its most advanced MS product in development is glatiramer, a Copaxone® generic. Its key oncology product is the trastuzumab monoclonal antibody, developed as a biosimilar to Herceptin®. It operates in Australia through its subsidiary Australia Synthon AU Pty Ltd.
	**Taisho Pharmaceutical** is focused on developing original new drugs. Its R&D strategy centres upon infections, orthopedic disorders, CNS and metabolic diseases. Taisho's main products include Clarith (macrolide antiobiotic), Zosyn (injectable antibiotic), Palux (peripheral vasodilator), Lorcam (nonsteroidal anti-inflammatory) and inflammation/immune-related products. Taisho is a world-class leading company in OTC products and through a network of overseas companies (including Abbott in the US), supplies prescription drugs to over 90 countries.

Supplier	Description
	**Takeda Pharmaceutical Co Ltd** is a global Japanese pharmaceutical company that develops prescription medicine and consumer healthcare products targeted at the following key therapeutic areas: cardiovascular and metabolic, central nervous system diseases, immunology and respiratory, general medicine and oncology. It also produces food, agrochemicals, and environment-related products such as pollution detectors. It researches, develops, and promotes the products through its related companies in the US, Europe, and Asia. In November 2012, the final stage in the transformation from Nycomed Australia to Takeda Australia was completed, with the company operating officially under the name Takeda Pharmaceuticals Australia Pty Ltd. The Nycomed history in Australia dates back to 2001.
	**The Tasly Pharmaceutical Group Co Ltd** is a Chinese hi-tech specialty pharmaceutical group whose scope of business includes modern TCM, herbal medicine, chemical medicine, biological medicine, healthcare products, functional food and medical equipment, covering the fields of research and development, planting, manufacturing and distribution. It researches, produces, and sells Chinese medicines which are mainly derived from the root of red-rooted salvia. Its products focus on the treatment of cardiovascular and brain blood vessel diseases.
	**Torrent Pharmaceutical** is a leading Indian pharmaceutical company particularly with respect to cardiovascular, CNS, gastro-intestinal, diabetology, anti-infective and pain management products. Torrent has world-class manufacturing facilities throughout India approved by USFDA, WHO, MHRA, TGA and other global regulatory bodies. It has a strong international presence spanning over 70 countries, with wholly owned subsidiaries in USA, UK, Germany, Brazil, Russia, Mexico, Philippines and other major markets. The company has announced plans to enter the Australian and New Zealand market.

Attachment D Glossary

ACE inhibitor	Angiotensin converting enzyme inhibitor. A type of antihyperintensive, it reduces peripheral arterial resistance by inactivating an enzyme that converts angiotensin I to the vasoconstrictor angiotensin II.
Analgesic	Also known as painkiller, is any member of the group of drugs used to achieve analgesia, relief from pain. Analgesic drugs act in various ways on the peripheral and central nervous systems. They are distinct from anesthetics, which reversibly eliminate sensation.
Angina	A chest pain due in general to obstruction or spasm of the coronary arteries.
Angiotensin II receptor antagonists	A type of antihyperintensive that blocks the binding of angiotensin II (A-II) to their cognate cell receptors—AT1, AT2 and others.
Antiarrhythmics	Drugs used to suppress abnormal rhythms of the heart and include all products recommended for use in arrhythmia, disorders of cardiac rhythm and tachycardia.
Antihypertensives	Drugs used to treat high blood pressure and the complications of such an indication, including stroke and myocardial infarction.
ANZTPA	Treaty agreeing to establish a joint scheme for the regulation of therapeutic products in New Zealand and Australia agreed to in September 2003 by the Government of New Zealand and the Government of Australia.
API	Active pharmaceutical ingredient, the chemicals in drug products that make the medications work.
Beta blocker	A type of antihypertensive that acts by way of beta-adrenergic blocking.
Bioequivalent	The property wherein a therapeutic agent has the same pharmacologic potency and bioavailability as another drug at the same dose.
Calcium antagonist	Also known as a calcium channel blocker, it is a type of antihyperintensive that inhibits movement of calcium ions across a cell membrane.
Cardiac disrhythmias	Also known as arrhythmia or irregular heart heart, is any group of conditions in which the electrical activity of the heart is irregular or is faster or slower than normal. This can occur in the upper chambers of the heart or the lower chambers of the heart.
Clone generics	A product identical in all respects to the originator brand, apart from its name and identifying details on the product label. In most cases, the clone generic comes from the same factor as the originator brand.
District Health Boards	Boards that are responsible for providing or funding the provision of health services in their district. There are 20 District Health Boards in New Zealand.
EphMRA	European Pharmaceutical Marketing Research Association. Under the EphMRA classification system there are 16 general categories of drugs which

	are then broken down into a series of four levels (ATC1 to ATC4). For further details, see section 5.8.
Generics	A pharmaceutical product intended to be interchangeable with the originator brand, manufactured without a licence from the originator manufacturer and marketed after the expiry of patent or other exclusivity rights. Generic medicines are marketed either under a non-proprietary name, under another approved name, or under a brand name (branded generics). There are three types of generic medicines: "clone generics", "licensed generics" or "true generics".
Hypertension	(also known as high blood pressure) A chronic condition in which the blood pressure in the arteries is elevated, putting strain on the heart, leading to hypertensive heart disease and coronary heart disease if not treated.
Indication	The use of a drug for treating a particular symptom, condition or disease. Indications can be either on-label (TGA approved uses for the drug) or off-label (uses for the drug not approved by the TGA). An indication could be off-label for a number of reasons, including that the TGA has not been asked to evaluate the indication or it is an uncommon indication.
Licensed generic	Products made with the same formulation as the originator brand but made by another company.
Hyperosmotic	Containing a higher concentration of salts or other dissolved materials than normal.
Laxative	Products that promote defecation through a range of mechanisms of action, including the attraction and holding of water in the intestinal lumen, increasing the peristaltic movement in the intestine, increasing the volume of the stool and softening the stool.
Macrolides	A class of safe and well tolerable antibiotics which are used in the treatment of infections. They are commonly used for a range of indications, including lower and upper respiratory tract infections, infections of skin and soft tissue, severe acne, and certain STDs.
Medicines Control	The regulatory team with the Ministry of Health that oversees the the local distribution of medicines and controlled drugs within New Zealand.
Medsafe	New Zealand Medicines and Medical Devices Safety Authority, which is responsible for the regulation of medicines and medical devices in New Zealand, ensuring that they are acceptably safe for supply and use.
Myocardial cells	Cells which make up the cardiac muscle.
Non-narcotic analgesics	A class of drugs used to relieve mild to moderate pain and inflammation. Popular OTC products such as Nurofen, Panadol and Advil are non-narcotic analgesics.
Non-steroidal anti-rheumatics	Anti-inflammatory drugs used primarily for the treatment of a range of arthritis, including rheumatoid arthritis. They inhibit the generation of prostaglandins by blocking cyclooxygenase enzymes.
Originator brand	The product that was first authorised worldwide for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety and

	quality, according to requirements at the time of authorisation. The originator product always has a brand name, however this brand name may vary between countries.
OTC	This means "over the counter". OTC products are those products that can be purchased without a prescription provided by a qualified medical professional.
PHARMAC	Pharmaceutical Management Agency, the New Zealand Crown agency that decides, on behalf of the District Health Boards, which medicines and related products will be subsidised for use in the community and public hospitals.
PTAC	Pharmacology and Therapeutics Advisory Committee, the principal adviser to PHARMAC.
"True" generic	Products made by a separate company to the company that makes the originator brand and for which the company has formulated its own recipe containing the active ingredient.
SKU	Stock keeping unit.
Specialty pharmaceutical	A pharmaceutical product that has some of the following characteristics: used to treat complex, chronic or rare conditions; high cost; exclusive, restricted or limited distribution; special storage or handling requirements; generally not taken orally; and ongoing monitoring for safety.
Tachyarrhythmia	An excessively rapid heartbeat accompanied by an irregular rhythm of the heart.

Attachment E Mylan NZ Annual Financial Report

Provided separately.

Attachment F Abbott NZ Annual Financial Report

Provided separately.