COMMERCE ACT 1986: BUSINESS ACQUISITION

SECTION 66: NOTICE SEEKING CLEARANCE

Date: 10 December 2019

The Registrar
Competition Branch
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.

Part A: Summary of Application

1. Executive Summary

Introduction

1.1 This clearance application concerns the proposed merger by Mylan N.V (**Mylan**) with Upjohn Inc. (**Upjohn**), (the **Proposed Transaction**). Upjohn and Mylan are together referred to as the **Parties**.

1.2 Mylan is a US-based global pharmaceutical company that develops, licenses, manufactures, markets and distributes generic, branded generic and specialty pharmaceuticals. Its product portfolio in New Zealand specialises in off-patent medicines (most of which are non-branded).

1.3 Upjohn is a newly created, currently wholly owned subsidiary of Pfizer Inc. (**Pfizer**). The Upjohn business was created as a focused division of Pfizer which operates Pfizer's off-patent branded and generic (non-sterile injectables) established medicines business. The Upjohn business has a portfolio of 20 off-patent molecules/21 established brands[1] organized across the following key therapeutic areas: (i) Cardiovascular, (ii) Central Nervous System/Psychiatry, (iii) Pain/Neurology, (iv) Urology and Ophthalmology. Pfizer (or a company that is now a member of the Pfizer group, such as Wyeth or Parke Davis) was the originator of these 20 molecules.[2] The Upjohn branded products have, with a few exceptions, lost exclusivity years ago, and all face generic competition in New Zealand.

Summary of competition analysis

1.4 The Proposed Transaction will combine Upjohn's portfolio of off-patent branded pharmaceutical products with Mylan's portfolio of generic pharmaceutical products. There are nine areas of potential overlap between the Parties (either at molecule and/or ATC4 level). However, the Proposed Transaction will not adversely affect competition in relation to any of these products.

1.5 As the relevant products supplied by the Parties in New Zealand are all off patent and the markets in question are genericised, funding by Pharmac is subject to tenders in which multiple suppliers can bid with the same molecules. These tenders are generally "winner takes all" competitions in which Pharmac awards sole supplier status for a given molecule on a nationwide basis: only the winning supplier's product will be funded. As a result, and since patients who are prescribed a given molecule overwhelmingly will choose to buy the product which at any given time is fully funded, competition is "for the market", and is not driven by pricing or quality interaction between suppliers and pharmacies or end customers. The Parties refer to this channel to market as the "public channel" on account of the public funding of the products selected in the tenders. Given the potential revenue available from these sole-supply tenders, in the public channel competition between suppliers of generic pharmaceuticals is particularly strong.

1.6 The "private channel" then refers to supply of non-subsidised products. For molecules that have lost exclusivity and in relation to which competition is genericised, the large majority of demand is through the public channel. Some patients may however choose not to purchase or switch to the product that at any given time is subsidised and instead (continue to) pay non-subsidised prices. The products sold through the private channel typically are branded products. Hence, while suppliers of off-patent, branded pharmaceuticals (such as Upjohn) may participate in the Pharmac tenders, they also invest in supply to the private channel typically through marketing and educational efforts. Mylan however is not focused on the private channel, and the Parties submit

[1] Sildenafil is separately marketed (depending on the strength) as both Viagra (treatment for erectile dysfunction) and Revatio (treatment for pulmonary arterial hypertension). In New Zealand, not all 21 brands are marketed and in some instances, the Upjohn molecules are also sold under non-branded names, such as Celecoxib Pfizer (referring to the molecule INN or International Non-Proprietary Name) instead of brand name Celebrex.

[2] For the sake of brevity, the Parties refer to "Upjohn" as the originator of the products throughout this filing.

that the Proposed Transaction will not have any meaningful impact on competition in this regard as the Parties do not compete or are at best distant competitors:

(a) there is no direct, ongoing competitive constraint between the public and private channels since the terms of supply in the public channel are fixed for the period for which the sole-supply contract is awarded and patients choose the products in question on the basis of the public funding;

(b) there also is no meaningful competition between the Parties within the private channel as competition is driven by brand loyalty, while any price sensitive patients are likely to switch to the funded products.

1.7 The one limited exception where there may be more direct competition between the Parties in the private channel concerns the supply of pharmaceuticals for indications that are not Pharmac funded. This is the case in relation to the Parties' overlapping sildenafil products, for which one of the indications (erectile dysfunction) is not Pharmac funded. In this case, competition for erectile dysfunction products takes place in the private channel among several rival suppliers.

Overlaps resulting from the Proposed Transaction

1.8 At a molecule level, there are five products where the Parties overlap in New Zealand. Four of these are subject to Pharmac tenders, and hence competition is driven almost exclusively by the Pharmac tender process "for" the market.

1.9 In relation to each of these four molecule overlaps, several competitors will remain in addition to the merged entity following completion of the Proposed Transaction. Furthermore, given the size of the tender contracts and the Pharmac process which encourages bids from both existing and new suppliers, there is also strong potential competition from suppliers not currently active in supplying the molecule in New Zealand.

1.10 In the fifth category with overlap at the molecule level (sildenafil), the relevant competition is between suppliers of erectile dysfunction treatments in the private channel. Pharmac does not fund any molecules for erectile dysfunction. However, Mylan's generic sildenafil product is Pharmac funded for other indications and this also limits the price at which its product is available for sale on a non-funded basis for the treatment of erectile dysfunction. In addition, there is strong existing and potential competition from other generics and other branded originator products within the broader ATC4 category.

1.11 Assessed at the broader "ATC4" level, there are five ATC4 categories where the Parties could be said to "overlap", albeit notionally only as they supply different molecules. In each case, competition at the molecule level is driven by Pharmac tenders and the Parties do not compete in this respect, and to the extent they would be considered to compete at all outside the Pharmac tenders (for residual supply through the private channel) they face strong competition from other generics and as well as suppliers of branded products with the same or similar therapeutic indications, such that no competition concerns arise.

1.12 The areas of (notional) overlap are set out below, grouped by reference to categories discussed above:

(a) overlaps at molecule level where competition is driven by Pharmac tenders;

(b) overlap at molecule level where competition occurs mainly across the private channel (i.e. it is not primarily driven by Pharmac, although Pharmac tender pricing does affect pricing in the private market); and

(c) notional overlaps at ATC4 level (but with no overlap at molecule level) where competition is driven by Pharmac tenders.

Overlaps at molecule level where competition is driven by Pharmac tenders

1.13 **Cholesterol and triglyceride regulators**: the Parties overlap in the supply of the atorvastatin molecule (a statin product). Atorvastatin is open to generic competition and supply is subject to Pharmac tenders. Mylan's Lorstat product is currently funded by Pharmac, while Upjohn's branded Lipitor product is not subsidised and does not make material sales. A number of competitors (including Apotex, Dr Reddy's, Carsl Consulting and Te Arai) have atorvastatin products registered in New Zealand and will be able to compete for future Pharmac tenders.

1.14 **Non-steroidal anti-rheumatics (in particular, coxibs)**: the Parties overlap in the supply of the celecoxib molecule, which is used for the treatment of pain and inflammation. Celecoxib is open to generic competition and supply is subject to Pharmac tenders. Upjohn's Celebrex product is currently funded by Pharmac, while Mylan's generic Celostea product is not subsidised and has been discontinued in New Zealand. Accordingly there is unlikely to be competition between the Parties for future celecoxib tenders irrespective of the Proposed Transaction. In any event, a number of competitors (including Apotex and Teva) have celecoxib products registered in New Zealand and will be able to compete for future Pharmac tenders.

1.15 **Anti-epileptics**: the Parties overlap in the supply of the gabapentin molecule, which is used for the treatment of epileptic seizures. Gabapentin is open to generic competition and supply is subject to Pharmac tenders. However, neither of the Parties' products are currently Pharmac funded, with Apotex's gabapentin product currently enjoying sole-supply status. Teva and Douglas also have gabapentin products that will be able to compete against Apotex and the merged entity in future Pharmac tenders.

1.16 The Parties also supply a range of other anti-epileptic products, but none of these have competitive overlaps at the molecule level (where competition for Pharmac tenders takes place) such that no competitive concerns will arise from the Proposed Transaction.[3]

1.17 **Antidepressants and mood stabilisers**: the Parties overlap in the supply of the venlafaxine molecule,[4] which is used for the treatment of depression. Venlafaxine is open to generic competition and supply is subject to Pharmac tenders. Mylan's Enlafax XR product is currently funded by Pharmac, while Upjohn's branded Efexor XR product is not subsidised, but makes a material amount of private sales. A number of competitors (including Teva and Rex) have venlafaxine products registered in New Zealand and will be able to compete for future Pharmac tenders.

1.18 The Parties also sell other antidepressant products, but there is no overlap at a molecule level (where competition for Pharmac tenders takes place). Accordingly, the Proposed Transaction will not result in any adverse competitive effects in this category.[5]

Overlap at molecule level where there is private market and Pharmac tender competition

1.19 **Erectile dysfunction products**: The Parties overlap in the supply of the sildenafil molecule, insofar as it is indicated for the treatment of erectile dysfunction. Upjohn supplies its branded Viagra product. Mylan supplies Vedafil, a generic version of the sildenafil molecule.

1.20 Vedafil is Pharmac funded for the treatment of pulmonary arterial hypertension (**PAH**), Raynaud's syndrome and erectile dysfunction secondary to spinal cord injury requiring pharmacological treatment. Pharmac does not otherwise fund products indicated for erectile dysfunction and

[3] These products are discussed in full at section 19.
[4] The venlafaxine molecule is classified in ATC4 N6A5 for serotonin-noradrenaline reuptake inhibitors (**SNRI**s), which sits within the broader ATC3 N6A for antidepressants. The Parties also have an ATC4 (but not molecular) overlap in the antidepressants category (in ATC4 N6A4 for selective serotonin reuptake inhibitors (**SSRI**s)). However, this overlap does not give rise to any competition issues and Upjohn's product has de minimis sales. The extent of the Parties' overlap in antidepressants is set out in section 20.
[5] These products are discussed in full at sections 20 and 25.

Upjohn does not participate in the Pharmac tenders for sildenafil. Accordingly, the relevant overlap is in the private channel for sales of erectile dysfunction treatments.

1.21 As the innovator product for erectile dysfunction treatment, Viagra enjoys substantial brand equity and sets its prices accordingly. On the other hand, Vedafil is available to pharmacists at price negotiated with Pharmac and published on the Pharmac Schedule. This price applies even where the pharmacist sells the product for the treatment of erectile dysfunction and the Pharmac subsidy does not apply. Accordingly, the price of Vedafil to pharmacists for onsale into the private erectile dysfunction market is effectively fixed by the Pharmac contract price. While this may impact on the price of erectile dysfunction products sold on the private market, there is not ongoing price competition between Vedafil and other erectile dysfunction products as the Vedafil price can only change at the next tender round.[6] It also means pharmacists currently have an incentive to promote sales of Vedafil over other sildenafil products (since they are able to increase the price at which they sell to consumers significantly above the funded price, and retain the mark-up). This advantage in terms of volume of sales could be taken up by a future winner of the Pharmac tender for sildenafil.

1.22 In any event, following the Proposed Transaction the merged entity will continue to be constrained by other generic suppliers with equivalent sildenafil products, particularly Douglas, which already has material sales. In addition, Teva has a generic sildenafil product registered in New Zealand for the treatment of erectile dysfunction and could re-commence making sales.

1.23 At the ATC4 level are other originator products indicated for erectile dysfunction including Lilly with Cialis. Cialis is based on a different molecule (tadalafil) that will soon face generic competition. In addition, Bayer with Levitra is also present. Levitra is based on vardenafil, which remains under patent in relation to treatment of erectile dysfunction.

1.24 As a result, the Proposed Transaction would not result in any detrimental effect on competition for supply of these products.

Additional ATC4 (but not molecular) overlaps where competition is driven by Pharmac tenders

1.25 **Anti-epileptic products**: as mentioned above, in addition to the molecule overlap concerning gabapentin the Parties also supply a range of other anti-epileptic products for which there is no molecule overlap in New Zealand. Mylan supplies lamotrigine and clonazepam, whereas Upjohn supplies phenytoin and pregabalin. Because Pharmac tenders for supply of these products at a molecular level and there are no material private sales, no competition effects will arise.

1.26 **Diuretics (in particular, potassium sparing diuretics)**: while the Parties both sell products in this category, there are no overlaps at a molecular level in New Zealand. Mylan supplies spironolactone, whereas Upjohn supplies eplerenone. Because Pharmac tenders for supply of these products at a molecular level and there are no material private sales, no competition effects will arise.

1.27 **Calcium antagonist**:[7] while the Parties both sell products in this category, there are no overlaps at a molecular level in New Zealand. Mylan supplies felodipine, lercandipine, nifedipine, and verapamil-based products, whereas Upjohn supplies amlodipine. Because Pharmac tenders for supply of these products at a molecular level and there are no material private sales, no competition effects will arise.

1.28 **Selective Serotonin Reuptake Inhibitors**: in addition to the antidepressant venlafaxine discussed above, which falls under the broader ATC4 category Selective Norepinephrine Reuptake Inhibitors (SNRIs), the Parties also supply a range of other antidepressant products for which there is no molecule overlap in New Zealand, falling within the ATC4 category for Selective

[6] Mylan sells product to pharmacies who claim reimbursement for Pharmac-funded products as part of their District Health Board contract.
[7] The overlap in this regard is the same at the ATC3 and ATC4 level as there is no difference in the classification of calcium antagonist products at either level.

Serotonin Reuptake Inhibitors (SSRIs). Mylan supplies citalopram, escitalopram, fluvoxamine, paroxetine and fluoxetine-based products, while Upjohn supplies sertraline. Because Pharmac tenders for supply of these products at a molecular level and there are no material private sales, no competition effects will arise.

1.29 **Miotics and anti-glaucoma**: while the Parties both sell products in this category, there are no overlaps at a molecular level in New Zealand. Mylan supplies travoprost and dorzolamide/timolol products, whereas Upjohn supplies latanoprost. Because Pharmac tenders for supply of these products at a molecular level and there are no material private sales, no competition effects will arise.

No coordinated effects, no vertical effects

1.30 Finally, the Proposed Transaction does not result in any coordinated effects given, *inter alia*, the presence of many strong competitors in each relevant product category and the active role of Pharmac. Equally, the Proposed Transaction also does not result in any potential foreclosure issues.

1.31 In light of the above, Mylan and Upjohn submit that the Proposed Transaction will not result in a substantial lessening of competition in any New Zealand market.

Part B: The Parties

2. **Mylan N.V.**

2.1 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**).

2.2 Globally, Mylan manufactures and markets more than 1,400 different medicines to retail, wholesale, government and institutional customers. Its product portfolio in New Zealand specialises in off-patent medicines. Products distributed by Mylan NZ include:

(a) non-prescription medicines, such as:

(i) EpiPen (adrenaline for extreme allergic reactions);

(ii) Ferrograd (iron supplement);

(iii) Lora-tabs (allergy relief);

(b) prescription medicines, such as:

(i) Brufen (ibuprofen pain relief);

(ii) Norpress (nortriptyline antidepressant);

(iii) Simvastatin Mylan (simvastatin cholesterol and triglyceride regulator); and

(c) Vaccines; including:

(i) Influvac Tetra (inactivated influenza vaccine).

2.3 The generic products of Mylan in New Zealand span a number of therapeutic categories, dosage forms and delivery systems. A full list of all the products involved in the Proposed Transaction is set out at **Annex 1.**

2.4 In May 2019 Mylan exercised an option in a distribution arrangement with Aspen to buy a portfolio of prescription and OTC products in Australia and New Zealand (the **Mylan / Aspen Transaction**). A full list of the products Mylan acquired in New Zealand as a result of this transaction is included at **Annex 2**. None of these products are directly relevant to the Proposed Transaction as they do not overlap with any product supplied by Upjohn.

2.5 Mylan's 2018 Annual Report is available at www.mylan.com and the most recent audited accounts of Mylan New Zealand are attached at **Annex 3**. Mylan New Zealand is situated at 2B George Bourke Drive, Mount Wellington, Auckland. Mylan's office and Distribution Centre are co-located at this address.

Management

2.6 [*redacted*].

2.7 Contact details for Mylan:

Address	Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England

Contact person	Anil Amin
Email Address	[*redacted*]
Telephone	[*redacted*]
Website	https://www.mylan.com/

2.8 Please direct all correspondence and notices for Mylan to:

Address	Bell Gully Barristers and Solicitors PO Box 4199 Auckland 1140
Attention	Torrin Crowther / Glenn Shewan
Email Address	torrin.crowther@bellgully.com glenn.shewan@bellgully.com
Telephone	+64 9 916 8621 +64 9 916 8726

3. Upjohn (Pfizer)

3.1 Upjohn is a division of Pfizer which operates Pfizer's off-patent branded and generic established medicines business and is headquartered in China.

3.2 Upjohn has a portfolio of 20 molecules / 21 established brands organised across the following key therapeutic areas: Cardiovascular, Central Nervous System/Psychiatry, Pain/Neurology, Urology and Ophthalmology. Upjohn is active globally, with a focus on key emerging markets.

3.3 In addition, the Upjohn division which is party to the Proposed Transaction includes Greenstone LLC, a US-focused generics business. Greenstone manufactures and sells non-branded authorised generic versions of Pfizer branded products (and a very small number of authorised generics from Allergan) exclusively in the United States.

3.4 Upjohn does not have its own separate annual report but Pfizer's 2018 Annual Report is available from www.pfizer.com. The most recent audited accounts of Pfizer New Zealand and Pfizer PFE[8] are at **Annex 3**.

3.5 Pfizer is a pharmaceuticals company active worldwide in the research, development, manufacturing and marketing of innovative medicines. Further information in relation to Pfizer in New Zealand can be found at https://www.pfizer.co.nz/.

3.6 Pfizer (Upjohn)'s New Zealand location is Level 1, Suite 1.4, 8 Nugent Street, Grafton, Auckland. [*redacted*].

Management

3.7 [*redacted*]

[8]The Parties note that prior to December 2018 the majority of Upjohn products were owned by Pfizer NZ, however one product (Lyrica) was owned by Pfizer PFE.

3.8 [*redacted*]

3.9 Contact details for Upjohn:

Address	Upjohn Inc. 235 East 42nd Street New York New York 10017 United States
Contact person	Marc Brotman
Email Address	[*redacted*]
Telephone	[*redacted*]
Website	https://www.pfizer.co.nz/

3.10 Please direct all correspondence and notices for Upjohn to:

Address	Chapman Tripp Barristers and Solicitors Level 17, 10 Customhouse Quay, Wellington 6011
Attention	Lucy Cooper / Sophie Harker lucy.cooper@chapmantripp.com / sophie.harker@chapmantripp.com
Telephone	+64 4 498 2406 / +64 4 498 2413

Part C: The Proposed Transaction

4. Transaction structure

4.1 Under the Proposed Transaction, Upjohn and Mylan will combine to create a new wholly-owned and independently operated public company which will be incorporated in Delaware and will be active globally in the pharmaceutical sector.

4.2 Specifically, the Proposed Transaction occurs as follows:

(a) Separation of the Upjohn Business: Pfizer contributes and transfers the assets and liabilities of the Upjohn business (those assets and liabilities listed at 2.02 and 2.03 of the Separation and Distribution Agreement) to Upjohn Inc., which is a newly established company (Upjohn Inc. which will upon completion become the **Merged Entity**), in partial consideration for which Pfizer will receive a USD 12.0 billion cash payment from Upjohn Inc., which will be funded by new indebtedness to be incurred by the Merged Entity.

(b) Distribution of Upjohn Inc. Common Stock: Pfizer distributes Upjohn Inc. common stock to its shareholders, either through a pro rata distribution as a stock dividend or an offer of Merged Entity common stock to Pfizer's shareholders as a non-pro rata exchange offer.

(c) Combination with Mylan: Upjohn Inc. and Mylan combine by implementing a merger or asset sale,[9] resulting in the transfer of all of Mylan's assets and liabilities to Upjohn Inc. Upjohn Inc. is now the Merged Entity.

4.3 All of these steps will take place virtually simultaneously. Upon completion of the Proposed Transaction, the Upjohn business and Mylan's business will be wholly-owned by the Merged Entity. Mylan and Pfizer have announced in November 2019 that the new company to be formed by the planned combination of Mylan and Upjohn will be called Viatris. The new name, Viatris, will be effective upon closing of the combination.

4.4 By way of consideration for the Proposed Transaction, each Mylan shareholder will receive one share of the Merged Entity common stock for every Mylan ordinary share held by such shareholder immediately prior to closing, resulting in pro forma ownership of the Merged Entity at closing of 43% - existing Mylan shareholders and 57% - existing Pfizer shareholders.[10]

4.5 The Merged Entity will be a publicly held company, separately listed. It will not be controlled by any shareholder, unilaterally or jointly. The Merged Entity will also have its own manufacturing, marketing and distribution capabilities.

4.6 Post-Transaction Pfizer will be completely independent of the Merged Entity; it will not hold any ownership interest or governance right, or any ongoing operational or managerial oversight in the Merged Entity. This is because Pfizer is not a party to the business combination. It will no longer hold any ownership interest or governance right in Upjohn nor will it at any point in time hold any

[9] Mylan and Upjohn Inc. will undertake a merger or, if the merger cannot be completed within six months of the merger filings and publications in the Netherlands, an asset sale under Dutch law.

[10] Separate from to the Proposed Transaction described above, [*redacted*] Mylan has the right to conduct due diligence on Pfizer's subsidiary Meridian Medical Technologies, Inc. (**Meridian**) [*redacted*]. In the course of the diligence period, Pfizer, Spinco and Mylan shall negotiate in good faith a purchase agreement (**Meridian Purchase Agreement**) whereby Pfizer will transfer the Meridian business to Spinco on terms to be agreed. If at the end of the diligence period, Mylan [*redacted*] is satisfied with the results of the diligence review and with the terms of the Meridian Purchase Agreement, Pfizer and Spinco shall as soon as possible enter into the Meridian Purchase Agreement for Spinco to acquire Meridian from Pfizer ("Meridian Acquisition"). If the Proposed Transaction is validly terminated pursuant to the Business Combination Agreement, the [*redacted*] Meridian Purchase Agreement, if entered into, will also terminate automatically. [*redacted*].
Meridian is entirely separate from the Upjohn Business. It manufactures emergency care treatment products for military and civilian use, some of which are sold to the US army and foreign ministries of defence or health (see www.meridianmeds.com/about). [*redacted*] Meridian has limited direct sales outside the United States. [*redacted*] there is no overlap between Meridian and either of the Parties in New Zealand. Given that the Meridian Acquisition, if it happens, is separate from the Proposed Transaction and does not generate any aggregation in any relevant market in New Zealand, the Parties do not discuss it further in this notice.

shares in or control Mylan, as the combination between Mylan and Upjohn occurs after Upjohn is separated from Pfizer.

4.7 Upon closing of the Proposed Transaction, Pfizer stockholders will own 57% of the Merged Entity's common stock and former Mylan shareholder will own 43% of the Merged Entity's common stock. Although there is some overlap between shareholders and stockholders of Mylan and Pfizer, respectively, no stockholder will own sole or joint control of the Merged Entity following closing of the Proposed Transaction. Since Mylan ordinary shares and Pfizer common stock are, and the Merged Entity's common stock will be, publicly traded, ownership is and will be widely dispersed with no shareholder in either company having any governance or control rights such that each company are and will be controlled by their respective boards and management teams.

4.8 Based on the current Mylan and Pfizer ownership structure, the largest shareholders in the Merged Entity, of which each will hold less than 10% as of closing, will be institutional investors (asset managers and pension funds) that make passive investments in publicly-traded companies and do not use their investment to direct or change the strategic conduct of companies in which they invest.

4.9 None of the persons selected by Pfizer to be on the board of the Merged Entity after the closing of the Proposed Transaction will be a director, officer or employee of Pfizer after the closing. The board members selected by Pfizer are intended to be board members of only Upjohn after the closing. Under Section 3.7 of the Business Combination Agreement, the three persons selected by Pfizer to be on the board of the Merged Entity will each be in a different class of the board, such that the first director's board seat will be up for election in 2021, the second director's board seat will be up for election in 2022 and the third director's board seat will be up for election in 2023. Each director of the Merged Entity, including the Pfizer-selected directors, will have a fiduciary duty to the Merged Entity. In accordance with US antitrust law, there will not be any interlocking board membership between Pfizer and the Merged Entity in the future.

4.10 The first Board of Directors of the Merged Entity will include its Executive Chairman and its CEO, as well as eight members designated by Mylan, and three members designated by Pfizer, for a total of thirteen members. As of the date of closing of the Proposed Transaction, the executive officers of the Merged Entity will include: (i) Robert J. Coury, Mylan's current Chairman, who will serve as Executive Chairman of the Merged Entity, (ii) Michael Goettler, current Group President of Upjohn, who will serve as CEO of the Merged Entity, (iii) Rajiv Malik, current Mylan President, who will serve as President of the Merged Entity, and (iv) a CFO jointly selected by Pfizer and Mylan, following a search initiated by Mylan. These initial appointments are made because the Merged Entity will require directors on day 1. Neither Party has any right to appoint directors on an ongoing basis – these will be appointed by the shareholders of the Merged Entity in accordance with the company's by-laws in the usual way for a public company.

4.11 The new company will be domiciled in the U.S. and incorporated in Delaware and will operate Global Centres in Pittsburgh, Pennsylvania; Shanghai, China, and Hyderabad, India.

5. Rationale

5.1 The Merged Entity will deliver enhanced global scale and geographic reach, including leading positions in China and other emerging markets.

5.2 The transaction will allow the new company to meaningfully expand the geographic reach of Mylan's existing broad product portfolio and future pipeline into new growth markets where Upjohn has existing sales infrastructure and local market expertise.

6. Transaction documents

6.1 Links to the relevant transaction documents follow:

(a) Business Combination Agreement;

(b) Separation and Distribution Agreement

6.2 The Parties will also enter additional agreements, including a Tax Matters Agreement, an Employee Matters Agreement, an IP Matters Agreement, Transition Service Agreements, Manufacturing and Supply Agreements, Trademark License Agreements, and other commercial agreements - as is customary in this type of transaction

7. Clearance sought

7.1 This application seeks clearance for the creation of the Merged Entity through the Proposed Transaction and in accordance with the steps described in section 4 above, following which current Mylan shareholders will own 43% and current Pfizer shareholders will own 57% of the Merged Entity, with no shareholder having the possibility of a substantial degree of influence over the Merged Entity.

8. Global filings

8.1 Table 1, below, sets out the jurisdictions in which the Proposed Transaction is subject to merger notification and the dates that the relevant agencies in those jurisdictions have been or will be notified.

Table 1 - Overseas competition agencies notified

Jurisdiction	Agency	Date of notification
[*redacted*]	[*redacted*]	[*redacted*][11]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*][12]
[*redacted*]	[*redacted*]	[*redacted*]

[11] [*redacted*].
[12] [*redacted*].

Jurisdiction	Agency	Date of notification
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]

8.2 Closing of the Proposed Transaction is conditional upon, *inter alia*, the Parties having obtained clearance from various competition authorities, including the US FTC and the European Commission. Closing is expected to take place in mid-2020, subject to necessary approvals.

Part D: Background

9. The regulatory regime applying to the Products

9.1 Pharmaceutical products are generally divided into two categories, prescription (**Rx**) and over the counter (**OTC**) medicines.

Medsafe

9.2 Before any pharmaceutical product can be supplied in New Zealand, it must be approved by the New Zealand Medicines and Medical Devices Safety Authority (**Medsafe**) which ensures that pharmaceutical products supplied in New Zealand have acceptable efficacy, quality and safety. If the medicine is approved, the supplying company then decides if the medicine will be supplied in New Zealand. The process for obtaining Medsafe approval is set out in detail in the *Ease of entry* section below.

Pharmac

9.3 Once a prescription medicine has been approved by Medsafe, the supply and funding of the vast majority of these medicines are controlled by the Pharmaceutical Management Agency (**Pharmac**).

(a) Pharmac decides, on behalf of District Health Boards, which medicines and related products are subsidised for use in the community and public hospitals.

(b) For genericised products such as those at stake here, once Pharmac has decided to subsidise a medicine, it will typically select its preferred supplier for that medicine through a tender process, with the winning bidder obtaining the right to be the sole supplier of that product for a fixed term (usually three years).

(c) Pharmac can also accept alternative commercial proposals from a supplier if it considers it is able to negotiate a better deal outside of the tender process (for example, when it is considering entering into agreements for the supply of multiple products from a single supplier).

Patented vs generic pharmaceuticals

9.4 Most pharmaceutical products are small molecule medicines, comprised of chemicals formulated to a standard chemical recipe. The active ingredient in a small molecule medicine has a chemical structure that is simple and small. The original manufacturer of the product (often referred to as a 'brand leader' or 'originator') will usually apply for, and be granted, a patent. A patent allows the brand leader to manufacture and sell that product exclusively for a period of time with limited competition, other than from alternative pharmaceutical products containing different molecules that treat the same condition.

9.5 Once a brand leader's patent has expired, other companies can make and sell generic pharmaceuticals which are copies of the original pharmaceutical product produced by the brand leader. Since clinical trial data on the safety and efficacy of the molecule is already available from the innovator, additional clinical trials and studies are not generally required for generics to be approved by regulators. Instead, simpler and cheaper bioequivalence studies, performed to internationally agreed standards, are accepted by regulatory authorities worldwide, including in New Zealand. Typically, there are a number of manufacturers developing generic medicines in anticipation of the expiry of the patent on the innovator medicine. Due to this regulatory framework and competition, generic medicines are typically cheaper than the original innovator medicine.

9.6 The Proposed Transaction involves only generic and off-patent branded prescription products. As such, there are no limits on generic competitors developing directly competitive products to those of the Parties using the same molecules.

10. Overview of the generic pharmaceutical industry in New Zealand

10.1 The manufacturing of a pharmaceutical product consists of a two-stage process: the production of raw materials and the actual manufacturing of the finished dosage product. The product is then packaged and provided for wholesale and retail distribution. In order to reduce the costs associated with the manufacturing process, pharmaceutical companies often outsource all or part of the manufacturing process to third parties. For products sold in New Zealand, most stages of manufacturing and packaging occur offshore (with some limited exceptions).

Production of Raw Materials

10.2 The first phase of generics production involves the production of chemicals used to manufacture pharmaceutical drugs. Any drug or medication is composed of two sets of components: Active Pharmaceutical Ingredients (**API**s) and excipients (inactive substances that serve as a vehicle for the API itself, e.g., the liquid, in the case of a drug delivered in syrup format).

10.3 Pharmaceutical suppliers often outsource the supply of APIs to third party bulk pharmaceuticals suppliers, many of which are located in India and China. Major manufacturers of APIs include: Aurobindo (India), Cipla (India), Dr. Reddy's (India), DSM (The Netherlands), Sun (India), and Teva (through its subsidiary Teva Active Pharmaceutical Ingredients) (Israel). Mylan also produces certain APIs for its own products and makes some sales of APIs to third parties (however none to third parties in New Zealand).

Manufacturing of Finished Dose Products

10.4 The manufacturing processes for finished dose pharmaceuticals from active ingredients is undertaken by suppliers themselves or outsourced. This involves combining the API and excipients into the required galenic form. This can either be done by the pharmaceutical supplier in-house or be outsourced to a third party.

Packaging

10.5 During packaging, the medicinal product is placed in containers that conforms to prescribed standards with respect to maintaining the integrity of the product, e.g., preventing any moisture or light. Packaging covers all steps of the pharmaceuticals supply chain from filling and assembling of the product, to labelling and storage at the manufacturing and shipping sites.

Wholesale distribution

10.6 Wholesale distribution refers to the storing, supplying, importing/exporting, and movement of pharmaceutical products prior to retail supply to patients. There are several different models for the distribution of pharmaceutical products. For the majority, pharmaceuticals are sold through wholesalers, who maintain their own transportation and warehousing networks. However, distribution services are also available to suppliers. In New Zealand, [*redacted*]. All products commercialised by Upjohn in New Zealand are manufactured and packaged offshore. For wholesale distribution, Upjohn uses [*redacted*].

The Parties' sales and support operations in New Zealand

Mylan

10.7 [*redacted*]

Upjohn

10.8 [*redacted*]

10.9 [*redacted*]

11. Overview of the competitive landscape

Strong existing competition

11.1 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. In addition, there are a range of strong global competitors that could enter New Zealand with relative ease. These entities will continue to exert a strong competitive constraint on the Merged Entity.

11.2 Pharmaceutical companies already active in New Zealand include the following:

The Parties' key competitors

(a) AFT Pharmaceuticals (**AFT**)

AFT is a multinational pharmaceutical company headquartered in New Zealand, and with a presence in many other countries in Asia Pacific, including Australia. AFT develops, markets and distributes a broad portfolio of pharmaceutical products across a wide range of therapeutic categories which are distributed across all major pharmaceutical distribution channels: over-the-counter, prescription and hospital.

AFT's product portfolio includes patented, branded and generic drugs. In New Zealand, AFT markets, products in several therapeutic areas, including: Cardiovascular (including nitroglycerin), Central Nervous System/Psychiatry and Ophthalmology.

https://www.aftpharm.com/

(b) Apotex

Apotex is a Canadian-owned multinational pharmaceutical company. It has research, development, manufacturing and distribution facilities worldwide and exports its products to over 115 countries around the globe. It also has an established presence through subsidiaries and joint ventures or licensing agreements in Australia, Belgium, Czech Republic, Mexico, Netherlands, New Zealand, Poland, and Turkey (amongst others).

Apotex's product portfolio includes more than 300 generic pharmaceuticals. In New Zealand, Apotex markets (among others) products in the following therapeutic areas: Cardiovascular (including amiloride), Pain/Neurology, Urology, Central Nervous System/Psychiatry (including gabapentin, escitalopram and paroxetine), and Opthalmology.

http://www.apotex.com

(c) AstraZeneca

AstraZeneca is one of the world's largest pharmaceutical companies and is engaged in the research, development, manufacture and supply of medicines. It has three state-of-the-art research and development sites in Gothenburg (Sweden), Maryland (USA) and Cambridge (UK), and an established local presence in more than 80 countries.

It has a large portfolio of products for major disease areas including cancer, cardiovascular, gastrointenstinal, infection, neuroscience, respiratory and inflammation. In New Zealand, AstraZeneca markets (among others) pharmaceutical products in the following therapeutic areas: Cardiovascular and Central Nervous System/Psychiatry.

https://www.astrazeneca.com/

https://www.astrazeneca.com.au/

(d) Bayer

Bayer is a Life Science company with a more than 150-year history and core competencies in the areas of health care and agriculture. It has three divisions – Pharmaceuticals, Consumer Health and Crop Science – and an Animal Health business unit, which are also its reporting segments. In 2018, the Bayer Group comprised 420 consolidated companies in 90 countries throughout the world. Pharmaceuticals, Bayer's largest segment in terms of sales, focuses on researching, developing and marketing specialty-focused innovative medicines primarily in the therapeutic areas of cardiology, oncology, gynecology, hematology and ophthalmology. In 2017, Bayer employed 900 people and generated sales of AUD$1.2 billion in Australia and New Zealand.

Bayer markets pharmaceutical products in New Zealand in several therapeutic areas, including: Cardiovascular, Urology, and Central Nervous System/Psychiatry.

https://www.bayer.com/

https://bayer.co.nz/

(e) Douglas

Douglas is an expanding New Zealand-headquartered pharmaceutical company which researches, develops, manufactures, markets and distributes pharmaceutical and nutraceutical products worldwide. It also supplies automated dispensing machines to New Zealand pharmacies, and manufactures and distributes a range of consumer healthcare products.

Douglas' pharmaceutical products marketed in New Zealand span numerous therapeutic areas, including the following: Cardiovascular (including nitroglycerine), Urology (including sildenafil), Pain/Neurology, and Central Nervous System/Psychiatry (including lamotrigine).

https://douglas.co.nz

(f) Glaxosmithkline (**GSK**)

GSK is a global pharmaceutical giant with three global businesses that research, develop and manufacture innovative pharmaceutical medicines, vaccines and consumer healthcare products. Its Pharmaceuticals business has a broad portfolio of innovative and established medicines with commercial leadership in respiratory and HIV. GSK's R&D approach focuses on science related to the immune system, use of genetics and advanced technologies. GSK's portfolio contains products treating a broad range of acute and chronic diseases and is made up of both patented and generic medicines.

GSK markets pharmaceutical products in New Zealand in several therapeutic areas, including: Cardiovascular, Pain/Neurology, and Central Nervous System/Psychiatry (including lamotrigine and paroxetine).

https://www.gsk.com

https://nz.gsk.com

(g) Lilly

Lilly (previously Eli Lilly & Co) is a global pharmaceutical company headquartered in the US with offices in 18 countries. It has a wide portfolio with key business areas spanning oncology, diabetes, bio-medicines, and a strong pipeline. It is also the world's largest manufacturer and distributor of medications used in a broad range of psychiatric and mental health related conditions (including clinical depression, generalised anxiety disorder, drug addition, schizophrenia and others). Its products are sold in 125 countries worldwide.

Lilly markets pharmaceutical products in New Zealand across multiple therapeutic areas including Urology and Central Nervous System/Psychiatry (including fluoxetine).

https://www.lilly.com

https://www.lilly.co.nz

(h) Merck Sharp & Dohme (**MSD**)

MSD (or Merck & Co. in the US and Canada) is a multinational pharmaceutical company with core businesses in pharmaceutical products, vaccines and animal health. It also has a robust pipeline with a wide range of product candidates across each phase of development. MSD New Zealand supplies pharmaceuticals and vaccines for New Zealand patients across a broad number of therapeutic areas, including; oncology, anaesthesia, immunisations, cardiovascular, musculoskeletal, women's health, fertility, HIV/AIDS, antibacterials and antifungals.

In addition to its vaccines portfolio, pharmaceutical products marketed by MSD in New Zealand span numerous therapeutic areas, including: Cardiovascular (including simvastatin), Pain/Neurology, Nervous System, and Opthalmology (including dorzolamide with timolol).

https://www.msd-newzealand.com

http://www.msd.com

(i) Novartis

Novartis is a Swiss multinational pharmaceutical company, which is one of the largest in the world by both market capitalisation and sales. It has an extremely broad portfolio with products across almost all therapeutic sectors and is a leader in generic pharmaceuticals and biosimilars (with all Novartis' generics consolidated into its subsidiary Sandoz). Novartis products reach more than 750 million people globally.

Pharmaceutical products marketed by Novartis in New Zealand span several therapeutic areas, including: Cardiovascular (including isosorbide mononitrate and nitroglycerin), Pain/Neurology, Nervous System, and Opthalmology (including travoprost).

https://www.novartis.com

(j) Teva

Teva is an Israeli multinational pharmaceutical company specialising primarily in generic drugs, but other business interests include active pharmaceutical ingredients and, to a lesser extent, proprietary pharmaceuticals. It is one of the largest generic drug manufacturers in the world and has facilities in Israel, North and South America, Europe, and Australia. Its portfolio consists of over 35,000 products in almost all therapeutic areas.

Along with its established presence in generics, Teva has significant innovative research and operations supporting its growing portfolio of specialty and biopharmaceutical products.

In New Zealand, its marketed products span multiple therapeutic areas including: Cardiovascular (including amiloride), Pain/Neurology, Urology, Nervous System (including gabapentin, escitalopram and paroxetine), and Opthalmology.

https://www.tevapharm.com/

https://www.tevapharm.co.nz/

Other pharmaceutical companies active in New Zealand

(k) Airflow Products

Airflow Products is a New Zealand pharmaceutical company associated with the Asthma and Respiratory Foundation. It supplies pharmaceuticals, respiratory medical devices, diabetes care products and anti-allergen products in New Zealand with profits going directly towards the funding of asthma research and support for those with respiratory conditions.

https://www.air-flow.co.nz

(l) API

API is a New Zealand-based pharmaceuticals and personal care manufacturer with two manufacturing plants in Manukau. It manufactures high-quality pharmaceuticals at all stages of formulation from concept development through to production and packaging. It supplies to both domestic and international markets and is Medsafe and TGA licensed.

https://www.api.net.nz

(m) Aspen

Aspen is a leading specialty and branded multinational pharmaceutical company originating in South Africa and with a global presence. It continues to market prescription pharmaceuticals in New Zealand across therapeutic areas such as cardiology (including calcium antagonists and diuretics).

https://www.aspenpharma.com/

http://www.aspenpharma.co.nz/

(n) CSL

CSL is a global biotech / pharmaceutical company. It conducts business in over 60 countries, with major facilities in Australia, Germany, Switzerland, the United Kingdom and the United States. It has a large product portfolio, with its two core businesses focusing on protein biotherapeutics (CSL Behring) and influenza vaccines and other biologics (Seqirus).

https://www.csl.com

(o) Inova

Inova is a global pharmaceutical company which distributes a wide range of market-leading, branded prescription medicines and non-prescription healthcare products to over 20 countries across Asia, Australasia, and Africa. Its portfolio contains numerous category

leading brands, with products relating to weight management, cough and cold, throat, pain management, vitamins, health supplements, dermatology, cardiology (including nitroglycerin), respiratory health, allergy and female health products.

https://inovapharma.com/

https://inovapharma.com.au

(p) Multichem

Multichem is a privately owned New Zealand pharmaceutical company which services pharmacy and supermarket channels and hospitals. Multichem is equipped with a fully qualified and experienced regulatory support team to assist in the registering and development of pharmaceuticals in New Zealand and the Pacific Island markets. Multichem supplies customers directly from its two warehouse facilities in Auckland and distributes its products throughout New Zealand and the Pacific Islands.

https://www.multichem.co.nz/

(q) Roche Products

Roche is a Swiss multinational healthcare company that operates worldwide under two divisions: Pharmaceuticals and Diagnostics. It is the second largest pharmaceutical company worldwide and spends more than any other global company on pharmaceutical R&D. It has an extremely broad product portfolio and is particularly strong in the therapeutic areas relating to cancer, viral diseases and metabolic disorders. Roche has an office in Auckland and has serviced New Zealand for over 40 years.

https://www.roche.com/

https://roche.co.nz/

(r) Sanofi

Sanofi S.A. is a French multinational pharmaceutical company engaged in the research and development, manufacturing and marketing of pharmaceutical drugs principally in the prescription market. Sanofi's products cover seven major therapeutic areas: cardiovascular, central nervous system, diabetes, internal medicine, oncology, thrombosis and vaccines.

https://www.sanofi.com/

https://www.sanofi.com.au

Ease of entry

11.3 In order to market any pharmaceutical product in New Zealand, a pharmaceutical company must make an application to Medsafe (called a New Medicine Application or **NMA**). This application includes information that demonstrates the medicine meets New Zealand and internationally recognised standards for quality, safety and efficacy. Medsafe reviews this information and makes a recommendation to the Minister as to whether the medicine is approvable, or otherwise. If the medicine is approved, the New Zealand sponsor company then decides if the medicine will be supplied in this country.

NMAs and the abbreviated approval process

11.4 If a full new medicine application process is undertaken for a drug, the registration process typically takes between 15 and 18 months. However, Medsafe will grant priority status (upon

application) to certain NMAs if the medicine for approval is likely to result in significant clinical advantage or significant potential cost savings to the tax payer.

11.5 However, of particular relevance to generic products, Medsafe will also allow medicines that have previously been approved for use overseas to go through an abbreviated approval process. If a medicine is already approved by a Medsafe recognised regulatory authority (such as the Australian Therapeutic Goods Administration (**TGA**), the Health Products and Food Branch of Health Canada, or the European Medicines Agency), the overseas regulatory evaluation report will form the basis of Medsafe's evaluation and significantly reduce the New Zealand registration time to between 9 and 12 months.

11.6 As a large proportion of generic drugs brought to the New Zealand market are already approved for use overseas, many will qualify for the abridged Medsafe registration process.[13] The registration fee for a new intermediate-risk prescription medicine is $43,875, and this fee is reduced for the abridged process to $21,940. Accordingly, the Medsafe approval process does not present a meaningful entry barrier for pharmaceutical companies who wish to introduce their existing medications to the New Zealand market.

11.7 Furthermore, it is particularly easy for products that are already registered in Australia to gain registration in New Zealand. That is because the relevant regulators are comparable in their data requirements and level of review, both jurisdictions have full evaluation and abbreviated evaluation processes and both align with ICH and European data standards.

11.8 In theory, products can remain registered indefinitely, and suppliers will maintain registration until they choose to de-register the product or allow registration to lapse. Factors that may influence a supplier's choice to deregister include:

(a) product or manufacturing site quality issues that cannot be resolved. Sites may then also lose GMP/Health authority approvals;

(b) production unit closure, where it is uneconomical or not technically feasible to transfer product production to a new site;

(c) product registration may be superseded by other registrations;

(d) product supply chain and cost of goods may not be competitive against competitor products, leading to abandonment of the product registration; and

(e) sustained exclusion from supply due to tenders being consistently won by competitors. It becomes more economic in this situation for suppliers to allow registration to lapse and then re-register when intending to compete for a specific tender.

Manufacturing facilities

11.9 Entry also does not require local manufacturing facilities, provided pharmaceutical companies can offer the regulatory requirements relating to supply security. Most of the largest multi-national pharmaceutical companies, including Mylan and Upjohn, do not have manufacturing facilities in New Zealand, but rather import (either finished or in bulk to be repackaged). Products can then be sold in New Zealand through distributors such as DHL, who supply products directly either to customers or other wholesalers.

Ability to participate in Pharmac tenders

11.10 The extent of new entry reveals that registration is not a barrier to participating in Pharmac tenders. Indeed, there are instances of registrations being lodged after tenders have closed (as a means of securing a competitive advantage by not disclosing an intention to bid) and Pharmac will

[13] For example, [*redacted*].

be incentivised to accommodate tenderers who are moving through the registration process where that tenderer's offering is attractive.

11.11 Further, subject to Pharmac's assessment of the level of uncertainty, if the price offered by a would-be supplier, conditional on Medsafe approval, is sufficiently attractive that there would be a material saving over the period of the tender (i.e. even taking into account the delay until supply is available during which time the incumbent would continue to supply at the existing price), Pharmac might be willing to delay awarding a tender until the product has received Medsafe approval.

11.12 There are no strict criteria by which Pharmac evaluates tender bids, but it likely takes into account the published criteria set out in schedule 3 of its Invitation to Tender. These include:

(a) ability to provide continuous supply;

(b) pack size;

(c) pricing;

(d) amount and timing of the potential cost savings;

(e) registration status of the product; and

(f) any other benefits to the funder.

11.13 [*redacted*]

11.14 For new entrants to New Zealand, Pharmac tends to assume large, well-known multinationals have reliable supply, and brand new, smaller, entrants may be awarded smaller or less critical tenders first, as a test of reliability. If those are successful trust will build up. Subject to proof in relation to supply reliability, suppliers do not need to be large to supply the New Zealand market and can do so with a small presence (e.g. they don't always need sales support/marketing or other facilities).

Generic substitution

11.15 In New Zealand, generic medicines are widely used. Pharmac applies a reference pricing policy to funded products to ensure that generic pharmaceuticals that have the same molecule and the same or similar therapeutic effect are subsidised at the level of the lowest priced 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 full subsidy occurs for the product with the lowest price.[14]

11.16 Pharmac's contracts with suppliers will sometimes also include an agreement to cap expenditure at a certain level, with the supplier agreeing to reimburse the cost of the pharmaceutical in excess of the cap in the form of rebates to Pharmac.

11.17 The increasing occurrence and promotion of generic substitution, and the pricing strategies employed by Pharmac, increase competition from bioequivalent medicines and limit the ability of pharmaceutical manufacturers to price above lowest cost generics.

[14] [*redacted*]

Supply outside Pharmac tenders

11.18 Prescription pharmaceuticals which are not Pharmac subsidised may still be purchased by consumers. This typically happens where:

(a) For off-patent products, consumers are willing to pay out of pocket for the product where Pharmac's funding is for an alternative version of the same molecule. In this scenario, sales of the Pharmac funded product (through the public channel) and any non-Pharmac funded version of the same molecule (through the private channel) do not materially constrain each other on an ongoing basis (given the Pharmac funded product remains subsidised at the same level through the period for which sole supply has been awarded). Rather, competition continues to be largely focused on the tender process for Pharmac funded sales, while ongoing non-funded sales are more likely to be constrained by rival branded products (if any).

For example, despite not remaining Pharmac funded, Upjohn's Effexor XR product has retained a material share of sales because some patients choose to pay for Effexor out of brand loyalty rather than receiving the funded generic product (Mylan's Enlafax XR) (see section 20 below). Accordingly while a company awarded a Pharmac tender usually will see its share of the relevant molecule increase very significantly to close to 100%, a small share of sales for the molecule may remain with non-subsidised products. Equally, while a company that was awarded a Pharmac tender will see its share again drop to close to 0% if the next tender is awarded to another company, it may retain a small share of sales.

As set out above, for the large majority of these sales competition for those patients has played out with the tender and there is no material constraint on Effexor from Enlafax subsequently. The Parties submit that the same applies for patients who never switch to a funded product, but from the outset decide to pay for the non-funded brand.

Upjohn but not Mylan actively invests in this private channel with its branded products. Further, branded products will tend to compete more closely with other branded products that are substitutable for a given treatment, in particular brands with significant brand equity. Such competition may take place between molecules, for example between originator products, as opposed to between originator products and their bioequivalent generic versions.

(b) Pharmac chooses not to subsidise pharmaceuticals for a particular therapeutic indication because this does not meet Pharmac's funding criteria.[15] For example, Pharmac does not subsidise products indicated for the treatment of erectile dysfunction.[16] In this scenario competition is not driven by Pharmac tenders so:

(i) Competition takes place at the prescriber level among all products with a similar therapeutic use. Patients may also influence the prescription decision given their knowledge of particular brands.

(ii) Where a prescription is written by a GP, once a molecule is prescribed, patients choose amongst products containing that molecule. Where a prescription is given by a pharmacist, the distinction between competition at the prescriber and consumer level is less clear.

(iii) Prescribers (GPs and, where relevant, pharmacists) will often be influenced by what support is provided around a product as in training resources and information, sample packs and educational information. When dispensing, pharmacists will in the first instance be influenced by what has been prescribed by the GP and what is requested by the consumer/patient. In assisting the consumer in choosing amongst

[15] Besides cost-effectiveness, Pharmac's criteria for funding decisions include availability of existing alternative medicines being already funded, clinical benefits and risks, as well as government priorities for health funding.
[16] Apart from erectile dysfunction caused by spinal cord injury. See also footnote 3 above.

products containing a prescribed molecule, pharmacists will also be influenced by the profitability opportunity that alternative products present and are also likely to be influenced by what product support is available with the product e.g. consumer leaflets, in-store training, consumer loyalty programmes.

(iv) In relation to ED in particular, sildenafil is available on pharmacist as well as GP prescription (as set out in the ED competition analysis below). However, the other molecules indicated for ED are available only on GP prescription. Marketing to patients and pharmacists is common for all molecules indicated for ED and there is not a lot of marketing to GPs. As noted above, pharmacists typically respond to patient specification of a product, although all else being equal they might prefer Vedafil sales over Viagra because they likely secure a higher margin from Vedafil. However, it is also important to note that pharmacists must follow a checklist to ensure their process is robust, and this may result in a recommendation to visit a GP.

(c) A health care professional would prefer not to switch a patient to the Pharmac funded product where the patient has been stabilised on another version of the molecule. In this scenario the health care professional can apply to Pharmac for the non-Pharmac funded product to be funded for this particular patient. The patient must meet very strict criteria for the pharmaceutical to be funded, and such funding is infrequent. Accordingly, in practice this has a negligible effect on sales of non-Pharmac funded products (and does not affect the competition analysis in relation to the Parties' products).

11.19 In any event, as the Parties discuss below, an analysis at the ATC4 level (which takes into account any potential competition between products with similar therapeutic effects) demonstrates that there are sufficient strong competitors remaining post-transaction to exclude any adverse impact on competition.

Pharmac as a monopsonist

11.20 Aside from the limited circumstances set out above, Pharmac exerts substantial countervailing power over the markets for all prescription pharmaceuticals. For the majority of generics, listing on the Pharmac schedule is necessary to have more than *de minimis* sales in New Zealand. Accordingly, competition 'for the market' happens during the Pharmac tendering process, rather than by any pricing or quality interaction between suppliers and end customers.

11.21 The Court of Appeal has acknowledged Pharmac's role as a monopsonist in *AstraZeneca Limited v Commission*:[17]

> *"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."*

11.22 It is likely that Pharmac, as the sole funder of generic molecules, would have the ability to manage the patient demand for any molecule in order to constrain a potential price increase post acquisition.[18] In addition, if at any tender bids are unsatisfactory, Pharmac is not bound to award a sole supply contract. Pharmac can instead roll over existing supply arrangements until a new supplier registers in New Zealand and may also accept alternative commercial proposals outside the tender.[19] Overall, Pharmac can use a broad range of procurement techniques in order to gain the best possible pricing.

[17] [2008] NZCA 479 at [19].
[18] *Mylan and Abbott Laboratories' Established Pharmaceuticals Division* [2014] NZCC 40 at [73].
[19] *Pfizer, Inc and Hospira, Inc* [2015] NZCC 19 at [43.1] to [43.5].

12. Summary of pharmaceutical product classifications

12.1 There are various ways of classifying or categorising pharmaceutical products, for example by molecule, or by the condition or symptom to be treated. One method of classification frequently used as a reference point in merger clearances in New Zealand and overseas is the Anatomical Therapeutic Chemical (**ATC**) classification system.

12.2 There are two main classification systems used in drug utilisation research worldwide – The ATC system developed and maintained by the European Pharmaceutical Marketing Research Association (**EphMRA**) and used by pharmaceutical data supplier IQVIA (formerly IMS), and the ATC classification developed by Norwegian researchers and used by the WHO.

12.3 The EphMRA ATC classification system is a generally adopted method of grouping certain pharmaceutical products used worldwide and adopted by the industry (including IQVIA) for providing market research statistics to the pharmaceutical industry. There are some technical differences between the EphMRA classification and the WHO ATC classification which means that the systems are not directly comparable for some drugs. Despite this, generally, codes are not be substantially different at the third level of classification, given the work on harmonisation of the two systems that has taken place. Consistent with the majority of merger decisions by competition authorities, including the European Commission (the **EC**)[20] and some decisions made by the New Zealand Commerce Commission (the **Commission**),[21] the present notification uses the EphMRA classification system in our analysis because the market share data on which our analysis is based has come from IQVIA/IMS (see section 14 below for further details on the use of ATC classification in market definition).

12.4 The EphMRA ATC classification guidelines classify medicinal products according to their indication, therapeutic use, composition and mode of action. As a general rule, any given product is assigned only a single ATC code, although different versions of a product available in different strengths or formulations with different indications may be assigned different ATC codes.

12.5 The EphMRA ATC classification system is a hierarchical and coded four-level system. The first level (ATC1) is the most general and the fourth level (ATC4) the most detailed. In the first and broadest level (ATC1), medicinal products are divided into one of the following 16 anatomical main groups:

Table 2 - EphMRA ATC Classification Level 1

LEVEL	MAIN GROUP	LEVEL	MAIN GROUP
A	Alimentary Tract And Metabolism	L	Antineoplastic And Immunomodulating Agents
B	Blood And Blood Forming Organs	M	Musculo-Skeletal System
C	Cardiovascular System	N	Nervous System
D	Dermatologicals	P	Parasitology
G	Genito-Urinary System And Sex Hormones	R	Respiratory System
H	Systemic Hormonal Preparations (Excluding Sex Hormones)	S	Sensory Organs

[20] See for example M.8974 *Procter & Gamble / Merck Consumer Health Business*, M.7919 *Sanofi/Boehringer Ingelheim Consumer healthcare Business*, M.6969 *Valeant Pharmaceuticals International/Bausch & Lomb Holdings*, M.577 *Novartis/Alcon*, and M.5865 *Teva/Ratiopharm.*

[21] For example, see *Schering Plough Corporation and Organon Biosciences NV* (Commerce Commission, Decision 621, 4 October 2007).

J	General Anti-Infectives Systemic	T	Diagnostic Agents
K	Hospital Solutions	V	Various

Source: EphMRA

12.6 The second level (ATC2) is either a pharmacological or therapeutic group, while the third level (ATC3) further groups medicinal products by specific therapeutic indications, i.e., their intended use.

12.7 The ATC4 level is a further subdivision which may be based on therapeutic, or 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. The Commission and the EC have previously had reference to the ATC3 class as a starting point for relevant product market definition purposes (see below).

12.8 The Parties have similarly used ATC3 as a reference point but have addressed competition at the molecule level below. ATC4 and, where relevant, ATC3 have then been considered.

13. Trade or industry associations

13.1 Relevant trade or industry associations that the Parties have involvement with are set out at **Annex 4.**

Part E: Relevant Markets

14. Introduction

14.1 The Proposed Transaction will result in the aggregation of Mylan's generic and Upjohn's generic and off-patent branded pharmaceutical products.

Previous approach to market definition by the Commission

14.2 The Commission defines markets in ways that best isolate the key competition issues that arise from the merger. In many cases this may not require the Commission to precisely define the boundaries of a market.

14.3 In previous decisions involving pharmaceutical products, the Commission has noted that there can be instances where it is necessary to take either a broad or a narrow approach to market definition. The approach will depend on the particular characteristics of the relevant pharmaceutical products and the conditions that the pharmaceuticals are used to treat.[22]

14.4 For generic medicines sold on prescription, the Commission has previously defined markets by beginning its analysis at the molecule level. For example, in *Mylan / Abbott*,[23] the merging Parties each supplied numerous antihypertensive products, but the only relevant overlap on a molecular level was for products containing the molecule verapamil. The Commission considered it appropriate in that context to define the relevant market on the basis of molecular overlap, being that for supply of verapamil-based products.

14.5 Similarly, in *Pfizer / Hospira*,[24] the Commission found it appropriate to define relevant markets by beginning at the molecule level, and further differentiating markets on the basis of route of administration and galenic form to reflect the granularity of Pharmac's demand.

14.6 The Commission has also assessed markets within therapeutic classes according to the ATC code. Within each level of ATC classification there can be a wide variety of products that contain different molecules which can be used to treat similar conditions and, therefore, may be considered to be substitutes for one another. Equally, narrower levels of the ATC classification such as ATC4 (the most granular level) can be used as a basis on which to distinguish particular products sitting in the same 'broader' category (such as ATC2 or ATC3). For example, in *Schering Plough / Organon*[25] which concerned products still under patent, the Commission used ATC classification as a basis on which to place products from a particular ATC4 (specifically B1B9) in a separate product market to similar products in the broader ATC3 (specifically B1B).

Previous approach to market definition by the EC

14.7 In relation to generic medicines sold on prescription, the EC has also considered that the most plausible product market is generally at the level of a molecule since generics are the closest substitutes to the originator product based on the same molecule. The EC then assesses the potential for these products to enter into competition with other products by reference to their characteristics, intended therapeutic use, and expected therapeutic and economic substitutability.[26]

14.8 A recent EC report to the European Parliament on pharmaceutical merger control notes in relation to defining markets for pharmaceutical products that *"if the main competitive threat comes from generic versions, which contain the same molecule, and the pressure from medicines containing*

[22] For example, see *GlaxoSmithKline Plc and Novartis AG* [2014] NZCC 37 and *Pfizer, Inc and Hospira, Inc* [2015] NZCC 19.
[23] *Mylan and Abbott Laboratories' Established Pharmaceuticals Division* [2014] NZCC 40, at [44] – [59].
[24] *Pfizer, Inc and Hospira, Inc* [2015] NZCC 19 at [63] – [85].
[25] *Schering Plough Corporation and Organon Biosciences NV* (Commerce Commission, Decision 621, 4 October 2007) at 11 – 12.
[26] See for example M.7746 *Teva/Allergan Generics*.

other molecules is significantly weaker, this may indicate that the market is narrower and limited to the investigated molecule alone."[27]

14.9 The EC has also referred to ATC3 as the starting point for defining the relevant product market. However, in a number of cases, the EC found that the ATC3 level classification did not yield the appropriate market definition within the meaning of 'market definition' in the 2004 EU Merger Regulation. In particular, in relation to branded and generic medicines, the EC has considered in previous decisions plausible product markets at the ATC4 level, at a level of a molecule or a group of molecules that are considered interchangeable so as to exercise competitive pressure on one another.[28] However, it should be borne in mind that the overlap in therapeutic uses does not necessarily imply any particular economic substitution patterns between products.

Approach taken by the Parties

14.10 The Parties consider that the Proposed Transaction will not raise competition concerns when assessed within any category. Given that the transaction only concerns products which have lost exclusivity and are supplied in markets where competition has been genericised, the large majority of the relevant sales in New Zealand are made through the public (Pharmac-funded) channel. Since Pharmac procurement processes are carried out by reference to individual molecules, the Parties have focused primarily on competition at the molecule level below. This has been done with reference to the most relevant precedent by the Commission.[29]

14.11 However, for completeness, the Parties have also provided information on notional overlaps at the ATC4 level (including for three areas in which there is overlap at ATC4 level but not at a molecule level).

14.12 ATC4 is however particularly relevant in relation to erectile dysfunction products where these products are exclusively sold in the private channel and other products with similar therapeutic uses may competitively constrain one another.

14.13 The product categories impacted by the Proposed Transaction are set out below. The sections are grouped by ATC3 class, and within each class the Parties first discuss the molecule overlap identified (where applicable), then add for completeness a discussion of the notional ATC4 overlap where relevant. That provides the following format:

(a) **ATC3** (ATC4):

(i) Molecule(s) supplied by both Parties.

(ii) ATC4.

14.14 The Parties have also grouped the chapters below according to the nature of the overlap (as indicated in the Executive Summary above) by:

(a) overlaps at molecule level where competition is driven by Pharmac tenders;

(b) overlap at molecule level for indications that are not funded (i.e. competition in the channel is not driven by Pharmac tenders); and

(c) notional overlaps at ATC4 level (but with no overlap at molecule level) where competition is driven by Pharmac tenders.

[27] Report from the Commission to the Council and the European Parliament "Competition Enforcement In The Pharmaceutical Sector" (2009-2017) https://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/report_en.pdf at 18.
[28] See Case M.8889 - *Teva / PGT OTC Assets* (2018) https://ec.europa.eu/competition/mergers/cases/decisions/m8889_375_3.pdf at [19].
[29] *Mylan and Abbot*t at [44] – [59].

14.15 The product categories addressed in this application are:

Overlaps at molecule level where competition is driven by Pharmac tenders

(a) **ATC3 C10A** Cholesterol and triglyceride regulators (C10A1 Statins (HMG-COA reductase inhibitors)):

(i) atorvastatin.

(b) **ATC3 M1A** Non-steroidal anti-rheumatics (M1A3 Coxibs plain):

(i) celecoxib.

(c) **ATC3 N3A** Anti-epileptics (N3A0 Anti-epileptics):

(i) gabapentin.

(d) **ATC3 N6A Antidepressants and mood stabilisers** (N6A5 SNRI antidepressants):

(i) venlafaxine.

Overlap at molecule level where competition is not driven by Pharmac tenders

(e) **ATC3 G4E Erectile dysfunction products** (G4E1 Erectile dysfunction products (PDE5 inhibitors)):

(i) sildenafil.

ATC4 (but not molecular) overlaps where competition is driven by Pharmac tenders[30]

(f) **ATC3 N3A** Anti-epileptics (N3A0 Anti-epileptics) (this ATC4 category also includes the gabapentin overlap set out above and is addressed in section 19 below alongside the assessment of the gabapentin overlap);

(g) **ATC3 C3A Diuretics** (C3A1 Potassium sparing agents plain);

(h) **ATC3 C8A Calcium antagonists** (C8A0 calcium antagonists plain);

(i) **ATC3 N6A Antidepressants and mood stabilisers** (N6A4 SSRI antidepressants);

(j) **ATC3 S1E Miotics and anti-glaucoma** (S1E2 Miotics and anti-glaucoma topical);

[30] The Parties note that New Zealand sales data indicates a potential ATC overlap in the ATC4 category C1E0, relating to nitrites and nitrates. Mylan supplies Duride (isosorbide mononitrate) in this category, while IQVIA data indicates sales of an Upjohn product, "nitroglycerin Pfizer". However Upjohn is not registered to sell this product in New Zealand. [*redacted*] In any event, there is no molecule overlap in relation to nitrites and nitrates and this category is not considered further in this application.

Part F: Competitive Assessment

15. The counterfactual

15.1 The Parties consider that, in the absence of the Proposed Transaction, there are two possible counterfactuals, either involving the continuation of the status quo [*redacted*]. These are expanded on below.

Status quo

15.2 Both Mylan and Upjohn would continue to operate as independent businesses on the market.

[*redacted*]

15.3 [*redacted*]

16. Note on market shares and the role of Pharmac tenders

16.1 Unless otherwise specified, the source of data used in this application is IQVIA (IMS), [*redacted*].[31] The data used is for the full year 2018. This has been cross checked against the year to date data for 2019. There are no material differences that could affect the competition assessment (and where major changes have occurred in Pharmac funding between years, this is described in the relevant section).

16.2 As set out above, for generic medicines Pharmac runs processes resulting in the successful bidder being granted sole subsidised supply of a medicine for a fixed term (usually three years), the security of which gives the supplier the maximum incentive to offer the best price. This dynamic results in the winning supplier 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 (and, *vice versa*, underestimate strength of competitors who may quickly gain a very large share of the market at the next round of tender). For example, in 2017 Pharmac awarded Mylan sole supply of the venlafaxine molecule, an SNRI antidepressant drug in ATC4 N6A5. Consequently, Mylan's share of this product category has increased from [*redacted*] in 2016 to [*redacted*] in 2018. This is discussed further in the competition assessment below.

16.3 Shares in relation to most of the relevant products are driven to a large extent by Pharmac's purchasing role. Display of shares at a molecule level is of limited use as high market shares in a given contract period might not be reflective of a stable market position, where market shares could quickly trend towards zero as a result of the outcome of the next tender (see below for more details). Nevertheless, market shares at the molecule level are provided for each molecular overlap, together with at the ATC4 level (for completeness) in the competition assessment in Part F below. All shares per product category are calculated based on value / revenue.

16.4 For the reasons set out above, market shares may not always reach 100% or fall to 0% with the award or loss of Pharmac funding because a small volume of residual demand remains outside the supply of funded products.

[31] [*redacted*]

Overlaps at molecule level where competition is driven by Pharmac tenders:

17. Competition assessment of C10A Cholesterol and triglyceride regulators

17.1 ATC code C10 is part of the anatomical group C relating to the cardiovascular system. ATC3 C10A contains lipid modifying agents, plain (meaning each molecule in this category is listed on its own rather than in combination with another molecule).[32]

17.2 Lipid modifying agents are used to regulate blood lipids (i.e. cholesterol and triglycerides), which are important biomolecules. Cholesterol, for example, is an essential component of the human cell membrane and a precursor for steroid hormones and bile acids. Triglycerides also play an important role in transferring energy from food into body cells. However, blood lipids in excess can be harmful to human health as they are a threat to coronary arteries and are therefore an important risk factor for coronary heart disease.[33]

17.3 Cholesterol and triglyceride regulators lower blood lipid levels and accordingly reduce the risk that patients with excess blood lipids will have an adverse health event. At ATC4 level there are several groups of cholesterol and triglyceride regulators all with slightly different mechanisms of action. Statins (ATC4 C10A1) and Fibrates (ATC4 C10A2) are the most widely used of these.

17.4 The Parties overlap in the supply of atorvastatin (C10A1 Statins). In addition, Mylan supplies simvastatin (also C10A1 Statins), but Upjohn does not. The Parties have therefore assessed this product category primarily on a molecular level, where they are competitors for the Pharmac tender. However, no competition issues arise in any market for cholesterol and triglyceride regulators however defined.

Atorvastatin - C10A1 Statins (HMG-COA reductase inhibitors)

17.5 Statins reduce the liver's natural production of LDL cholesterol and triglycerides, and raise HDL cholesterol. They accordingly help lower patients' overall risk of heart attack and stroke.[34] Upjohn's Lipitor was once the best-selling statin globally but following the expiry of its patent in 2011, several generic statins have become available in the last five years and this product category is now highly competitive.

The Parties' products

17.6 Mylan and Upjohn each supply statin products.

(a) Mylan:

(i) Lorstat (atorvastatin)

(ii) Simvastatin Mylan (simvastatin)

(b) Upjohn:

(i) Lipitor (atorvastatin)

17.7 Both atorvastatin and simvastatin work by blocking an enzyme that produces cholesterol in the liver, and in this way slow the production of cholesterol in the body.

[32] Anatomical classification guidelines 2019 at 47 https://www.ephmra.org/media/2485/atcguidelines2019final.pdf
[33] K Pahan "Lipid-lowerind drugs" Cell Mol Life Sci (2006) 63(10) at 1165–1178. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1986656/
[34] https://www.heartfoundation.org.nz/your-heart/heart-treatments/medications/statins

Competition for Pharmac funding of atorvastatin

17.8 Atorvastatin has lost exclusivity and is subject to Pharmac tenders. Mylan's product Lorstat is Pharmac funded for sole supply of atorvastatin. Mylan obtained funding for this product in 2017, [*redacted*] and, as a result, its market share at molecule level in 2017 went up to [*redacted*] from [*redacted*] in 2016. Upjohn's product currently has limited presence in the category [*redacted*] sales in 2018 and only [*redacted*] share at molecule level from sales outside Pharmac funding).[35]

Table 3 – 2018 shares for supply of atorvastatin

Competitors	Products	Total share	USD total
MYLAN	LORSTAT	[*redacted*]	[*redacted*]
UPJOHN	LIPITOR	[*redacted*]	[*redacted*]
Merged Entity		[*redacted*]	[*redacted*]
		[*redacted*]	[*redacted*]

17.9 The following competitors are also Medsafe registered to supply atorvastatin (although are not currently making sales) and would be able to compete with the Merged Entity at the next Pharmac tender for atorvastatin:

(a) Apotex;

(b) Dr Reddy's;

(c) Carsl Consulting; and

(d) Te Arai Biofarma.

17.10 In addition, there are a number of large pharmaceutical companies such as Teva, Novartis and Stada that sell atorvastatin-based products at a global level and who could easily enter the market in New Zealand. Novartis and Teva are already present in the New Zealand market with other products, which would make launch of atorvastatin in the country even easier. The revenue generated by Mylan over a one-year period from sale of atorvastatin (see table above) is sufficiently high to encourage entry.

17.11 In any case, given the sophisticated and powerful role of Pharmac, even the presence of two participants would be sufficient to ensure Pharmac could drive a competitive outcome. As such, given the number of Medsafe registered suppliers for atorvastatin, as well as the number of large multinational companies that could easily enter, there is no likely prospect that competition for the supply of atorvastatin in New Zealand could be impaired by the Proposed Transaction.

17.12 [*redacted*].[36]

17.13 Finally, as stated above, Pharmac has strong countervailing power and the means to intervene if the Merged Entity were to attempt to increase the price of atorvastatin post-Transaction above competitive levels (at the next tender round), thus making any attempt to try and raise profits to the expense of New Zealand consumers virtually impossible.

17.14 The Merged Entity is accordingly constrained by strong competition at tender level for this molecule and could easily lose Pharmac funding for Mylan's Lorstat (and the associated volume of sales of this product) at the next tender round. Accordingly no competition issues arise.

[35] As an aside, the factors that drive the price set by the Parties for unfunded products include [*redacted*].
[36] [*redacted*].

Broader ATC4 category for statins

17.15 The broader ATC4 class is described and analysed below for completeness.

17.16 Atorvastatin is one of the older statins in this ATC4 class. Pfizer's patent on the innovator atorvastatin product Lipitor expired in 2011, following which the statins product category generally has experienced an increasing penetration of generic drugs. This is evident in the fact that Mylan now has Pharmac funding for its generic atorvastatin product Lorstat, and there are other generics in this category (including those supplied by Apotex and Dr Reddys).

17.17 Suppliers of other statin products in this ATC4 include:

(a) AstraZeneca: Crestor (rosuvastatin)

(b) Apotex: Pravastatin Apotex (pravastatin)

(c) Merck & Co: Zocor (simvastatin)

(d) Teva: Simvistatin Teva (simvastatin)

(e) Douglas: Cholvastin (pravastatin)

Pharmac funding for other statin molecules (not including atorvastatin)

17.18 Simvistatin Mylan is currently Pharmac funded for sole supply of simvastatin.

17.19 Apotex's pravastatin product is also currently Pharmac funded for sole supply of pravastatin.

ATC4 category shares

17.20 The Parties' combined share at ATC4 level is lower than at molecule level. This is due to the fact that, within the ATC4 category, there are molecules for which: (i) Pharmac is funding a product offered by a competing supplier (e.g. Apotex' pravastatin) or (ii) are not yet funded by Pharmac (rosuvastatin) but make material sales. Table 4 below sets out the shares and products of the Parties and each of their competitors for 2018 by revenue (in $USD).

Table 4 - 2018 category shares for C10A1 statins

Competitors	Products	Molecule	Product share	Total share	$USD product	$USD total
MYLAN	LORSTAT	ATORVASTATIN	[*redacted*]		[*redacted*]	
	SIMVASTATIN MYLA	SIMVASTATIN	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
UPJOHN	LIPITOR	ATORVASTATIN	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
Merged Entity				[*redacted*]		[*redacted*]
ASTRAZENECA	CRESTOR	ROSUVASTATIN	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
APOTEX	PRAVASTATIN APTX	PRAVASTATIN	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
MERCK & CO	ZOCOR	SIMVASTATIN	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
TEVA	ARROW-SIMVASTATIN	SIMVASTATIN	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
DOUGLAS	CHOLVASTIN	PRAVASTATIN	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
Others				[*redacted*]		[*redacted*]
				[*redacted*]		[*redacted*]

ATC4 Analysis

17.21 As the table above illustrates, Mylan has a significant existing share of [*redacted*] but this is due to having Pharmac funding for the sole supply (by molecule) of both of its products. Upjohn has [*redacted*] of this product category (as it is not Pharmac funded).

17.22 At ATC4 level there is a host of large, well-resourced statin manufacturers including AstraZeneca, Apotex, Merck Sharp & Dohme, Teva and Douglas.

17.23 The ongoing trend in this product category is penetration by statins with new and more effective molecules. Rosuvastatin, one of the newest statin molecules, has been shown to materially outperform atorvastatin in reducing LDL cholesterol, total cholesterol, and non-high-density lipoprotein.[37] AstraZeneca's patent over Crestor, the innovator rosuvastatin product, expired in 2016, meaning the statin product category is likely yet to see the effects of generic penetration in relation to rosuvastatin. Rosuvastatin is not yet funded by Pharmac, but makes material sales. The Parties understand it is included in the draft 2019/20 tender.

17.24 On this basis, the Proposed Transaction does not give rise to any competition concerns for the Pharmac tender of atorvastatin, or in the statins category (or any broader category).

18. Competition assessment of M1A non-steroidal anti-rheumatics

18.1 ATC code M1A is part of the anatomical group M relating to the musculo-skeletal system. ATC3 M1A contains non-steroidal anti-rheumatics, which includes all non-hormonal anti-inflammatory products for systemic treatment of musculoskeletal inflammation (c.f. corticosteroids, which also treat inflammation but have a broad range of other effects and are designed to act like human hormones).[38]

18.2 Non-steroidal anti-inflammatory drugs (commonly referred to as **NSAID**s) are amongst the most widely used pharmaceutical products, both OTC and via prescription, for broad spectrum reduction of pain, fever, and inflammation. NSAIDs work by inhibiting the activity of cyclo-oxygenase enzymes (COX-1 and/or COX-2). COX-1 enzymes are useful to the body and are partly responsible for maintaining the lining of the stomach, whereas COX-2 is responsible for pain and inflammation in diseases such as arthritis.

18.3 There are two main NSAID categories: traditional NSAIDs (**tNSAID**s) such as ibuprofen, which fall within ATC4 M1A1, and coxibs, which fall within ATC4 M1A3. Coxibs specifically inhibit COX-2 where tNSAIDS inhibit both COX-1 and COX-2, meaning coxibs are likely to cause less stomach irritation than tNSAIDs. Products in each category are otherwise very similar in effect.

18.4 The M1A overlap between the Parties occurs in the coxib category, namely for supply of the celecoxib molecule.[39]

Celecoxib - ATC4 M1A3 Coxibs, plain

18.5 As set out above, coxibs specifically inhibit the COX-2 enzymes responsible for pain and inflammation (where traditional NSAIDS inhibit both COX-1 and COX-2). Coxibs are slightly newer than tNSAIDs and were developed to reduce the risk of peptic ulceration (stomach ulcers), which is associated with prolonged NSAIDs use. They are otherwise equally as effective as tNSAIDS in reducing pain and inflammation.

[37] M Bullano et al "Effectiveness of Rosuvastatin versus Atorvastatin in Reducing Lipid Levels and Achieving Low-density-lipoprotein Cholesterol Goals in a Usual Care Setting" (2007) 64(3) American Journal of Health-System Pharmacy at 276-284. https://www.medscape.com/viewarticle/551604

[38] Anatomical classification guidelines 2019 at 106. https://www.ephmra.org/media/2485/atcguidelines2019final.pdf

[39] Pfizer's Ponstan (mefenamic acid) product is not an Upjohn product and will remain with Pfizer. Ponstan falls within the tNSAID category.

18.6 There are three key coxibs sold in New Zealand: celecoxib, parecoxib (injectable) and etoricoxib.

The Parties' products

18.7 Mylan and Upjohn each supply products containing celecoxib, and [*redacted*].

(a) Mylan:

(i) Celostea (celecoxib)

(ii) [*redacted*].

(b) Upjohn:

(i) Celebrex (celecoxib) (which is marketed and supplied in NZ as **Celecoxib Pfizer**)

Competition for Pharmac funding of celecoxib

18.8 The only overlap between the Parties on the basis of molecule is for celecoxib. Upjohn's product Celecoxib Pfizer is Pharmac funded for the sole supply of celecoxib. Upjohn (then Pfizer) won this tender in 2017 (with Mylan also participating). With a share of [*redacted*], Mylan's product currently has *de minimis* presence in the category from sales outside Pharmac funding as set out in the market shares below.

Table 5 – 2018 shares for supply of celecoxib

Competitors	Products	Total share	USD total
MYLAN	CELOSTEA	[*redacted*]	[*redacted*]
UPJOHN	CELECOXIB PFIZER	[*redacted*]	[*redacted*]
	CELEBREX	[*redacted*]	[*redacted*]
Merged Entity		[*redacted*]	[*redacted*]
		[*redacted*]	[*redacted*]

18.9 The following competitors are also Medsafe registered to supply celecoxib and would be able to compete with the Merged Entity at the next Pharmac tender for celecoxib:[40]

(a) MSD;

(b) Teva; and

(c) Apotex.

18.10 In addition, there are a number of large pharmaceutical companies such as Teva, Zentiva and Novartis that sell celecoxib-based products at a global level and who could easily enter the market in New Zealand. Novartis and Teva are already present in the New Zealand market with other products, which would make launch of celecoxib in the country even easier. The revenue generated by Upjohn over a one-year period from sale of celecoxib (see table above) is sufficiently high to encourage entry.

18.11 In any event, even the presence of two participants would be sufficient to ensure a competitive tender. As such, given the number of Medsafe registered suppliers for celecoxib, as well as the presence of large multinational companies that could easily enter this space in New Zealand,

[40] [*redacted*].

there is no likely prospect that competition for the supply of celecoxib in New Zealand could be impaired by the Proposed Transaction.

18.12 Finally, as stated above, Pharmac has a strong countervailing power and has the means to intervene if the Merged Entity were to increase the price of celecoxib post-Transaction, thus making any attempt to try and raise profits to the expense of New Zealand consumers virtually impossible.

18.13 The Merged Entity is accordingly constrained by strong competition at tender level for this molecule and could easily lose funding for Upjohn's Celecoxib Pfizer (and the associated volume of sales of this product) at the next tender round. Moreover, there is a potential for future entry from large global suppliers which sell celecoxib in other countries. Accordingly no competition concerns arise.

Broader ATC4 category for coxibs

18.14 The broader ATC4 class is considered below for completeness.

18.15 As noted above, there are three key coxibs sold in New Zealand: celecoxib, parecoxib (injectable) and etoricoxib. Coxib injections and coxib tablets are not considered close substitutes as the injection is more commonly used for acute post-operative pain in the hospital setting and the tablets are used for both acute and chronic longer-term pain relief. From a prescribing perspective, etoricoxib and celecoxib are similar treatment choices however only celecoxib is funded.

Competitor products

18.16 There are three other strong existing competitors in the coxib product category, supplying products which compete with those supplied by the Parties:

(a) Teva: Celexocib Actavis (celecoxib). This product is currently not marketed but can compete in a future tender.

(b) MSD New Zealand: Arcoxia (etoricoxib).

(c) Pfizer: Dynastat (parecoxib). This product is Pharmac funded for the sole supply of parecoxib.

ATC4 category shares

18.17 The Parties' combined share at ATC4 level is lower than on a molecule basis. This is due to the fact that, within the ATC4 category, there are molecules where: (i) Pharmac is funding a product offered by a competing supplier (e.g. Pfizer's parecoxib) or (ii) are not yet funded by Pharmac (etoricoxib) but yet make material sales. Table 6 below sets out the shares and products of the Parties and each of their competitors for 2018 by revenue (in $USD).

Table 6 – 2018 category shares for M1A3 coxibs, plain

Competitors	Products	Molecule	Product Share	Total Share	$USD product	$USD total
MYLAN	CELOSTEA	CELECOXIB	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
UPJOHN	CELECOXIB PFIZ	CELECOXIB	[*redacted*]		[*redacted*]	
	CELEBREX	CELECOXIB	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
Merged Entity				[*redacted*]		[*redacted*]
PFIZER	DYNASTAT	PARECOXIB	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
MSD	ARCOXIA	ETORICOXIB	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
TEVA	CELECOXIB ACTAVIS	CELECOXIB	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
				[*redacted*]		[*redacted*]

ATC4 analysis

18.18 As set out above, Upjohn's Celebrex (celecoxib) is Pharmac subsidised. The category shares reflect this, with Upjohn holding [*redacted*] of this category with its funded supply of celecoxib. Mylan's Celostea celecoxib product is not subsidised and accordingly makes de minimis sales [*redacted*]. [*redacted*].

18.19 The Proposed Transaction does not give rise to any competition concerns on a molecular level or in the ATC4 category for M1A3 plain coxibs (or any other relevant NSAID category).

19. Competition assessment of N3A / N3A0 antiepileptics

19.1 ATC code N3A is part of the anatomical group N relating to the nervous system, and contains antiepileptics. Products in this category may be used to treat both seizures caused by epilepsy or neuropathic pain (caused by damage or disease affecting the somatosensory nervous system). Molecules in this category work in different ways to prevent seizures and pain, but generally they either alter electrical activity in neurons (nerve cells) by affecting ion channels in the cell membrane, or alter chemical transmission between neurons by affecting neurotransmitters (chemical messengers) in the synapses (the junctions between nerve cells).

Gabapentin – ATC4 NA30 antiepileptics

19.2 The relevant overlap between the Parties in this category occurs on a molecular level, for supply of products containing gabapentin. The only ATC4 subgroup in this category is N3A0, which contains all the products in ATC3 N3A (i.e. there is no difference in the classification of anti-epileptic products between ATC3 and ATC4). Accordingly, the analysis below has been carried out on the basis of molecular overlap, with an examination of constraint from products in the broader ATC3 category for completeness.

The Parties' products

19.3 Products supplied by Mylan in this category include:

(a) Nupentin (gabapentin);

(b) Logem (lamotrigine);

(c) Paxam (clonazepam); and

(d) [*redacted*].

19.4 Products supplied by Upjohn include:

(a) Neurontin (gabapentin);

(b) Dilantin (phenytoin); and

(c) Pregabalin Pfizer (pregabalin).[41]

Competition for Pharmac funding of gabapentin

19.5 As above, the relevant overlap between the Parties on the basis of molecule is for gabapentin. Gabapentin is an anticonvulsant medication used to treat partial seizures, which is tendered separately from the other antiepileptic molecules.

19.6 Neither of the gabapentin products supplied by the Parties are Pharmac funded. [*redacted*] Apotex's gabapentin product is currently the only one funded by Pharmac which is reflected in the molecule level shares below (including 2019 shares showing the change in the Pharmac contract).

Table 7 – shares for supply of gabapentin 2018 - 2019

Competitors	Products	2019 share	2019 USD	2018 share	2018 USD
MYLAN	NUPENTIN	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
UPJOHN	NEURONTIN	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Merged Entity		[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
APOTEX	APO-GABAPENTIN	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
TEVA	ARROW-GABAPENTIN	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
		[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]

19.7 The following competitors are also Medsafe registered to supply gabapentin and would be able to compete with the Merged Entity at the next Pharmac tender for gabapentin in 2020:

(a) Apotex;

(b) Teva; and

(c) Douglas.

19.8 The Pharmac funded brand of gabapentin changed to Apo-Gabapentin (supplied by Apotex) in mid-2018, where previously Arrow, Mylan and Upjohn's products had been funded. Prescribing restrictions were also removed. Accordingly, there is substantial competition at tender level for this product, and the Merged Entity will not have the opportunity to increase its share of sales in the short term.

19.9 In addition, there are a number of large pharmaceutical companies such Servier, Teva and Novartis that sell gabapentin-based products at a global level and who could easily enter the market in New Zealand. All of these international competitors are already present in the New Zealand market with other products, which would make launch of gabapentin in the country even easier. The revenue generated by Apotex over a one-year period from sale of gabapentin (see table above) is sufficiently high to encourage entry.

19.10 In any event, as noted above, given the power role of Pharmac, as few as two participants would likely be sufficient to ensure a competitive tender. As such, given the number of Medsafe registered suppliers for gabapentin, as well as the presence of large multinational companies that

[41] [*redacted*].

could easily enter this space in New Zealand, there is no likely prospect that competition for the supply of gabapentin in New Zealand could be impaired by the Proposed Transaction.

19.11 Finally, Pharmac has a strong countervailing power and has the means to intervene if the Merged Entity were to increase the price of gabapentin post-Transaction, thus making any attempt to try and raise profits to the expense of New Zealand consumers virtually impossible.

19.12 On this basis, no competition concerns arise at molecule level.

Broader ATC3 / ATC4 category for antiepileptics

19.13 The broader ATC3/ATC4 class has been considered for completeness. As indicated above, there are a number of products in the broader ATC3 / ATC4 category and a range of different molecules. It is an extremely crowded category with 20 other competitors making sales.

Pharmac funding for other molecules:

19.14 Lamotrigine: GSK's Lamictal is funded for 2 and 5 mg tabs (per 30), Teva's Arrow Lamotrigine is funded for 5mg tabs (per 56), and Mylan's Logem is funded for 25mg, 50mg, and 100mg tabs with a brand switch fee payable.[42] Teva, GSK and Rex Medical are also registered for supply of 25mg, 50mg, and 100mg tabs and could compete with the Merged Entity for funded supply of these forms. Douglas and Apotex have also previously been registered for supply of lamotrigine in New Zealand and in theory could re-register.

19.15 Clonazepam: Mylan's Paxam is funded for 500mcg and 200mg tabs, and Roche's Rivotril is funded for oral drops.

19.16 Phenytoin: Upjohn's Dilantin (plus its paediatric solution) is funded for supply of oral forms of Phenytoin. Phenytoin is indicated for focal seizures and generalised tonic clonic seizures; other molecules indicated for these include carbamazepine, gabapentinoids (for focal seizures), lamotrigine. [*redacted*].

19.17 Pregabalin: Upjohn is also funded for supply of Pregabalin. Like gabapentin, pregabalin is an anticonvulsant medication, but it is less effective than some other medications in this category. It is generally only used in combination with other treatments when those other treatments have not controlled the epilepsy symptoms. Gabapentin and Pregabalin are not subsidised in combination with each other (i.e. patients can only receive one of these molecules subsidised, not both). Gabapentin and pregabalin are used as adjunctive therapy for focal seizures. Competitors for pregabalin include phenytoin and vigabatrin.

ATC4 category shares

19.18 The Parties' combined share at ATC4 is lower than on a molecule basis. This is due to the fact that, within the ATC4 level, there are molecules for which Pharmac is funding a product offered by a competing supplier (e.g. Sanofi's sodium valporate product Epilim and GSK's lamotrigine product Lamictal). Table 8 below sets out the shares and products of the Parties and each of their competitors for 2018 by revenue (in $USD) at ATC3/ATC4 level.

[42] A brand switch fee is paid to pharmacists if there is a need to support a difficult brand change (e.g. if the pre-existing brand had been supplied for a long time).

Table 8 - 2018 category shares for N3A / N3A0 antiepileptics[43]

Competitors	Products	Molecule	Product share	Total share	$USD product	$USD total
MYLAN	NUPENTIN	GABAPENTIN	[*redacted*]		[*redacted*]	
	LOGEM	LAMOTRIGINE	[*redacted*]		[*redacted*]	
	PAXAM	CLONAZEPAM	[*redacted*]		[*redacted*]	
	FELBAMATE	FELBAMATE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
UPJOHN	NEURONTIN	GABAPENTIN	[*redacted*]		[*redacted*]	
	DILANTIN	PHENYTOIN	[*redacted*]		[*redacted*]	
	PREGABALIN PFIZ	PREGABALIN	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
Merged Entity				[*redacted*]		[*redacted*]
SANOFI	DEPAKINE	VALPROIC ACID	[*redacted*]		[*redacted*]	
	SABRIL	VIGABATRIN	[*redacted*]		[*redacted*]	
	URBANYL	CLOBAZAM	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
GLAXOSMITHKLINE	LAMICTAL	LAMOTRIGINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
REX MEDICAL LTD	EVERET	LEVETIRACETAM	[*redacted*]		[*redacted*]	
	MOTRIG	LAMOTRIGINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
TEVA	ARROW-LAMOTRIGINE	LAMOTRIGINE	[*redacted*]		[*redacted*]	
	TOPIRAMATE TEVA	TOPIRAMATE	[*redacted*]		[*redacted*]	
	ARROW-GABAPENTIN	GABAPENTIN	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
JOHNSON & JOHNSON	TOPAMAX	TOPIRAMATE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
NOVARTIS	TEGRETOL	CARBAMAZEPINE	[*redacted*]		[*redacted*]	
	TRILEPTAL	OXCARBAZEPINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
CSL	VIMPAT	LACOSAMIDE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
APOTEX	APO-GABAPENTIN	GABAPENTIN	[*redacted*]		[*redacted*]	
	APO-PRIMIDONE	PRIMIDONE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
Others				[*redacted*]		[*redacted*]
				[*redacted*]		[*redacted*]

*[*redacted*]

ATC4 analysis

19.19 Mylan's total share of this product category at ATC3 / ATC4 level is [*redacted*] and Upjohn's is [*redacted*] giving the Merged Entity an aggregate share of only [*redacted*]. There are strong competitors in this category, with Sanofi and Glaxosmithkline each holding [*redacted*] and [*redacted*] shares respectively, driven by their Pharmac funded products (Sanofi's sodium valporate product Epilim and GSK's lamotrigine product Lamictal).

19.20 Given there is competition at tender level for all the molecules supplied by the Parties, the Proposed Transaction does not give rise to any competition issues on a molecular level or in the product category for ATC3 N3A antiepileptics (or any broader category).

20. Competition assessment of N6A antidepressants

20.1 ATC code N6A is part of the anatomical group N relating to the nervous system. ATC3 N6A contains anti-depressants and mood stabilisers.[44] Antidepressants are drugs used for the treatment of major depressive disorders and other conditions, including some anxiety disorders and to help manage some addictions.

[43] While the IQVIA data references de minimis sales of Mylan's Felbamate, this has never been registered by Mylan and is not available in New Zealand.
[44] Anatomical classification guidelines 2019 p. 117 https://www.ephmra.org/media/2485/atcguidelines2019final.pdf

20.2 There are several kinds of antidepressants, including herbal antidepressants (which contain only herbal substances) and serotonin reuptake inhibitors. The modes of action differ slightly for each, but the most commonly used medical antidepressants work by blocking the reabsorption of serotonin, a neurotransmitter with a role in numerous physiological process but believed to strongly influence feelings of mental health and wellbeing. Serotonin reuptake inhibitors make more serotonin available to the brain and help regulate mood. They are 'second generation' antidepressants and have gradually replaced other antidepressants as the drugs of choice for treatment of major depressive disorder due to their improved tolerability and safety profile.

20.3 The Parties supply anti-depressants in the following ATC4 categories:

(a) ATC4 N6A5 serotonin-noradrenaline reuptake inhibitor antidepressants (**SNRI**s); and

(b) ATC4 N6A4 selective serotonin reuptake inhibitor antidepressants (**SSRI**s).

20.4 The only overlap between the Parties on a molecular level is for SNRI products containing venlafaxine.

Venlafaxine – ATC4 N6A5 SNRIs

20.5 SNRIs such as venlafaxine specifically inhibit the reuptake of serotonin and norepinephrine (whereas SSRIs inhibit the reuptake of serotonin only). There are three molecules in this product category, the most popular being venlafaxine (which is the only Pharmac funded molecule in this category).

The Parties' products

20.6 Mylan and Upjohn each supply a venlafaxine product.

(a) Mylan: Enlafax XR (venlafaxine)[45]

(b) Upjohn: Efexor XR (venlafaxine)

Competition for Pharmac funding of venlafaxine

20.7 The only overlap between the Parties is on a molecule basis is for venlafaxine.

20.8 Mylan's Enlafax XR is Pharmac funded for the sole supply of venlafaxine. Mylan obtained funding for this product in 2016 [*redacted*], and as a result, its market share at molecule level went from [*redacted*] in 2016 to [*redacted*] in 2018.

Table 9 - 2018 shares for supply of venlafaxine

Competitors	Products	Total share	USD total
MYLAN	ENLAFAX XR	[*redacted*]	[*redacted*]
UPJOHN	EFEXOR XR	[*redacted*]	[*redacted*]
Merged Entity		[*redacted*]	[*redacted*]
TEVA	ARROW-VENLAFAXINE	[*redacted*]	[*redacted*]
		[*redacted*]	[*redacted*]

20.9 Despite not being funded, Upjohn has continued to market its Efexor XR product through the private/non-Pharmac funded channel and has retained a material share of sales ([*redacted*] with US[*redacted*] sales in 2018) at molecule level. This share is driven by patients who choose to pay

[45] Note Mylan sources this from a third party Pharmathen (Greece). Pharmathen manufacture the product and Mylan is the local distributor and sponsor.

for Efexor XR out of brand loyalty rather than receive the funded generic. As Upjohn now has a private script market, it is able to set its own price for Efexor XR, outside of the Pharmac process.

20.10 The combined share of the Parties is purely a function of the fact that Mylan's product is Pharmac funded and Upjohn continues to benefit from brand loyalty. Accordingly, despite both being venlafaxine based, Mylan's Enlafax XR and Upjohn's Efexor XR do not exercise a relevant competitive constraint on each other. That is, sales of the Pharmac funded product and any non-Pharmac funded products do not materially constrain each other on an ongoing basis (given the Pharmac funded product remains subsidised at the same level through the period for which sole supply has been awarded). Rather, competition continues to be largely focused on the tender process for Mylan's Pharmac funded sales, and between rival branded products for Upjohn's ongoing non-funded sale (of which there are currently no others in the case of venlafaxine).

20.11 [*redacted*].

20.12 The following competitors are also Medsafe registered to supply venlafaxine and would be able to compete with the Merged Entity at the next Pharmac tender for venlafaxine:[46]

(a) Teva (who already has existing sales of its product Arrow-Venlafaxine in New Zealand);

(b) Arrow;

(c) Rex Medical; and

(d) Apotex.

20.13 In addition, there are a number of large pharmaceutical companies such as Novartis, Aurobindo, Teva and Servier that sell venlafaxine-based products at a global level and who could easily enter the market in New Zealand. Novartis, Servier and Teva are already present in the New Zealand market with other products, which would make launch of venlafaxine in the country even easier. The revenue generated by Mylan over a one-year period from sale of venlafaxine (see table above) is sufficiently high to encourage entry.

20.14 In any event, even the presence of two participants in a Pharmac tender would be sufficient to ensure strong competition. As such, given the number of Medsafe registered suppliers for venlafaxine, as well as the presence of large multinational companies that could easily enter this space in New Zealand, there is no likely prospect that competition for the supply of atorvastatin in New Zealand could be impaired by the Proposed Transaction.

20.15 Finally, as stated above, Pharmac has a strong countervailing power and has the means to intervene if the Merged Entity were to increase the price of atorvastatin post-Transaction, thus making any attempt to try and raise profits to the expense of New Zealand consumers virtually impossible. Accordingly no competition issues arise in relation to venlafaxine.

Broader ATC4 category for SNRIs

20.16 The broader ATC4 class has been considered below for completeness.

20.17 There are several other competitors with active sales in the SNRI category, supplying products that may be substitutable on a therapeutic basis for those supplied by the Parties (albeit some with different molecules):

(a) Teva: Arrow-Venlafaxine (venlafaxine)

[46] [*redacted*].

(b) Lilly: Cymbalta (duloxetine).

(c) Pfizer: Pristiq (desvenlafaxine).

ATC4 category shares

20.18 Table 10 below sets out the shares and products of the Parties and each of their competitors for 2018 by revenue (in $USD).

Table 10 – 2018 category shares for ATC4 N6A5 SNRIs

Competitors	Products	Molecule	Product share	Total share	$USD product	$USD total
MYLAN	ENLAFAX XR	VENLAFAXINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
UPJOHN	EFEXOR XR	VENLAFAXINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
Merged Entity				[*redacted*]		[*redacted*]
TEVA	ARROW-VENLAFAXINE	VENLAFAXINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
LILLY	CYMBALTA	DULOXETINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
PFIZER	PRISTIQ	DESVENLAFAXINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
				[*redacted*]		[*redacted*]

ATC4 analysis

20.19 Mylan's [*redacted*] share of this product category is solely attributable to Enlafax XR (venlafaxine), which is the only Pharmac funded product in this category. It replaced Arrow-Venlafaxine and Upjohn's Efexor XR as the subsidised Pharmac product in 2017 which saw Mylan's Enlafax XR share of sales go from [*redacted*] to [*redacted*].

20.20 Upjohn's venlafaxine product, Efexor XR, has [*redacted*] share, giving the combined entity a total share of [*redacted*].

20.21 Given there is competition at tender level for the molecule supplied by the Parties, the Proposed Transaction does not give rise to any competition concerns for supply of any molecule, or in the broader ATC4 (or any other antidepressant category).

Overlap at molecule level where there is private market and Pharmac tender competition:

21. **Competition assessment of G4E erectile dysfunction products**

21.1 ATC code G4E is part of the anatomical group G relating to the genito-urinary system and sex hormones. ATC3 G4E contains erectile dysfunction (**ED**) products, which are products for the treatment of male impotence.[47]

21.2 ED treatments work by increasing blood flow to the male genital area. Most ED products are phosphodiesterase type 5 (**PDE5**) inhibitors which work by increasing the amount of nitric oxide in the body. The nitric oxide works with other substances to allow more blood to flow into the penis and less blood to flow out of it, thus prolonging an erection.

21.3 Pharmac does not fund any products for the treatment of ED.[48] However, it does fund sildenafil, a molecule used in treating ED, for treatment of patients with Reynaud's Syndrome. and PAH. While these products sit within the same ATC4 category, the competitive drivers are different depending on whether a supplier is tendering for a Pharmac contract (for funded uses) or seeking to sell into the private market for treatment of ED.

21.4 There are several molecules with a therapeutic indication for ED, and these molecules make up the ATC4 category. There are two ED product categories at ATC4 level: ATC4 G4E1 PDE5 inhibitors, and ATC4 G4E9 for other ED products. Both Parties' products contain the molecule sildenafil.

Sildenafil - ATC4 G4E1 PDE5 inhibitors

21.5 PDE5 inhibitors dilate narrow blood vessels, facilitating erection by allowing increased blood flow through the corpora cavernosa of the penis. Viagra (sildenafil) was the first effective oral treatment available for ED. Pfizer's patent over sildenafil expired outside the US in 2012.

21.6 In addition to sildenafil, there are a number of other molecules used for ED products in this category, including tadalafil (Lilly's Cialis) and vardenafil (Bayer's Levitra). The ED product category is likely to become progressively more crowded with generics [*redacted*]. Lilly's patent over the tadalafil compound expired in 2015, although its Cialis product has several additional patents which expire next year. Bayer's patent over the vardenafil compound expired in October 2018, although it has a further patent, which expires in 2023.

21.7 Sildenafil for ED was in 2014 reclassified in New Zealand from a prescription medicine to a "prescription medicine; except when supplied by a pharmacist who has successfully completed the approved training programme for the treatment of erectile dysfunction in males aged 35–70 years". Men suffering erectile dysfunction are therefore able to buy sildenafil on prescription or from specially trained pharmacists without a GP's prescription.

The Parties' products

21.8 Mylan and Upjohn each supply a sildenafil product, Mylan's being Vedafil and Upjohn's being the innovator product Viagra. Both of these contain the sildenafil molecule and are taken orally in tablet form:

(a) Mylan:

[47] Anatomical classification guidelines 2019 p. 66 https://www.ephmra.org/media/2485/atcguidelines2019final.pdf
[48] Other than for erectile dysfunction secondary to spinal cord injury requiring pharmacological treatment.

(i) Vedafil (sildenafil)

(b) Upjohn:

(i) Viagra (sildenafil)[49]

Competition for Pharmac funding for sildenafil

21.9 Mylan's Vedafil is Pharmac funded for the sole supply of sildenafil tablets, but primarily[50] for treatment of Raynaud's syndrome and PAH.[51]

21.10 Upjohn does not participate in Pharmac tenders for sildenafil. [*redacted*]. Accordingly, no competition issues will arise in relation to Pharmac tenders for sildenafil.

21.11 In any event, in relation to the competition for Pharmac funding for sildenafil for non-ED (other than ED from spinal injury) indications, there are two other competitors that also have sildenafil products registered following the expiry of Pfizer's patent:

(a) Douglas: Silvasta (sildenafil); and

(b) Teva: Silagra (sildenafil).

21.12 Douglas and Teva could compete at the next Pharmac tender round for the sole supply contract currently held by Mylan and can also compete using these products for private market sales of erectile dysfunction medications (see further below)

Competition for ED sales

21.13 As noted above, Pharmac does not fund any products in relation to ED (apart from when this is caused by a spinal cord injury and requires pharmacological intervention). Accordingly, competition for products used to treat ED occurs outside of the Pharmac tender process, although is affected to some degree by the prices agreed with Pharmac for the other indications, as set out below.

21.14 As the innovator product for erectile dysfunction treatment, Viagra enjoys substantial brand equity and sets its prices accordingly. As noted at paragraph 11.18 above, where products are sold through the private channel, patients have a high chance of influencing prescribers and as such brand loyalty plays an important role here. On the other hand, Vedafil is available to pharmacists at the price negotiated with Pharmac and published on the Pharmac Schedule. This price applies even where the pharmacist sells the product for the treatment of erectile dysfunction and the Pharmac subsidy does not apply. In that case, the pharmacist is free to set whatever price to final consumers it chooses. Mylan is not aware of how much of its product is sold for funded treatments and how much is sold privately because the pharmacist seeks reimbursement for funded products directly from the relevant DHB and Mylan is not involved in this step. [*redacted*].

21.15 As a result of this, the price of Vedafil to pharmacists for onsale into the private erectile dysfunction market is effectively fixed by the Pharmac contract price, while pharmacies are free to set the retail price charged to end-customers. While this may impact on the price of erectile dysfunction products sold on the private market, there is not ongoing price competition between Vedafil and other erectile dysfunction products as the Vedafil price can only change at the next tender round (when it will again face substantial competition from other generic suppliers). It also means pharmacists currently have an incentive to promote sales of Vedafil over other sildenafil

[49] [*redacted*].
[50] Patients can also receive Pharmac funded sildenafil for ED but only if their ED is caused by a spinal cord injury and requires pharmacological intervention.
[51] The efficacy of sildenafil in increasing bloodflow through constricted vessels has also seen it prescribed for some circulatory disorders such as Raynaud's syndrome, a medical condition in which arterial spasms cause episodes of reduced blood flow to extremities such as fingers and toes.

products (since they are able to increase the price at which they sell to consumers significantly above the funded price, and retain the mark-up). This advantage in terms of volume of sales could be taken up by a future winner of the next Pharmac tender for sildenafil - for the reasons described in paragraph 21.10 above, this is unlikely to be Upjohn as Upjohn does not participate in Pharmac tenders for sildenafil [*redacted*].

21.16 In addition to the parties' products, Douglas' Silvasta sildenafil product is a material competitive constraint, and could expand if the Merged Entity sought to increase prices above competitive levels or otherwise attempted to exercise market power following the expiry of current Pharmac funding. Upjohn understands Teva has withdrawn its product from the market due to low sales, which suggests it could re-enter (by participating in a Pharmac tender, or launching its product privately, or both) if market conditions changed. There are also a number of other suppliers of generics outside New Zealand, including Apotex, Ranbaxy, Sandoz and Dr Reddy's, which could register their product and enter if a market opportunity presented.

21.17 Furthermore, products within the broader ATC4 category may compete at the prescriber level, with doctors and pharmacists choosing between products with similar therapeutic effects rather than necessarily focusing on the particular molecule. In the private channel brand equity is important; brand equity can mean patients have a view on, and can influence, which molecule is prescribed (i.e. a patient may request a branded product by name). In the case of a GP writing a prescription, a molecule is specified and at that point the patient chooses among the available products containing the relevant molecule; for pharmacists' sildenafil prescriptions that distinction is less clear, since the pharmacist is both writing the prescription and overseeing the sale to the patient.

21.18 As such, the constraint from substitutable products in the wider ATC4 ED category is also relevant.

21.19 There are two competitors in the ATC4 category supplying originator molecules with the same therapeutic indication as sildenafil (for ED). The products supplied by these competitors are branded, but generic versions are likely to enter the market over the next five years:

(a) Lilly: Cialis (tadalafil)

(b) Bayer: Levitra (vardenafil)

ATC4 category shares

21.20 Table 11 below sets out the shares and products of the Parties and each of their competitors for 2018 by revenue (in $USD). Mylan's share in the table below includes Pharmac funded supply for sildenafil for treatment of Raynaud's syndrome and PAH and sales to pharmacists at the Pharmac Schedule price that are sold to customers for the treatment of ED without Pharmac funding, at a price set by the pharmacists.

Table 11 – 2018 category shares for G4E1 PDE5 inhibitors

Competitors	Products	Molecule	Product share	Total share	$USD product	$USD total
MYLAN	VEDAFIL	SILDENAFIL	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
UPJOHN	VIAGRA	SILDENAFIL	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
Merged Entity				[*redacted*]		[*redacted*]
LILLY	CIALIS	TADALAFIL	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
DOUGLAS	SILVASTA	SILDENAFIL	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
BAYER	LEVITRA	VARDENAFIL	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
PFIZER	PAPAVERINE PFIZ	PAPAVERINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
TEVA	SILAGRA	SILDENAFIL	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
				[*redacted*]		[*redacted*]

ATC4 analysis

21.21 When Mylan's sales are combined with Upjohn's [*redacted*] share from Viagra the aggregated share of this category held by the Merged Entity would be [*redacted*]. Upjohn's market position is attributable to the historic marketing of Viagra and strong brand association that accompanies an innovator product. Mylan's share of this ATC4 category is partly attributable to its Pharmac subsidised supply of Vedafil for the treatment of Raynaud's syndrome, PAH and ED associated with spinal cord injuries, although it appears the majority may be attributable to its non-Pharmac subsidised supply of Vedafil for ED at Pharmac Schedule prices.[52]

21.22 The low price point of the product means Mylan's volume share would be much higher. However, as a result of the competitive dynamics described above shares of supply are not a meaningful measure of market position in this case.[53]

21.23 As noted above, the Merged Entity would be constrained in relation to the supply of sildenafil for ED by competing suppliers such as Douglas and Teva; at the ATC4 level there is competition from ED products with different molecules including tadalafil (Cialis) and vardenafil (Levitra).

Cialis and Levitra

21.24 As set out above, the tadalafil compound that is the active ingredient in Cialis came off patent in 2015, while three other patents over Cialis expire next year, allowing generic entry. Similarly, the vardenafil (Levitra) compound patent has also recently expired (although the Levitra vardenafil product is still subject to an active patent until 2023). Accordingly, generic versions of these products are yet to reach the New Zealand market and are likely to add additional competition to this product category in the near future.

21.25 The Parties understand tadalafil is on the draft 2019 / 2020 tender, and each of Mylan and Apotex have generic versions of tadalafil registered (or in registration) with Medsafe for supply in New Zealand. The draft tender indicates that the same Pharmac funding restrictions would apply to tadalafil as sildenafil (being that it is only funded for Reynaud's Syndrome, PAH and ED for spinal injury patients), but it may provide further encouragement for suppliers to register generic versions of tadalfil in New Zealand. As is the case with Vedafil, it is likely that the Pharmac funded price of

[52] As set out above, Mylan does not have information available to it to quantify the split of sales of Vedafil attributable to the Pharmac subsidy (for Reynaud's syndrome, PAH and spinal cord ED) and the sales attributable to non-subsidised sales for ED. All sales to pharmacists are made on the same terms, being those set by reference to the Pharmac Schedule price.
[53] Pfizer's papaverine product is injectable and is generally only prescribed where oral therapies such as sildenafil are not effective or suitable.

tadalafil will also impact the price at which pharmacists can acquire that product for private sales to customers for ED treatment.

21.26 In light of the analysis above and the dynamics of this product category, the Proposed Transaction does not give rise to any competition concerns on a molecular level or in the ATC4 category for G4E1 PDE5 inhibitors (or in any other relevant category).

ATC4-only overlaps where competition is driven by Pharmac:[54]

22. **Competition assessment of C3A diuretics**

22.1 ATC code C3A is part of the anatomical group C relating to the cardiovascular system. ATC3 C3A contains diuretics, which are a class of pharmaceutical product designed to help the kidneys get rid of unneeded water and salt. This eases the swelling and water retention caused by many cardiac issues including heart failure, and reduces strain on the heart by lowering the volume of blood in the body. Fluid build-up can also cause shortness of breath and swelling, so diuretics can also help relieve these symptoms.

22.2 There are several different types of diuretics which have subtle differences in effect. For example, Thiazide and analogous diuretics (ATC4 C3A3) will work to eliminate a moderate amount of water, and can be used for longer periods. Comparatively, Loop diuretics (ATC4 C3A2) are more powerful and induce greater fluid loss which can be useful in emergencies. Potassium sparing diuretics (ATC4 C3A1) also reduce the amount of water in the body, but while other diuretics cause the body to lose potassium in the process, this type does not.

22.3 There is no overlap between the Parties on a molecule basis; there is only overlap at ATC4 C3A1 for potassium sparing diuretics.

22.4 Given Pharmac tendering plays a key role in determining sales of C3A products in New Zealand, and there is no overlap between the Parties on molecular level, the Proposed Transaction does not raise any competition concerns for supply of any molecule in this category. Nevertheless, the Parties have included analysis of the broader ATC4 category below for completeness.

ATC4 C3A1 potassium sparing agents, plain

22.5 ATC4 C3A1 contains potassium sparing diuretics, plain (meaning each molecule in this category is listed on its own rather than in combination with another molecule).[55] Potassium sparing diuretics are generally used for treatment of hypertension and congestive heart failure, in combination with other diuretic drugs that would otherwise tend to reduce potassium levels to below healthy levels.

The Parties' products

22.6 Mylan and Upjohn each supply potassium sparing diuretics, but do not supply the same molecules. Mylan supplies a product containing the molecule spironolactone,[56] while Upjohn's product contains eplerenone.

22.7 Spironolactone and eplerenone work similarly in that they block the effects of the hormone aldosterone, but eplenerone does not have any estrogenic effects (while spironolactone does).

22.8 The products supplied by the Parties are:

(a) Mylan:

(i) Spiractin (spironolactone);

[54] This section only includes overlaps between the Parties of products registered and marketed in New Zealand. It does not include reference to unregistered products, the import of which is permitted by Medsafe under s 29 of the Medicines Act 1981. For example, Upjohn's Caduet, Nitroglycerin Pfizer, Cardura, Relpax, Sermion, Xalacom, Revatio and Xanax are not marketed in New Zealand and have either never been supplied here or have been discontinued, however some of these products may have been imported (generally on a *de minimis* basis) in 2018 and 2019 in accordance with s 29 of the Medicines Act.
[55] Anatomical classification guidelines 2019 at 39 https://www.ephmra.org/media/2485/atcguidelines2019final.pdf
[56] Its amiloride product, Kaluril, is not registered in New Zealand, but may have been imported under section 29 of the Medicines Act and therefore has indicated *de minimis* sales here.

(b) Upjohn: Inspra (eplerenone);

22.9 As above, there is no overlap between the Parties on molecular level and accordingly the Proposed Transaction does not raise any competition concerns for the Pharmac tender of any single molecule. There is also existing competition for the tender of each molecule.

Broader ATC4 category for potassium sparing agents, plain

Pharmac funding

22.10 Spironolactone: Mylan's product Spiractin is Pharmac funded for supply of spironolactone in tablet form.[57] Other parties capable of tendering for the supply of spironolactone in tablet form include MaxHealth, which has a registration for supply of spironolactone in progress with Medsafe.

22.11 Eplerenone: Upjohn's Inspra is Pharmac funded for the sole supply of eplerenone (25mg). Te Arai BioFarma is also Medsafe registered for the supply of eplerenone (in both 25mg and 50mg dosages).

22.12 Amiloride: Biomed's Biomed amiloride is Pharmac funded for supply of amiloride.

Competitor products

22.13 The other products in this ATC4 category include:

(a) Biomed (NZ):

(i) Biomed Spironolactone (spironolactone in liquid form)

(ii) Biomed amiloride (amiloride)

(b) Pfizer: Aldactone (spironolactone).[58]

22.14 Apotex's Apo-amiloride tablets made sales in 2018 but this product is no longer available in New Zealand.

ATC4 category shares

22.15 Table 12 below sets out the shares and products of the Parties and each of their competitors for 2018 by revenue (in $USD).

[58] The Parties note that the Medsafe registration for Pfizer's spironolactone product Aldactone has lapsed. This product does not form part of the Upjohn portfolio and will not transfer to the Merged Entity.

Table 12 – 2018 category shares for C3A1 potassium sparing agents, plain[59]

Competitors	Products	Molecule	Product share	Total share	$USD product	$USD total
MYLAN	SPIRACTIN	SPIRONOLACTONE	[*redacted*]		[*redacted*]	
	KALURIL	AMILORIDE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
UPJOHN	INSPRA	EPLERENONE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
Merged Entity				[*redacted*]		[*redacted*]
BIOMED (NZ)	BIOMED SPIRONOLACT	SPIRONOLACTONE	[*redacted*]		[*redacted*]	
	BIOMED AMILORIDE	AMILORIDE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
APOTEX	APO-AMILORIDE	AMILORIDE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
				[*redacted*]		[*redacted*]

ATC4 analysis

22.16 Mylan currently holds a significant share of this category, with [*redacted*] share attributable to its Pharmac funded spironolactone product, Spiractin.

22.17 Upjohn's Inspra product has a different molecule (eplerenone) to the Mylan product and is separately tendered and subsidised by Pharmac. Upjohn's total share is [*redacted*].

22.18 As set out above, although the Merged Entity's combined share of this ATC4 category is high, this is attributable to Pharmac funding. The ATC4 combined share of [*redacted*] therefore substantially overstates the Merged Entity's position because its sales are attributable to products subsidised by Pharmac in separate tenders. As above, the Parties' products do not place any price constraint on each other either in tenders or on an ongoing basis.

22.19 Given:

(a) Pharmac's influence of the shares in this ATC4 category; and

(b) the lack of overlap between the Parties on a molecule basis;

the Proposed Transaction does not give rise to any competition concerns within the ATC4 category for C3A1 potassium sparing diuretics or in any other category of diuretics.

23. Competition assessment of C8A Calcium antagonists

23.1 ATC code C8A is part of the anatomical group C relating to the cardiovascular system. ATC3 C8A contains plain calcium antagonists (hypertensive drugs that disrupt the movement of calcium through calcium channels). The ATC4 subgroup in this category is C8A0, which contains all the products in ATC3 C8A (i.e. there is no difference in the classification of calcium antagonist products between ATC3 and ATC4).

The Parties' products

23.2 Products supplied by Mylan include:

(a) Felo (felodipine);

(b) Zircol (lercanidipine);

[59] See above regarding sales of Kaluril.

(c) Adefin (nifedipine);[60]

(d) Verpamil (verapamil);[61] and

(e) Isoptin (verpamil).

23.3 Upjohn's product is Norvasc (amlodipine).

Broader ATC3 / ATC4 category for C8A / C8A0 calcium antagonists

23.4 Although there is no overlap between the Parties at molecule level, the range of products in this ATC4 category is considered below, for completeness.

23.5 There are a number of other calcium antagonist products in this ATC4 supplied in New Zealand, based on several different molecules, including:

(a) Apotex:

(i) Diltiazem Apotex (diltiazem);

(ii) Amlodipine Apotex (amlodipine);

(b) Astrazeneca: Plendil (felodipine);

(c) Aspen: Pexsig (perhexiline);

(d) Douglas:

(i) Dilzem (diltiazem);

(ii) Nyefax (nifedipine);

(e) Bayer: Adalat (nifedipine);

(f) Sanofi: Tildiem (diltiazem);

(g) Global Pharmaceuticals:

(i) Isradipine (isradipine);

(ii) Nicardipine (nicardipine);

(h) Novartis: Lomir (isradipine).

Pharmac funding

23.6 Mylan's Felo (felodipine) and Isoptin (verapamil) are funded. Mylan's Adefin (nifedipine) [*redacted*]. Mylan's Verpamil (verapamil) is funded [*redacted*]. AstraZeneca and Bayer are also Medsafe registered for all dosages of felodipine and nifedipine (and currently making sales of these products).

23.7 There are currently no Medsafe registered competitors for supply of verapamil, but it would be possible for a competing supplier to register before the next tender round in order to compete with

[60] [*redacted*].
[61] [*redacted*].

the Merged Entity. In any event, the Proposed Transaction does not lead to any aggregation in suppliers of verapamil products, so does not raise any competition issues in this regard.

ATC4 category shares

23.8 Table 13 below sets out the shares and products of the Parties and each of their competitors for 2018 by revenue (in $USD).

Table 13 - 2018 category shares for ATC3 C8A / ATC4 C8A0 calcium antagonists

Party	Product	Molecule	Product share	Total share	$USD product	$USD total
MYALN	FELO	FELODIPINE	[*redacted*]		[*redacted*]	
	VERPAMIL	VERAPAMIL	[*redacted*]		[*redacted*]	
	ADEFIN	NIFEDIPINE	[*redacted*]		[*redacted*]	
	ISOPTIN	VERAPAMIL	[*redacted*]		[*redacted*]	
	ZIRCOL	LERCANIDIPINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
UPJOHN	NORVASC	AMLODIPINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
Merged Entity				[*redacted*]		[*redacted*]
APOTEX	DILTIAZEM APTX	DILTIAZEM	[*redacted*]		[*redacted*]	
	AMLODIPINE APTX	AMLODIPINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
ASTRAZENECA	PLENDIL	FELODIPINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
ASPEN	PEXSIG	PERHEXILINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
DOUGLAS	NYEFAX		[*redacted*]		[*redacted*]	
	DILZEM		[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
BAYER	ADALAT	NIFEDIPINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
Others				[*redacted*]		[*redacted*]
				[*redacted*]		[*redacted*]

ATC4 analysis

23.9 Mylan's total share of sales in this category is [*redacted*].Upjohn's is negligible (at [*redacted*]) giving the Merged Entity a total combined share of [*redacted*]. As set out above, there is no overlap between the Parties on a molecular level.

23.10 In addition to the Parties, there are a total of 9 competitors in this category, 8 of which make sales in New Zealand. Most of the market is currently held by Apotex who has a [*redacted*] share, and AstraZeneca who has [*redacted*].

23.11 Given:

(a) Pharmac's influence of the shares in this ATC4 category; and

(b) the lack of overlap between the Parties on a molecular level at which Pharmac would tender;

the Proposed Transaction does not give rise to any competition concerns within the ATC3 / ATC4 category for C8A / C8A0 calcium antagonists.

24. Competition assessment of N6A antidepressants

24.1 As set out in section 20 above, ATC code N6A is part of the anatomical group N relating to the nervous system. ATC3 N6A contains anti-depressants and mood stabilisers.[62] The Parties supply anti-depressants in the following ATC4 categories:

(a) ATC4 N6A5 serotonin-noradrenaline reuptake inhibitors antidepressants (**SNRI**s); and

(b) ATC4 N6A4 selective serotonin reuptake inhibitors antidepressants (**SSRI**s).

24.2 The molecular overlap between the Parties' for the SNRI molecule venlafaxine is addressed in section 20 above.

24.3 There is no molecular overlap between the Parties at ATC4 N6A4 for SSRIs. However, an overview of the broader ATC4 category is set out below for completeness.

ATC4 N6A4 SSRIs

24.4 SSRIs are the most commonly prescribed antidepressants, with fewer side effects than SNRIs and include well known products such as Teva's Fluoxetine. Comparatively, SNRIs are generally used for severe depression or when SSRIs have not been successful. For completeness, the Parties provide details of this ATC4 category although there is no overlap on a molecular level and the Parties' products do not compete with each other.

The Parties' products

24.5 Mylan supplies five products in this category, while Upjohn supplies one.

24.6 Mylan:

(a) Celapram (citalopram)

(b) Loxalate (escitalopram)

(c) Luvox (fluvoxamine)

(d) Loxamine (paroxetine)

(e) Fluox (fluoxetine)

24.7 Upjohn:

(a) Zoloft (sertraline)

24.8 There is no overlap between the Parties on a molecule basis and as such the Parties' products would not participate in any of the same Pharmac tenders, irrespective of the Proposed Transaction. Accordingly, no detrimental effect on competition can arise.

Broader ATC4 category for SSRIs

24.9 The range of products in this ATC4 category is considered below, for completeness.

[62] Anatomical classification guidelines 2019 at 117 https://www.ephmra.org/media/2485/atcguidelines2019final.pdf

24.10 There are a number of other SSRI products in this ATC4, based on several different molecules, including:

(a) Airflow Products: Escitalopram Airflow (escitalopram)

(b) API: Citalopram PSM (citalopram)

(c) Apotex:

(i) Escitalopram Apotex (citalopram)

(ii) Paroxetine Apotex (paroxetine)

(d) GSK: Seroxat (paroxetine)

(e) Lilly: Prozac (fluoxetine)

(f) Lundbeck:

(i) Cipralex (escitalopram)

(ii) Cipramil (citalopram)

(g) Teva:

(i) Citalopram Teva (citalopram)

(ii) Fluoxetine Teva (fluoxetine)

(iii) Sertraline Teva (sertraline)

Pharmac funding

24.11 Each of the molecules above is Pharmac funded for various dosages but all of the funded products are supplied by the Parties' competitors.[63]

ATC4 category shares

24.12 Table 14 below sets out the shares and products of the Parties and each of their competitors for 2018 by revenue (in $USD).

[63] Note: Mylan has recently won the fluoxetine tender from the incumbent, Teva, [*redacted*].

Table 14 – 2018 category shares for ATC4 N6A4 SSRIs

Competitors	Products	Molecule	Product share	Total share	$USD product	$USD total
MYLAN	CELAPRAM	CITALOPRAM	[*redacted*]		[*redacted*]	
	LOXALATE	ESCALITOPRAM	[*redacted*]		[*redacted*]	
	LUVOX	FLUVOXAMINE	[*redacted*]		[*redacted*]	
	LOXAMINE	PAROXETINE	[*redacted*]		[*redacted*]	
	FLUOX	FLUOXETINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
UPJOHN	ZOLOFT	SERTRALINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
Merged Entity				[*redacted*]		[*redacted*]
TEVA	SERTRALINE TEVA	SERTRALINE	[*redacted*]		[*redacted*]	
	FLUOXETINE TEVA	FLUOXETINE	[*redacted*]		[*redacted*]	
	CITALOPRAM TEVA	CITALOPRAM	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
APOTEX	PAROXETINE APTX	PAROXETINE	[*redacted*]		[*redacted*]	
	ESCITALOPRAM APTX	ESCALITOPRAM	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
API	CITALOPRAM PSM	CITALOPRAM	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
AIRFLOW PRODUCTS	ESCITALOPRAM AIRF	ESCALITOPRAM	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
GLAXOSMITHKLINE	SEROXAT	PAROXETINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
Others				[*redacted*]		[*redacted*]
				[*redacted*]		[*redacted*]

ATC4 analysis

24.13 Mylan and Upjohn make negligible sales for each of their products in this ATC4, as the Pharmac funded products for each relevant molecule are supplied by the Parties' competitors. There is also a competing supplier of each of the molecules supplied by the Parties.

24.14 Given:

(a) Pharmac's influence of the shares in this ATC4 category; and

(b) the lack of overlap between the Parties on a molecular level at which Pharmac would tender;

the Proposed Transaction does not give rise to any competition concerns within the ATC4 category for N6A4 SSRI antidepressants or any other antidepressant category.

25. Competition assessment of S1E Miotics and Antiglaucoma preparations

25.1 ATC code S1E is part of the anatomical group S relating to the sensory organs. ATC3 S1E contains miotics and antiglaucoma preparations, both topical (ATC4 S1E2) and systemic (ATC4S1E1). Glaucoma is an eye disease in which problems with the eye's drainage system cause progressively increasing pressure in the eye. This gradually damages the optic nerve and eventually leads to vision loss.

25.2 Products in this ATC category work to reduce intra-ocular pressure and thereby limit damage to the optic nerve. Some are taken systemically (e.g. in tablet form) but many are topical (i.e. in the form of eye drops). As all of the Parties' products are topical, the relevant overlap occurs at ATC4 S1E2. There is no overlap between the Parties on a molecular level and the Parties' products would not participate in any of the same Pharmac tenders, regardless of the Proposed Transaction.

ATC4 S1E2 topical miotics and antiglaucoma preparations

The Parties' products

25.3 Products in this category supplied by Mylan include:

(a) Dortimopt (dorzolamide / timolol) . Mylan launched Dortimopt in November 2018 and now sells approximately [*redacted*]; and

(b) Travopt (travoprost).

25.4 Upjohn's products include:[64]

(a) Hysite (latanoprost), which is known elsewhere as "Xalatan".[65]

25.5 There is no overlap between the Parties on a molecule basis, so the Parties' products would not compete in the same Pharmac tenders; accordingly, no competition can be reduced as a result of the Proposed Transaction. Nevertheless, the broader ATC4 category is considered below, for completeness.

Broader ATC4 category for topical miotics and antiglaucoma preparations

Pharmac funding

25.6 Mylan's Dortimopt is Pharmac funded for supply of dorzolamide with timolol. Teva is also Medsafe registered for supply of this molecule combination and is capable of competing with the Merged Entity for the Pharmac tender.

25.7 Mylan's Travopt is Pharmac funded for supply of travoprost. Novartis is also funded for this supply at a different dosage, and is capable of competing with the Merged Entity for the Pharmac tender.

25.8 There is no overlap between the Parties at molecule level so the Proposed Transaction does not give rise to any competition issues for supply of either of the products supplied by Mylan.

25.9 Neither of Upjohn's products are funded by Pharmac. While Hysite was funded up to the beginning of 2019, [*redacted*].

Other competitors

25.10 The topical antiglaucoma / miotics product category is crowded. It contains a range of 17 different molecules which are all prescribed for similar therapeutic indications, spread across more than 20 different products supplied by eight competitors (ten including the Parties). The Parties only supply a total of four of these molecules across four separate products.[66]

ATC4 category shares

25.11 Table 15 below sets out the shares and products of the Parties and each of their competitors for 2018 by revenue (in $USD).

[64] Xalacom (latanoprost / timolol maleate) is also a Pfizer product but is not imported/sold by Pfizer/Upjohn in New Zealand (and is not Pharmac funded).
[65] [*redacted*].
[66] The Commission in *Novartis / Alcon* (Decision No. 692, 6 May 2010) defined a separate market for prescription only miotics for use in cataract surgery. However, as market shares were well inside the Commission's then-safe harbour guidelines the Commission did not consider the market further.

Table 15 - 2018 category shares for ATC4 S1E2 topical miotics / antiglaucoma preparations[67]

Competitors	Products	Molecule	Product share	Total share	$USD product	$USD total
MYLAN	TRAVOPT	TRAVOPROST	[*redacted*]		[*redacted*]	
	DORTIMOPT	DORZOLAMIDE / TIMOLOL	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
UPJOHN	HYSITE	LATANOPROST	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
Merged Entity				[*redacted*]		[*redacted*]
NOVARTIS	AZOPT	BRINZOLAMIDE	[*redacted*]		[*redacted*]	
	TRAVATAN	TRAVOPROST	[*redacted*]		[*redacted*]	
	BETOPTIC	BETAXOLOL	[*redacted*]		[*redacted*]	
	ISOPTO CARPINE	PILOCARPINE	[*redacted*]		[*redacted*]	
	IOPIDINE	APRACLONIDINE	[*redacted*]		[*redacted*]	
	DUOTRAV	TIMOLOL / TRAVOPROST	[*redacted*]		[*redacted*]	
	MIOSTAT	CARBACHOL	[*redacted*]		[*redacted*]	
	MIOCHOL-E	ACETYLCHOLINE	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
ALLERGAN	COMBIGAN	BRIMONIDINE / TIMOLOL	[*redacted*]		[*redacted*]	
	VISTAGAN	LEVOBUNOLOL	[*redacted*]		[*redacted*]	
	ALPHAGAN	BRIMONIDINE	[*redacted*]		[*redacted*]	
	LUMIGAN	BIMATOPROST	[*redacted*]		[*redacted*]	
	GANFORT	BIMATOPROST / TIMOLOL	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
TEVA	BIMATOPROST ACT	BIMATOPROST	[*redacted*]		[*redacted*]	
	DORSOF T	DORZOLAMIDE / TIMOLOL	[*redacted*]		[*redacted*]	
	BRIMONIDINE TEVA	BRIMONIDINE	[*redacted*]		[*redacted*]	
	TIMOLOL TEVA	TIMOLOL	[*redacted*]		[*redacted*]	
	LATANOPROST TEVA	LATANOPROST	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
MERCK & CO	BLOCADREN	TIMOLOL	[*redacted*]		[*redacted*]	
	TRUSOPT	DORZOLAMIDE	[*redacted*]		[*redacted*]	
	COSOPT	DORZOLAMIDE / TIMOLOL	[*redacted*]		[*redacted*]	
				[*redacted*]		[*redacted*]
Others				[*redacted*]		[*redacted*]
				[*redacted*]		[*redacted*]

ATC4 analysis

25.12 At ATC4 S1E2, Mylan's share of sales is [*redacted*] and Upjohn's is [*redacted*]. However, Upjohn's substantial sales figures are a result of it previously having Pharmac funded status for Hysite. As set out above, Hysite is no longer Pharmac funded (having been replaced by Teva) so its share is now overstated.[68]

25.13 In any event, there are six other strong competitors in this category making sales in New Zealand, and another one (Apotex) currently not making sales but capable of supply.

25.14 Given:

(a) Pharmac's influence of the shares in this ATC4 category; and

(b) the lack of overlap between the Parties on a molecular level at which Pharmac would tender;

the Proposed Transaction does not give rise to any competition concerns within the ATC4 category for S1E2 topical miotics / antiglaucoma preparations, or any other category for miotic and antiglaucoma products.

[67] As set out above, Mylan's Doptimopt product is now Pharmac funded (from November 2018 and makes sales in the region of [*redacted*]).
[68] Hysite's share has dropped more than [*redacted*] to an estimated [*redacted*] of this ATC4 in 2019 (sales of approximately [*redacted*]), and this is expected to continue to drop.

26. **Barriers to entry are low**

26.1 For the reasons set out in the product sections above and section 11, there are no markets in which the Proposed Transaction would increase market power of the Merged Entity. However, even if this were not the case, barriers to entry into New Zealand generic pharmaceutical markets are very low. This can be seen from the description of New Zealand pharmaceutical markets in sections 9 – 11 above. In particular:

(a) freight costs for pharmaceutical products are very low compared to their value. Accordingly, manufacturers across the globe can readily sell into New Zealand. Indeed, both Mylan and Upjohn import all the products they sell in New Zealand, as do the vast majority of their competitors;

(b) Medsafe registration is relatively straightforward for sophisticated pharmaceutical manufacturers and much easier where (as is frequently the case) their products are registered overseas by Medsafe recognised regulators, particularly Australia (see above). Furthermore, manufacturers can participate in Pharmac tenders subject to Medsafe registration;

(c) Pharmac's procurement processes are geared towards obtaining the lowest cost for the New Zealand government and it has a great deal of flexibility in how it goes about procurement. As mentioned at paragraph 11.9 above, there are instances of registrations being granted after tenders have closed and Pharmac accommodating tenderers who are moving through the registration process where that tenderer's offering is attractive.

(d) the prospect of achieving sole subsidised supply of a product in New Zealand acts as a strong incentive for generics manufacturers to take the necessary steps (including Medsafe registration) to sell their products in New Zealand;

(e) while, all things being equal, the incumbent tender holder may have a timing advantage over a new entrant in competing for Pharmac tenders due to the supply chain lead time required for new suppliers (and Pharmac may therefore view the certainty of supply as being greater with an incumbent), Pharmac is still likely to switch to a new entrant if there are meaningful cost savings to be made notwithstanding any supply delays;

(f) in relation to new entrants, while Pharmac tends to assume large, well-known multinationals have reliable supply, brand new, smaller, entrants may still be awarded smaller or less critical tenders as a test of reliability; if those are successful to build Pharmac's trust, suppliers do not need to be large to supply the New Zealand market and can do so with a small presence (e.g. they don't always need sales support/marketing or other facilities); and

(g) more generally, for existing generics manufacturers, it is relatively straightforward to begin manufacturing a new generic product. Often there are a range of suppliers of the APIs, and generics manufacturers already have strong capabilities with respect to mixing APIs with excipients, packaging and marketing.

26.2 Accordingly, if other generics manufacturers considered that there was "above normal" profit to be made in New Zealand in respect of a particular product, they would readily be able to take the steps necessary to bid for the next Pharmac tender (or for non-subsidised products begin selling directly to pharmacists).

27. **Parties are subject to strong countervailing power**

27.1 As set out above in section 9, Pharmac exerts substantial countervailing power on suppliers by acting as a monopsonist in New Zealand for funded pharmaceuticals. Its procurement techniques have been fine-tuned over a number of years to enable it to extract very low prices for generic

(and branded) pharmaceuticals. The Proposed Transaction will in no way change this – in all cases Pharmac will continue to have competitive options for its tenders.

28. **Vertical effects**

28.1 The Proposed Transaction will not give rise to any vertical competition effects.

28.2 Mylan is already active in the production of APIs for its products and it makes some third party sales, but it makes no API sales to other suppliers in New Zealand.[69] Accordingly, the Proposed Transaction will not increase the level of vertical integration. As set out in section 10 above, there are a large number of API manufacturers operating globally.

29. **No coordinated effects**

29.1 The Proposed Transaction will not give rise to coordinated effects. The transaction does not impact any of the factors which contribute to the current absence of co-ordinated behaviour.

(a) Prices in the generics pharmaceuticals industry are not transparent (until such time as a tender is awarded), and are negotiated in private.

(b) Pricing is strongly constrained by Pharmac, a virtual monopsonist and highly sophisticated purchaser of pharmaceuticals.

(c) The relevant markets (however defined) are characterised by the presence of multiple large, well-resourced, and vigorous competitors that would quickly disrupt any attempt to coordinate behaviour.

(d) For each market there are strong competitors outside the market that could easily enter in response to prices 'drifting up'.

(e) The products are not homogenous. Products are highly differentiated both by composition/molecule and therapeutic use.

(f) The Proposed Transaction will not result in the removal of an aggressive competitor.

[69] [*redacted*]. In any event, Mylan is a relatively small player in this space and the Proposed Transaction does not increase the level of vertical integration or give rise to vertical links in New Zealand.

Part G: Confidentiality

30. **Reasons for seeking confidentiality**

30.1 Confidentiality is sought in respect of the information in this application that is highlighted, (the **Confidential Information**). Confidentiality is sought for the Confidential Information for the purposes of section 9(2)(b) of the Official Information Act 1982 on the following grounds.

(a) The Confidential Information is commercially sensitive and valuable information which is confidential to either, or both, Parties.

(b) Disclosure of the Confidential Information would be likely to unreasonably prejudice the commercial position of the Parties.

30.2 The Parties request that they are notified if the Commission receives any request under the Official Information Act 1982 for the release of any part of the Confidential Information. They also request that the Commission seek and consider their views as to whether the Confidential Information remains confidential and commercially sensitive before it responds to such requests.

Part H: Declaration

I, Anil Amin, have prepared, or supervised the preparation, of this notice seeking clearance.

To the best of my knowledge, I confirm that:

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

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

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

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

Name and title of person authorised to sign:

Anil Amin, Head of Global Business Development

Sign:  **Date:** 12/9/19

PART H: DECLARATION

I, Alison L. M. O'Neill, have prepared, or supervised the preparation, of this notice seeking clearance.

To the best of my knowledge, I confirm that:

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

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

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

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

Name and title of person authorised to sign:

Alison L. M. O'Neill, Vice-president

Sign:  **Date:** November 25, 2019

Part I: Annexures

Contents

Annex 1 – List of products involved in the Proposed Transaction

Note: the list of Mylan products below includes products supplied by Mylan in New Zealand that are listed in the IQVIA (IMS) data and have the same ATC3 code as at least one of the Upjohn products. It is not a complete list of all Mylan products involved in the transaction globally.

Mylan			
Molecule	**Mylan Brand Name**	**ATC3**	**ATC4**
atorvastatin	Lorstat	C10A Cholest&Trigly.Regulator	C10A1 Statins (Hmg-Coa Red)
simvastatin	Simvastatin Mylan	C10A Cholest&Trigly.Regulator	C10A1 Statins (Hmg-Coa Red)
bezafibrate	Fibilip	C10A Cholest&Trigly.Regulator	C10A2 Fibrates
ezetimibe	Ezemibe	C10A Cholest&Trigly.Regulator	C10A9 Oth.Cholest&Trigly.Regul
isosorbide mononitrate	Duride	C1E Nitrites And Nitrates	C1E0 Nitrites And Nitrates
clondine	Clondine Mylan	C2A Antihypertens(Non Veg)Pl	C2A1 Antihyper.Pl Mainly Cent
methyldopa	Prodopa	C2A Antihypertens(Non Veg)Pl	C2A1 Antihyper.Pl Mainly Cent
amiloride	Kaluril (not registered and discontinued)	C3A Diuretics	C3A1 Pot Sparing Agents Plain
spironolactone	Spiractin	C3A Diuretics	C3A1 Pot Sparing Agents Plain
furosemide	Diurin (discontinued)	C3A Diuretics	C3A2 Loop Diuretics Plain
indapamide	Dapa-Tabs	C3A Diuretics	C3A3 Thiazide+Analogue Plain
bosentan	Bosentan Mylan	C6A Pulmonary Arterial Hypertension (Pah) Products	C6B1 Endothelin Rec Antag Pah
bosentan	Bosentan Mylan	C6B Pulmonary Arterial Hypertension (Pah) Products	C6B1 Endothelin Rec Antag Pah

felodipine	Felo ER	C8A Calcium Antagonist Plain	C8A0 Calcium Antagonist Plain
	Zircol Not registered in NZ	C8A Calcium Antagonist Plain	C8A0 Calcium Antagonist Plain
nifedipine	Adefin To be discontinued	C8A Calcium Antagonist Plain	C8A0 Calcium Antagonist Plain
verapamil	Isoptin	C8A Calcium Antagonist Plain	C8A0 Calcium Antagonist Plain
solifenacin	Solifenacin Mylan	G4D Urinary Incontinence Prd	G4D4 Urinary Incontinence Prd
sildenafil	Vedafil	G4E Erectile Dysfunction Prd	G4E1 Erect Dys Prd Pde5 Inhib
ibuprofen	Brufen	M1A Antirheumatic N-Steroid	M1A1 Antirheumatics Non-S Pln
ibuprofen	Ibuprofen Relieve	M1A Antirheumatic N-Steroid	M1A1 Antirheumatics Non-S Pln
indomethacin	Rheumacin SR (not marketed)	M1A Antirheumatic N-Steroid	M1A1 Antirheumatics Non-S Pln
naproxen	Noflam	M1A Antirheumatic N-Steroid	M1A1 Antirheumatics Non-S Pln
sulindac	Aclin	M1A Antirheumatic N-Steroid	M1A1 Antirheumatics Non-S Pln
tenoxicam	Tilcotil	M1A Antirheumatic N-Steroid	M1A1 Antirheumatics Non-S Pln
Ibuprofen/paracetamol	Brufen Extra	M1A Antirheumatic N-Steroid	M1A2 Antirheumatic Non-S Comb
celecoxib	Celostea	M1A Antirheumatic N-Steroid	M1A3 Coxibs Plain
Rizatriptan	Rizamelt	N2C Anti-Migraine Preps	N2C1 Antimigraine Triptans
sumatriptan	Sumagran Active	N2C Anti-Migraine Preps	N2C1 Antimigraine Triptans
clonazepam	Paxam	N3A Anti-Epileptics	N3A0 Anti-Epileptics

gabapentin	Nupentin	N3A Anti-Epileptics	N3A0 Anti-Epileptics
lamotrigine	Logem	N3A Anti-Epileptics	N3A0 Anti-Epileptics
amisulpride	Sulprix	N5A Antipsychotics	N5A1 Atypical Antipsychotics
clozapine	Clozaril	N5A Antipsychotics	N5A1 Atypical Antipsychotics
Olanzapine ODT	Zypine ODT	N5A Antipsychotics	N5A1 Atypical Antipsychotics
olanzapine	Zypine	N5A Antipsychotics	N5A1 Atypical Antipsychotics
quetiapine	Quetapel	N5A Antipsychotics	N5A1 Atypical Antipsychotics
risperidone	Risperon	N5A Antipsychotics	N5A1 Atypical Antipsychotics
busiprone	Pacific Busiprone (discontinued)	N5C Tranquillisers	N5C0 Tranquillisers
lithium	Lithicarb (to be discontinued)	N6A Antidepress.& Mood Stab.	N6A3 Mood Stabilisers
citalopram	Celapram	N6A Antidepress.& Mood Stab.	N6A4 SSRI Antidepressants
escitalopram	Loxalate	N6A Antidepress.& Mood Stab.	N6A4 SSRI Antidepressants
fluoxetine	Fluox	N6A Antidepress.& Mood Stab.	N6A4 SSRI Antidepressants
fluvoxamine	Luvox (discontinued)	N6A Antidepress.& Mood Stab.	N6A4 SSRI Antidepressants
paroxetine	Loxamine	N6A Antidepress.& Mood Stab.	N6A4 SSRI Antidepressants
venlafaxine	Enlafax ER	N6A Antidepress.& Mood Stab.	N6A5 SSRI Antidepressants

amitriptyline	Amitrip (discontinued)	N6A Antidepress.& Mood Stab.	N6A9 Antidepressants All Oth
dosulepin	Dosulepin Mylan	N6A Antidepress.& Mood Stab.	N6A9 Antidepressants All Oth
doxepin	Anten (to be discontinued)	N6A Antidepress.& Mood Stab.	N6A9 Antidepressants All Oth
moclobemide	Aurorix	N6A Antidepress.& Mood Stab.	N6A9 Antidepressants All Oth
nortriptyline	Norpress	N6A Antidepress.& Mood Stab.	N6A9 Antidepressants All Oth
dorzolamide timolol	Dortimopt	S1E Miotics+Antiglauc.Preps.	S1E2 Miotics+Antiglaucoma Top
travoprost	Travopt	S1E Miotics+Antiglauc.Preps.	S1E2 Miotics+Antiglaucoma Top

Upjohn Global products[70]			
Molecule	**Upjohn Brand Name**	**ATC3**	**ATC4**
atorvastatin	Lipitor	C10A Cholest&Trigly.Regulator	C10A1 Statins (Hmg-Coa Red)
amlodipine / atorvastatin	Caduet	C11A Lipreg.Cv.Mult-Th.Combs	C11A1 Lipreg.Cv.Mult-Th.Fx.Com
nitroglycerin	Nitrostat	C1E Nitrites And Nitrates	C1E0 Nitrites And Nitrates
doxazosin	Cardura	C2A Antihypertens(Non Veg)Pl	C2A2 Antihyper.Pl Mainly Peri
eplerenone	Inspra	C3A Diuretics	C3A1 Pot Sparing Agents Plain

[70] This table includes Upjohn's entire global portfolio, however Caduet, Cardura, Relpax, Sermion, Xalacom, Revatio and Xanax are not marketed in New Zealand and have never been supplied here. Some of these products may have been imported as Medsafe allows the import of unregistered medicines for use in New Zealand per s 29 of the Medicines Act 1981.

nicergoline	Sermion	C4A Cerebr/Periph Vasotherap	C4A1 Cereb/Periph Vasotheraps
sildenafil	Revatio	C6B Pulmonary Arterial Hypertension (Pah) Products	C6B2 Pde5 Inhibitor Pah Prods
amlodipine	Norvasc	C8A Calcium Antagonist Plain	C8A0 Calcium Antagonist Plain
tolterodine	Detrol LA	G4D Urinary Incontinence Prd	G4D4 Urinary Incontinence Prd
sildenafil	Viagra	G4E Erectile Dysfunction Prd	G4E1 Erect Dys Prd Pde5 Inhib
celecoxib	Celebrex	M1A Antirheumatic N-Steroid	M1A3 Coxibs Plain
eletriptan	Relpax	N2C Anti-Migraine Preps	N2C1 Antimigraine Triptans
gabapentin	Neurontin	N3A Anti-Epileptics	N3A0 Anti-Epileptics
phenytoin	Dilantin	N3A Anti-Epileptics	N3A0 Anti-Epileptics
pregabalin	Lyrica	N3A Anti-Epileptics	N3A0 Anti-Epileptics
ziprasidone	Geodon	N5A Antipsychotics	N5A1 Atypical Antipsychotics
alprazolam	Xanax[71]	N5C Tranquillisers	N5C0 Tranquillisers
sertraline	Zoloft	N6A Antidepress.& Mood Stab.	N6A4 SSRI Antidepressants
venlafaxine	Effexor	N6A Antidepress.& Mood Stab.	N6A5 SNRI Antidepressants
latanoprost	Xalatan	S1E Miotics+Antiglauc.Preps.	S1E2 Miotics+Antiglaucoma Top
Latanoprost / timolol maleate	Xalacom	S1E Miotics+Antiglauc.Preps.	S1E2 Miotics+Antiglaucoma Top

[71] Any sales of Xanax in 2018 may be related to the last of the inventory being sold into community pharmacies prior to the brand being discontinued. Any evidence of sales in 2019 would be latent demand from patients in New Zealand accessing the alprazolam molecule via s 29.

Annex 2 – List of products involved in the Mylan / Aspen Transaction

[*redacted*].

[*redacted*].			
[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*][72]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*][73]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]

[72] [*redacted*].
[73] [*redacted*].

Annex 3: The Parties' most recent audited accounts

Attached

Annex 4 – Trade / Industry Associations

Trade / industry associations in pharmaceuticals market		
Association	**Brief description**	**Contact details**
New Zealand Self-Medication Industry (Mylan NZ is a member of and has a seat on the Executive Committee).	NZSMI is the voice of the consumer self-care products industry. SMI represents members by positively and proactively influencing key interest groups in their attitudes towards availability of and access to over-the-counter medicines. We keep our members up to date with all relevant industry news as well as changes across marketing, regulations and industry trends.	Scott Milne Phone +64 9 528 8217 Email: scott.milne@nzsmi.org.nz
Medicines New Zealand (Mylan NZ is not a member of but works closely with)	Medicines New Zealand advocates to improve access to modern medicines for New Zealand patients. Medicines New Zealand is an industry association whose members are engaged in the research, development, manufacture and marketing of modern prescription medicines.	Dr Graeme Jarvis, CEO Phone: +64 4 499 4277 Email: Graeme.jarvis@medicinesnz.co.nz info@medcinesnz.co.nz
Pharmacy Council Te Pou Whakamana Kaimatu o Aotearoa (Mylan NZ is not a member of)	The Pharmacy Council is established under the Health Practitioners Competence Assurance Act 2003 (HPCAA) and has a duty to protect the public and promote good pharmacist practice.	Dr Jeff Harrison, Chair Phone +64 4 495 0330 Email: enquiries@pharmacycouncil.org.nz
Pharmacy Guild of New Zealand	The Pharmacy Guild of New Zealand provides support and services to community pharmacy owners.	Andrew Gaudin, Chief Executive Phone +64 4 802 8200 Email: enquiries@pgnz.org.nz
Pharmaceutical Society of New Zealand incorporated (Mylan NZ is not a member of but works closely with)	The Pharmaceutical Society of New Zealand Inc. (the Society) is the professional association representing	Ian McMichael, President Phone +64 4 802 0030

Trade / industry associations in pharmaceuticals market		
Association	**Brief description**	**Contact details**
(Pfizer NZ is a member)	over 3,700 pharmacists from all sectors of pharmacy practice. We provide pharmacists with professional support, representation, training for continuing professional development, integration frameworks tools, and assistance to enable them to deliver to all New Zealanders the best pharmaceutical practice and professional services in relation to medicines	Email: p.society@psnz.org.nz
New Zealand Therapeutic Products Manufacturers Association Incorporated (Mylan NZ is not a member of)	The New Zealand Therapeutic Products Manufacturers Association Inc. (**TPMA**) is the voice for members representing laboratories, manufacturers and packers operating under codes of Good Manufacturing Practice and/or Good Laboratory Practice, in relation to the production and testing of therapeutic products.	Silena Kirkconnell-Kawana, Chair (Douglas Manufacturing) Email: info@tpma.org.nz
New Zealand Hospital Pharmacists' Association (**NZHPA**)	The NZHPA is a not for profit voluntary member organisation which represents the views of and advocates for hospital pharmacists. NZHPA also provides a voice for members on national pharmacy related issues and enables hospital pharmacist representation on national pharmacy bodies.	http://www.nzhpa.org.nz

Annex 5: Competitor contact details

Cholesterol and triglyceride regulators	
Party	**Contact details**
Apotex	[*redacted*]
AstraZeneca	[*redacted*]
Douglas	[*redacted*]
Novartis	[*redacted*]
Teva	[*redacted*]

Nitrites and nitrates	
Party	**Contact details**
AFT Pharmaceutical	[*redacted*]
Douglas	[*redacted*]
Inova	[*redacted*]
Novartis	[*redacted*]
HCL	[*redacted*]

Diuretics	
Party	**Contact details**
Aft Pharmaceutical	[*redacted*]
CSL now Seqirus	[*redacted*]
Sanofi	[*redacted*]
Teva	[*redacted*]

Erectile dysfunction products	
Party	**Contact details**
Bayer	[*redacted*]
Douglas	[*redacted*]
Lilly	[*redacted*]
Teva	[*redacted*]

Anti-rheumatic and anti-inflammatory products	
Party	**Contact details**
Apotex	[*redacted*]
Glaxosmithkline	[*redacted*]
Multichem	[*redacted*]
Merck & Co (Merck Sharp and Dome)	[*redacted*]
Novartis	[*redacted*]
Roche Products	[*redacted*]
Teva	[*redacted*]

Antidepressants and mood stabilisers	
Party	**Contact details**
Airflow Products	[*redacted*]
API	[*redacted*]
Apotex	[*redacted*]
Go Healthy	[*redacted*]
Lilly	[*redacted*]
Teva	[*redacted*]

Annex 6: Mylan's key customers

Mylan's key customers (all market segments)			
Party	**Revenue 2018 (NZD)**	**Revenue 2019 (NZD)**	**Contact details**
Pharmac	Government procurement agency. Revenues represented by market shares		[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*][74]	[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]

[74] [*redacted*].

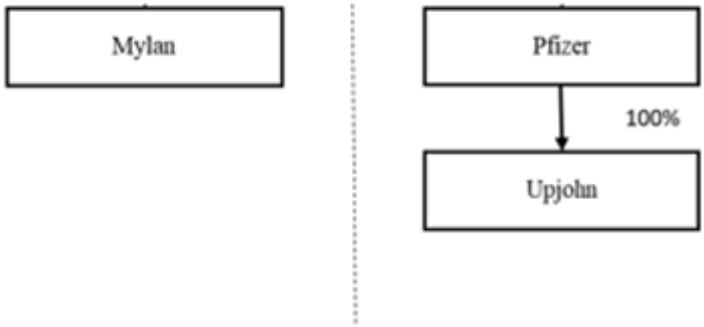
Annex 7: Upjohn's Key Customers[75]

Upjohn's five largest customers in New Zealand		
Name	**FY2018 revenue (NZD)**	**Contact details**
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]
[*redacted*]	[*redacted*]	[*redacted*]

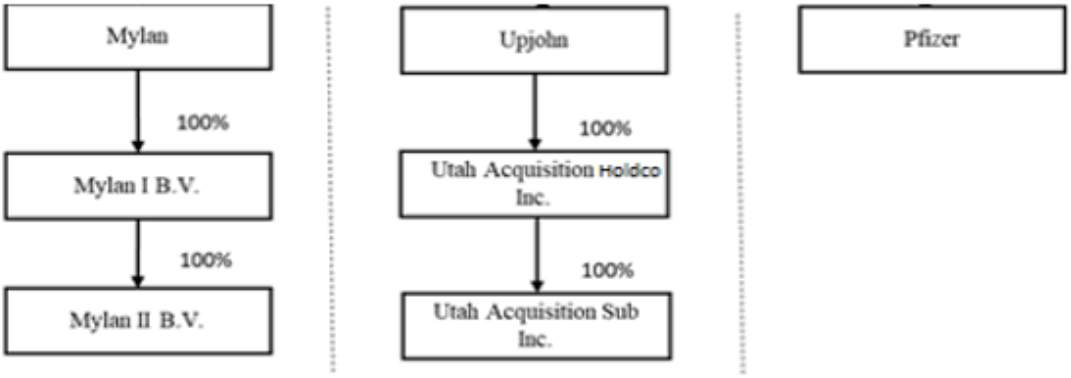
[75] For 2018.

Annex 8 – Pre and post transaction structure chart

Before separation of Upjohn Business



After Separation of Upjohn Business



Organization chart of the Parties after implementation of the Proposed Transaction