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Determination

Mylan N.V. and Upjohn Inc. [2020] NZCC 18

The Commission:	Anna Rawlings Dr Derek Johnston Dr John Small
Summary of application:	An application from Mylan N.V. and Upjohn Inc. seeking clearance to combine Upjohn's portfolio of off-patent branded pharmaceuticals with Mylan's portfolio of generic pharmaceuticals in New Zealand.
Determination:	Under section 66(3)(a) of the Commerce Act 1986, the Commerce Commission determines to give clearance to the proposed merger (subject to the divestment undertaking dated 8 September 2020 provided by Mylan N.V. and Upjohn Inc. and Upjohn New Zealand ULC under section 69A of the Commerce Act 1986).
Date of determination:	9 September 2020

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

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Glossary

Term	Description
Active ingredient	The chemical ingredient in a medicine that is responsible for the clinical or therapeutic effects.
ATC classification system	A method developed by the European Pharmaceutical Marketing Research Association for classifying pharmaceutical products according to their indication, therapeutic use, composition and mode of action.
DHB	District Health Board. DHBs are Crown entities that are responsible for providing, or funding the provision of, health services in their district.
Funded medicine	Medicines that are subsidised by DHBs for use in the community and hospitals.
Galenic form	Refers to the physical form of the medicine, eg, whether it is a tablet, capsule, or ointment.
Generic medicine	A medicine that has been developed to be equivalent to an innovator medicine, ie, it has the same active ingredient(s), dosage, method of administration as the innovator medicine.
Innovator medicine	A medicine that is the first to receive approval for use containing its specific active ingredient(s). Innovator medicines are usually branded and patented by the developing firm.
Medsafe	The New Zealand Medicines and Medical Devices Safety Authority. Medsafe's role is to ensure that medicines and medical devices supplied in New Zealand have acceptable efficacy, quality and safety.
Medsafe approval	Approval given by Medsafe to confirm that a medicine or medical device is effective, safe and of sufficient quality to be used in New Zealand. Firms cannot supply a medicine in New Zealand unless they hold Medsafe approval for that medicine.
Molecule	A particle made up of two or more atoms that are bonded together. The medicines referred to in this determination have active ingredients that consist of single molecules.
OTC medicine	'Over-the-counter' medicines that can be bought by customers without first needing to obtain a prescription.
PHARMAC	The Pharmaceutical Management Agency, which is the Crown entity responsible for deciding which medicines are publicly funded in New Zealand.
Registered medicine	A medicine that has been approved by Medsafe (see Medsafe approval).

Specialty medicine	A type of medicine that is high cost or high complexity. Speciality medicines are often derived from living cells.

The proposed merger

1. On 18 December 2019, the Commerce Commission (the Commission) registered an application (the Application) from Mylan N.V. (Mylan) and Upjohn Inc. (Upjohn) (together, the Parties) seeking clearance under section 66(1) of the Commerce Act 1986 (the Act) to merge. This would involve combining Upjohn's portfolio of off-patent branded pharmaceutical products (medicines) with Mylan's portfolio of generic medicines (the Proposed Merger).[1]

2. The Parties have offered an undertaking to divest assets required to supply specific Upjohn medicines in New Zealand (the Divestment Undertaking) as part of the Application. We set out our assessment of the Divestment Undertaking in more detail below. A copy of the Divestment Undertaking is provided as **Attachment A**.

Our decision

3. The Commission gives clearance to the Proposed Merger (subject to the Divestment Undertaking) as it is satisfied that the Proposed Merger together with the Divestment Undertaking will not have, or would not be likely to have, the effect of substantially lessening competition in a market in New Zealand.

4. In New Zealand, both Parties compete to supply off-patent prescription medicines. This includes competing to win contracts to supply medicines that are subsidised by the Pharmaceutical Management Agency (PHARMAC) and competing to supply unsubsidised medicines outside the PHARMAC process.

5. The focus of our analysis is on whether the loss of direct competition between the Parties in the supply of certain medicines would enable the merged entity to profitably raise prices or reduce quality. We identified the medicines that both Parties supplied (or could supply). For most of those medicines, we are satisfied that the merged entity would face sufficient competition post-merger. However, we identified four medicines (gabapentin, pregabalin, celecoxib and sildenafil) that raised competition concerns.

6. The Parties offered to divest those products from Upjohn to enable another rival to compete in those markets. We consider that the divestments would allow another firm to become a credible competitor for the four medicines. As such, subject to the divestment being undertaken, we are satisfied the merged entity would face sufficient constraints to prevent it raising prices or reducing quality or service.

[1] A public version of the Application is available on our website at: https://comcom.govt.nz/__data/assets/pdf_file/0027/197226/Mylan-N.V.-and-Upjohn-Inc-Clearance-application-10-December-2019.pdf.

Our framework

7. Our approach to analysing the competition effects of the Proposed Merger is based on the principles set out in our Mergers and Acquisitions Guidelines (our guidelines).[2]

The substantial lessening of competition test

8. As required by the Act, we assess mergers and acquisitions using the substantial lessening of competition test.

9. We determine whether a merger is likely to substantially lessen competition in a market by comparing the likely state of competition if the merger proceeds (the scenario with the merger, often referred to as the factual), with the likely state of competition if the merger does not proceed (the scenario without the merger, often referred to as the counterfactual).[3]

10. A lessening of competition is generally the same as an increase in market power. Market power is the ability to raise prices above the price that would exist in a competitive market (the 'competitive price'),[4] or reduce non-price factors such as quality or service below competitive levels.

When a lessening of competition is substantial

11. Only a lessening of competition that is substantial is prohibited. A lessening of competition will be substantial if it is real, of substance, or more than nominal.[5] Some courts have used the word 'material' to describe a lessening of competition that is substantial.[6]

12. As set out in our guidelines, there is no bright line that separates a lessening of competition that is substantial from one which is not. What is substantial is a matter of judgement and depends on the facts of each case.[7]

13. A lessening of competition or an increase in market power may manifest itself in a number of ways, including higher prices or reduced services.[8]

14. While we commonly assess competition effects over the short term (up to two years), the relevant timeframe for assessment depends on the circumstances. A longer timeframe will be appropriate if, on the evidence, competition effects are likely to arise in later years.[9]

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2 Commerce Commission, *Mergers and Acquisitions Guidelines* (July 2019).
3 *Commerce Commission v Woolworths Limited* (2008) 12 TCLR 194 (CA) at [63].
4 Or below competitive levels in a merger between buyers.
5 *Woolworths & Ors v Commerce Commission* (2008) 8 NZBLC 102,128 (HC) at [127].
6 Ibid at [129].
7 *Mergers and Acquisitions Guidelines* above n2 at [2.23].
8 Ibid at [2.21].
9 *Woolworths & Ors v Commerce Commission* (2008) 8 NZBLC 102,128 (HC) at [131].

When a substantial lessening of competition is likely

15. A substantial lessening of competition is 'likely' if there is a real and substantial risk, or a real chance, that it will occur. This requires that a substantial lessening of competition is more than a possibility but does not mean that the effect needs to be more likely than not to occur.[10]

The clearance test

16. We must clear a merger if we are satisfied that the merger would not be likely to substantially lessen competition in any market.[11] If we are not satisfied – including if we are left in doubt – we must decline to clear the merger.

Divestment undertakings

17. We may accept undertakings to dispose of assets or shares.[12] If we accept a divestment undertaking, it is deemed to form part of the clearance.

18. As set out in our divestment guidelines,[13] upon receiving a divestment undertaking, we will consider whether the proposed divestment is sufficient to remedy any substantial lessening of competition that would otherwise arise from the proposed merger.

The Parties and the transaction

Mylan

19. Mylan is a global pharmaceutical company based in the United States. Mylan develops, licenses, manufactures, markets and distributes generic, branded generic, and specialty medicines. Globally, Mylan manufactures and markets more than 1,400 different medicines to retail, wholesale, government and institutional customers.[14]

20. Mylan is active in New Zealand through its wholly owned subsidiary, Mylan NZ Limited. Its product portfolio in New Zealand specialises in medicines that no longer have patents that apply to them (ie, off-patent medicines, most of which are non-branded).

Upjohn

21. Upjohn is currently a subsidiary of Pfizer Inc, but Pfizer proposes to divest Upjohn and establish it as a standalone entity before completing the Proposed Merger. Pfizer is a global pharmaceutical company involved in the research, development, manufacturing and supply of medicines. Upjohn has a portfolio of 21 off-patent branded medicines including the brands Viagra, Lipitor, and Lyrica.[15] In New Zealand,

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10 Ibid at [111].

11 Section 66(3)(a).

12 Under section 69A(2) of the Act, we are only able to accept structural undertakings. This means that we are unable to accept behavioural undertakings.

13 *Mergers and Acquisitions Guidelines* above n2 at Attachment F.

14 The Application at [2.1]-[2.2].

15 Viagra (active ingredient is sildenafil) is commonly used to treat erectile dysfunction. Lipitor (active ingredient is atorvastatin) is commonly used to prevent cardiovascular disease. Lyrica (active ingredient is

Upjohn currently operates this portfolio of medicines under the registered company Upjohn New Zealand ULC.

Rationale for the Proposed Merger

22. The Application states that the rationale for the Proposed Merger is to deliver enhanced global scale and geographic reach, including leading positions in China and other emerging markets.[16]

Industry background

The main types of medicine

23. Medicines can be divided into two categories: prescription and over-the-counter (OTC) medicines.

    23.1 Prescription medicines are only available with a prescription from a doctor and are dispensed by pharmacies (community medicines) or to a patient in a hospital (hospital medicines).

    23.2 Consumers can buy OTC medicines without a prescription from pharmacies.

24. The Proposed Merger relates to prescription medicines.

25. Medicines can also be distinguished based on whether they are innovator (original) products or generics.

    25.1 Original medicines are new products – for example, entirely new medicines, or sometimes new formulations – and are typically patented by the firm that developed them. A firm with a patent over a medicine enjoys the right to sell it exclusively for the life of the patent.

    25.2 Once the patent for an originator medicine expires, other firms can make and supply their own versions of it.[17] These products are known as generic medicines, or generics. A generic:

        25.2.1 has the same active ingredient(s) as the original version, but may have different non-active ingredients; and

        25.2.2 is generally considered to be equivalent to the original medicine in that it can be used for the same medical purpose.

26. The Proposed Merger relates to both originator and generic medicines.

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pregabalin) is used to treat epilepsy, nerve pain, and generalised anxiety disorder (among other indications).

16 The Application at [5.1].

17 Provided they obtain the necessary regulatory approvals to do so.

How medicines are classified

27. One method for classifying medicines is the Anatomical Therapeutic Chemical (ATC) classification system.[18] This uses a "tree-like" structure with five levels that become progressively more specific in how they group medicines. For example, ATC1 groups medicines broadly according to the part of the body that they act on. ATC5 lists individual molecules, which are the active ingredients that pharmaceutical companies develop and patent, and later become available as generics.

28. In our analysis below, we mainly use and refer to the ATC5 (specific molecule) and ATC4 levels of the ATC system. At the ATC4 level there are numerous groups of molecules, and the molecules in each group typically have the same mode of action and therapeutic use.[19]

The regulatory process to supply medicines in New Zealand

29. Medicines cannot be supplied in New Zealand unless they have been approved and registered by the New Zealand Medicines and Medical Devices Safety Authority (Medsafe). Medsafe's role is to ensure that medicines and medical devices supplied in New Zealand have acceptable efficacy, quality and safety.[20]

30. Firms that wish to supply a medicine in New Zealand must first apply to Medsafe for approval. An application to register a medicine must include information such as what active and inactive ingredients the medicine contains and how it will be manufactured and packaged. Medsafe assesses the application and decides whether to approve and register the medicine for supply in New Zealand.

31. It normally takes 15 to 18 months for Medsafe to register a medicine.[21] Medicines that already have regulatory approval in other countries, such as Australia, can qualify for an abbreviated process. In this case, the New Zealand approval process can be shortened to 9 to 12 months.

32. We refer to medicines that are Medsafe-approved as being "registered medicines".

Government subsidies for medicines in New Zealand

33. In New Zealand, the supply of many prescription medicines to patients are subsidised by the government – that is, the government pays for part or all of the

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18 See for example World Health Organization "Anatomical Therapeutic Chemical (ATC) Classification" www.who.int.

19 The Application at [12.7]. To illustrate, the WHO ATC4 group "HMG CoA reductase inhibitors" (commonly called statins) are all molecules that treat cholesterol by the same mode of action (blocking the same enzyme involved in the production of harmful cholesterol), although the different molecules (atorvastatin, simvastatin, etc) differ in their efficacy, speed of action, and other characteristics. Molecules in another ATC4 group, "Fibrates" can also treat cholesterol via a different biochemical process. Statins and fibrates may also have other therapeutic uses beyond treating cholesterol. We note that statins and fibrates are in the same ATC3 group: "Lipid modifying agents, plain".

20 Medsafe "About Medsafe" www.medsafe.govt.nz.

21 The Application at [11.4].

cost of the medicine on behalf of patients.[22] PHARMAC decides which registered medicines and related products are subsidised for use in the community and in public hospitals. District Health Boards (DHBs) pay the subsidies.[23]

34. We refer to medicines that PHARMAC has selected to be subsidised as "funded medicines".

35. PHARMAC's decisions as to which medicines will be funded are based on a number of factors including:[24]

    35.1 the impact of the disease or condition that a medicine will address;

    35.2 benefits and/or side effects of the medicine;

    35.3 costs and savings that would result from the funding the medicine; and

    35.4 suitability of the medicine for patients.

36. Once PHARMAC decides that a medicine will be funded, it will normally select its preferred supplier through a tender or a request for proposal (RFP) process.[25] PHARMAC will choose the winning bidder based on factors such as:

    36.1 the prices at which bidders are willing to supply; and

    36.2 the reliability of bidders as suppliers.

37. A winning bidder typically gains the right to be the sole supplier of a funded medicine for a fixed term, for specified clinical uses. The winning bid price is fixed for the life of the contract. Contracts usually last for three years, although:

    37.1 [ ]; and

    37.2 after the initial term, a supplier continues to supply under the contract until it gives notice to PHARMAC, or until PHARMAC retenders the contract.

38. PHARMAC can also negotiate deals with a supplier outside of the tender or RFP process (for example, when it is considering entering into agreements for the supply of multiple products from a single supplier).

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22 There are around 20,000 medicines that the government funds. See Pharmac "Medicines" www.pharmac.govt.nz.

23 DHBs fund hospitals, which pay for funded medicines. In the community, pharmacies dispense a funded product for just the prescription fee and DHBs reimburse pharmacies for the purchase cost, which is set by the PHARMAC contract.

24 See Pharmac "How medicines are funded" www.pharmac.govt.nz.

25 The majority of PHARMAC tenders are for sole-supply.

The prices that consumers pay for medicines

39. Most consumers get their prescriptions filled at pharmacies. If the consumer has a prescription for a medicine that is funded by PHARMAC and is for the specified clinical use, they will usually only have to pay a prescription fee.

40. Consumers can also purchase registered medicines that are not funded by PHARMAC. Consumers might choose to do this in the following circumstances.

    40.1 PHARMAC has chosen not to fund a medicine, but a consumer is prepared to pay the full price for it. For example, PHARMAC does not subsidise products for the treatment of erectile dysfunction.

    40.2 There is a PHARMAC-funded version of the medicine, but the consumer prefers the unfunded version and is willing to pay the additional cost for it. For example, there are funded and unfunded versions of venlafaxine.

        40.2.1 Mylan's venlafaxine product Enlafax is currently PHARMAC-funded. Consumers who have a prescription for venlafaxine can obtain Enlafax at pharmacies at no additional cost to the prescription fee.

        40.2.2 Upjohn's Efexor product (also a venlafaxine medicine) is not funded by PHARMAC but is available at some pharmacies. Pharmacies are free to set their retail price for Efexor. Consumers who have a prescription for venlafaxine can purchase Efexor for the retail price in addition to the prescription fee.

The wholesale and retail prices of medicines

41. If a medicine is PHARMAC-funded, the wholesale price that pharmacies pay is fixed at the PHARMAC contract price. Pharmacies are reimbursed by DHBs when they dispense a PHARMAC-funded medicine. The pharmacy is not permitted to add a retail mark-up but can charge a prescription fee.

42. If a medicine is not funded by PHARMAC, pharmacies pay a commercial wholesale price to the pharmaceutical supplier and then add a retail mark-up when selling to consumers.

Market definition

Introduction

43. Market definition is a tool that helps identify and assess the competitive constraints the merged firm would face. Determining the relevant market requires us to judge whether, for example, two products are sufficiently close substitutes as a matter of fact and commercial common sense to fall within the same market.

44. We define markets in the way that we consider best isolates the key competition issues that arise from a merger. In many cases this may not require us to precisely define the boundaries of a market. What matters is that we consider all relevant competitive constraints, and the extent of those constraints. For that reason, we also

consider products and services that fall outside the market, but which would still impose some degree of competitive constraint on the merged entity.

Previous decisions involving markets for medicines

45. The Commission has taken different approaches to market definition in previous cases involving medicines, due to the circumstances of each case.

    45.1 In *Mylan Abbott* (2014) we defined the relevant market at the ATC5, or molecule, level – for verapamil, a molecule which both parties supplied.[26] This was on the basis that there were patients for whom no other molecule was a good substitute to verapamil. We did not consider that treatments where the parties supplied products with different active ingredients were close substitutes.

    45.2 In *Pfizer Hospira* (2015) we defined the market at the level of the galenic form of the molecule.[27] For example, it defined a market for "methotrexate tablets, 2.5mg". This more narrowly defined market (compared with the market for verapamil in *Mylan Abbott*) was used because, for the medicines being considered, patients required precise means of administration.[28]

    45.3 In *Schering-Plough Organon* (2007) the merging parties both had cardiovascular and cancer therapy products. We found it was not necessary to precisely define the relevant markets, as the parties' products were in different ATC2 categories and were not close substitutes, and therefore there was no aggregation as a result of the proposed merger.[29]

The Parties' view of the relevant markets

46. In the Application, the Parties identified two channels for the supply of medicines in New Zealand, which they defined as the public and private channels.

    46.1 In the public channel, PHARMAC typically runs tenders to select a sole-supplier for each medicine that it schedules for public subsidy. Since tenders are usually awarded to sole suppliers, competition is usually 'for the market', typically for a period of three years – ie, the winning bidder will supply all volumes that DHBs will fund in hospitals and in the community – and takes place at the time of the tender.[30]

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26 *Mylan and Abbott Laboratories' Established Pharmaceuticals Division* [2014] NZCC 40 at [57].

27 *Pfizer, Inc and Hospira, Inc* [2015] NZCC 19 at [77]. Galenic form refers to the physical form of the dosage (eg 10mg, 20mg, 80mg) and means of administration (eg tablet, liquid, ointment) for a given molecule. This is different to the ATC categorisation which, as explained above, categorises medicines into increasingly specific groupings of substitutability.

28 At [68].

29 Commerce Commission *Schering-Plough Corporation and Organon Biosciences NV* (5 October 2007, Decision No 621) at [102] and [108].

30 After PHARMAC has awarded a contract to supply a medicine in all publicly funded uses for three years, the winning bidder may also supply some volumes for therapeutic uses that PHARMAC does not fund, to consumers who have to pay the full retail price. However, such volumes tend to be low since when PHARMAC funds medicines it tends to fund them for their main uses.

46.2 In the private channel, firms supply medicines that are not publicly funded. Products sold through the private channel are typically branded products, for which some patients are willing to pay non-subsidised prices.

47. In addition to distinguishing the public and private channels for medicines, the Application provides an assessment of the medicines where the Parties consider there to be a supply overlap between them at both the:

47.1 ATC5 (molecule) level (ie, medicines that have the same active ingredient); and

47.2 ATC4 level (ie, groups of medicines that have the same therapeutic use or similarities in their formulation or mode of action).

The Commission's view of the relevant markets

Separate public and private markets

48. We consider that the public and private channels of supply give rise to separate markets. In many cases, medicines are only supplied via one channel. Occasionally, the same medicine is sold in both channels, but for different uses.[31] In any event, the conditions of competition differ significantly between the two channels.

49. We have outlined in paragraphs [36] to [38] the public procurement of medicines. In that channel competition is mainly 'for the market'. Consumer demand is driven by doctors' prescriptions, and where patients are stabilised on medicines over a longer term (eg, when treating chronic conditions), they are not likely to switch.

50. In the private channel conditions are different:

50.1 Suppliers compete to sell branded pharmaceuticals to final consumers via pharmacy chains and other resellers. Suppliers use marketing to appeal to the final consumers, who can make only occasional purchases if they choose, and who can switch easily.

50.2 Suppliers also negotiate with pharmacy chains over wholesale prices and try to provide incentives for pharmacies to influence consumers' choices. For example, a supplier may offer a pharmacy chain a volume-based deal or rebate that sees wholesale prices fall as sales increase, to encourage the pharmacy to promote a medicine.

50.3 Consumers pay full, unsubsidised retail prices that are set by pharmacies in competition with one another, and that are influenced by suppliers' wholesale prices. Consumers decide which of sometimes several competing medicines to buy after considering prices, brands and other factors.

[31] For example, Mylan's sildenafil product, Vedafil, is sold in the public channel for treatment of Reynaud's Syndrome, pulmonary arterial hypertension and erectile dysfunction caused by spinal injuries, and in the private channel to treat ordinary cases of erectile dysfunction.

51. While we treat the public and private channels as separate markets, in some instances PHARMAC-funded medicines provide a constraint on medicines sold in the private channel. We have taken this into account in our competition assessment.

Product dimension

52. In the public markets, we consider it appropriate to assess competition using separate markets for each molecule where the Parties overlap. This is for the following reasons.

    52.1 Typically, PHARMAC tenders at the molecule level, and does not seek or receive bids for alternative medicines that may be substitutable for treating the underlying condition. Once PHARMAC has determined that a given molecule is the best overall choice for treating a publicly-funded condition – on the grounds of clinical efficacy and expected cost-effectiveness – it then procures that molecule and no others, in nearly all cases.
    [
    ][32]

    52.2 In principle, a doctor may still be able to prescribe another product if the reimbursement price of the PHARMAC-funded one were to increase between tenders, for example out of regard for the public purse. However, although doctors must have regard to prescription costs, their primary obligation is to prescribe the treatments that are most effective for patients.[33] So, on balance, in response to price increases, doctors are unlikely to switch patients between molecules, especially once treatment is established.

53. In the private markets, we also consider it appropriate to assess competition using separate markets for each molecule where the Parties overlap. Although consumers can choose to switch between medicines with different active ingredients that treat the same condition, in most cases the closest substitute for one medicine will be another medicine with the same active ingredient. Put another way, where a medicine with a given active ingredient works for a consumer, they are more likely to switch between suppliers offering medicines with the same active ingredient if a particular medicine increases in price before switching to a different molecule.[34] Switching to a different molecule is more likely to be on the basis of efficacy rather than price. The closest competitors for a given medicine will therefore be those firms that supply medicines with the same active ingredient.

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32 [ ]

33 Medical Council, "Statement on good prescribing practice" (March 2020) https://www.mcnz.org.nz/assets/standards/ceae513c85/Statement-on-good-prescribing-practice.pdf.

34 For example, in respect of sildenafil [ ] told us that patients are most likely to switch from Viagra to other sildenafil options (Silvasta or Vedafil) but will switch to tadalafil if sildenafil is not working. Switching to other molecules is "fairly uncommon" as sildenafil works for most people. [ ].

54. While we have treated each molecule as a separate market in both the public and private channels, where appropriate we have also considered the constraint imposed by other products with different active ingredients.

Geographic dimension

55. We consider that the relevant markets are national in scope, given that:

    55.1 in the public channel, PHARMAC tenders or RFPs are for supply of a particular medicine to New Zealand as a whole;

    55.2 in the private channel:

        55.2.1 medicines are distributed nationwide; and

        55.2.2 competitive conditions do not seem to differ by region.

The markets we have assessed

56. We have analysed the Parties' portfolios, and have conducted a competition assessment on markets where the Parties might impose a constraint on one another if not for the Proposed Merger. In most cases this was because both Mylan and Upjohn had a registered medicine and so are likely to see each other as current competitors. We also included markets where the Parties both had the molecule in their portfolios and so are potential competitors, even though one did not have a registration to supply in New Zealand.

57. Based on this approach, the markets we have considered are the national markets for the supply of medicines with the active ingredients as set out in Table 1.

Table 1: Molecules that we have considered

Molecule	Commonly used to treat	Market (public or private)
amlodipine	High blood pressure and coronary artery disease	Public market
atorvastatin	Cardiovascular disease, abnormal lipid levels	Public market
celecoxib	Pain and inflammation	Public market
doxazosin	Enlarged prostate	Public market
eplerenone	Chronic heart failure, high blood pressure	Public market
gabapentin	Epileptic seizures and neuropathic pain	Public market
latanoprost	High pressure inside the eye	Public market
phenytoin	Epileptic seizures	Public market
pregabalin	Epileptic seizures and neuropathic pain	Public market
tolterodine	Bladder control issues	Public market
ziprasidone	Schizophrenia and bipolar disorder	Public market
sildenafil	Erectile dysfunction, pulmonary arterial hypertension	Both public and private markets
venlafaxine	Anxiety and depression	Both public and private markets

58. We also considered whether any of the medicines supplied by the Parties are close competitors despite containing different active ingredients (such that they impose a constraint on one another). However, we did not identify any medicines that are likely to raise competition concerns on this basis.

With and without scenarios

59. To assess whether a merger is likely to substantially lessen competition in a market, we compare the likely state of competition if the merger proceeds (the scenario with the merger, often referred to as the factual), with the likely state of competition if

the merger does not proceed (the scenario without the merger, often referred to as the counterfactual).[35]

With the merger

60. In the factual, Mylan and Upjohn would combine their businesses in New Zealand and globally.

Without the merger

61. The Parties submitted that if the Proposed Merger does not proceed there are two possible counterfactuals.[36]

    61.1 The status quo: both Mylan and Upjohn would continue to operate as independent businesses.

    61.2 [

    ]

62. On the basis of the information provided to us by the Parties, we consider that the likely state of competition without the Proposed Merger is best reflected by the status quo.

How the Proposed Merger could substantially lessen competition

63. We considered whether the Proposed Merger would be likely to substantially lessen competition due to:

    63.1 horizontal unilateral effects, ie, whether the loss of direct competition between the Parties in the supply of a range of medicines would enable the merged entity to profitably raise prices or reduce quality by itself;

    63.2 coordinated effects, ie, whether the Proposed Merger would change the conditions in the relevant markets so that coordination is more likely, more complete or more sustainable; and

    63.3 conglomerate effects, ie, whether the merged entity would be able to bundle or tie its products to prevent or inhibit rivals from competing.

64. Another way mergers can adversely affect competition is through vertical effects. Vertical effects can arise where there is a merger between firms operating at different levels of a supply chain. Vertical mergers can give merged entities the

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35 *Mergers and Acquisitions Guidelines*, above n 2, at [2.29].

36 The Application at [15].

ability and incentive to prevent or inhibit downstream rivals from competing, for example by refusing to supply an input. In this case, neither Mylan nor Upjohn provide inputs to rivals and there is no apparent demand for them to do so.

65. Vertical mergers can also give merged entities the ability and incentive to prevent or inhibit upstream rivals from competing, if the merged entity is able to limit access to customers. In this case, neither Mylan nor Upjohn controls access to customers. As such, we do not consider vertical effects further.

Horizontal unilateral effects in public markets

How we have assessed competition in public markets

66. The most common way that firms gain sales in the relevant public markets is by bidding in and winning PHARMAC tenders and RFPs. PHARMAC tenders and RFPs are "sealed bid" auctions, meaning that bidders do not know who else has bid, or the prices offered by other bidders. The winner and winning price are only revealed once the tender or RFP has been awarded.

67. Given these characteristics, we have set out below the principles on which we have assessed the extent of competition between the Parties and the competitive constraints that the merged entity would face.

Likely competitors in future PHARMAC tenders and RFPs

68. In analysing the public markets we have sought to identify which firms would be most likely to compete, or offer a credible competitive constraint, in future PHARMAC tenders or RFPs for the relevant products. This allows us to identify:

    68.1 whether the Parties are likely to view each other as close competitors; and

    68.2 which other rivals may be in a position to replace any lost competition.

69. In the Application, the Parties submitted that for each product where the Parties overlap the merged entity would be constrained by firms that have a registered medicine, but also by the possibility of other firms bidding without a registered medicine.[37] In their response to our Statement of Issues, the Parties provided examples of new entrants winning PHARMAC contracts without having previous experience supplying the public market,[38] and submitted that it is not uncommon for firms to bid without having a registered medicine.[39]

70. Our view is that, for each overlap product, the merged entity and other bidders are likely to see the strongest competition coming from those firms that already have a registered medicine with the same active ingredient, and particularly those that have been funded in the recent past. Such firms have already demonstrated a willingness and ability to compete for the relevant PHARMAC tender (including by bearing the

[37] In particular, the Parties submitted that Medsafe registration is not a barrier to participating in PHARMAC tenders or RFPs, as suppliers can apply for registration after bidding.

[38] Mylan and Upjohn, Submission on Statement of Issues, 14 April 2020 at [2.5]-[2.8].

[39] Mylan and Upjohn, Submission on Statement of Issues, 14 April 2020 at [5.2].

cost and effort of obtaining Medsafe registration), and (if they have previously been funded) willingness and ability to supply the medicine.[40]

71. We do not consider that rivals without a registered medicine would impose as strong a constraint as those with a registered medicine. We accept that there is a degree of uncertainty about which firms will bid in future tenders, and that bidders will take this into account when deciding their bid. In this sense, firms without a registered medicine may offer some level of constraint. However, we placed less weight on the constraint from such possible entrants than on the constraint from those with a registered medicine for the following reasons.

    71.1 A firm that does not have a registered medicine may not consider that it has a good chance of winning the tender or RFP and therefore may be less likely to bid. Our evidence suggests that firms are most likely to seek Medsafe approval if:

        71.1.1 it is confident it can establish a stable supply in New Zealand at a commercially viable cost; and

        71.1.2 the expected value of the tendered medicine is sufficiently high to warrant the cost and effort.[41]

    71.2 While firms without a registered medicine can bid in PHARMAC tenders (with the intent to apply for Medsafe approval for the product if it wins the contract), the evidence we have seen suggests that it is rare for such firms to win PHARMAC contracts.[42] This is because:

        71.2.1 it can take over a year to gain Medsafe approval; and

        71.2.2 we consider there can be risks to both PHARMAC and the firm if Medsafe approval is outstanding when supply is supposed to commence under the PHARMAC contract.

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40 For example, we understand it costs $43,875 NZD to register a new medicine with Medsafe ($21,940 if the abbreviated process is used). For smaller PHARMAC contracts (and noting that firms cannot be certain they will win PHARMAC contracts) the Medsafe fee can be a proportionately significant cost (for example, the value of [ ] sales in New Zealand in 2018 was [ ].

41 This is particularly the case where a medicine has been off-patent and funded in New Zealand for some time. In such cases, prices have been driven down by successive tenders. Potential entrants may find these medicines less attractive compared with newer medicines that have recently lost exclusivity. See Commerce Commission interview with [ ] at 6; Commerce Commission interview with [ ] at 6.

42 For example, we analysed the bidding patterns of a range of medicines for which we received bidding data from PHARMAC. We found that around [ ] of the bidders had a registered medicine but none of the tenders/RFPs were won by a firm that did not have a registered medicine. Although there are some examples for other medicines where a firm without a registered medicine has won, these examples are rare.

(a) For PHARMAC, awarding a tender to a firm with an unregistered medicine may create supply risk if there is any delay in the Medsafe approval process.

(b) For the firm, winning a tender with an unregistered product increases the possibility of the firm being exposed to contractual penalties in the event of any supply issues resulting from delays in the Medsafe approval process.

72. Firms that do not currently supply any medicines in New Zealand face an additional barrier with the need to establish a presence or find a means to distribute its product.

73. We therefore consider that bidders are likely to view firms with a registered medicine as a greater competitive constraint than firms without a registered product. Accordingly, in our assessment of public markets we have placed more weight on the constraint from firms with registered medicines than firms with unregistered medicines.

The extent of PHARMAC's countervailing power

74. In the Application, the Parties submitted that PHARMAC exerts substantial countervailing power over the public markets for medicines, arguing that PHARMAC:

74.1 has several strategies to promote competition, including direct negotiation, alternative commercial proposals and RFPs;

74.2 is not bound to award a tender if bids are unsatisfactory, and can instead roll over existing supply arrangements or accept alternative commercial proposals outside of a tender or RFP process;

74.3 can drive competitive bids in its tenders/RFPs because firms cannot be "complacent" when they have imperfect information about which rivals will compete and how competitive their prices will be; and

74.4 can, in some cases, manage patient demand for a medicine in order to exert countervailing power.

75. In previous decisions we have taken the view that PHARMAC has some countervailing power, as it is the sole decision-maker in respect of which medicines are publicly funded.[43]

76. In respect of the public markets relevant to this Application, we consider that PHARMAC may have some degree of countervailing power, but also consider there would be limits to PHARMAC's ability or willingness to constrain the merged entity.

[43] See: *Mylan and Abbott Laboratories' Established Pharmaceuticals Division* [2014] NZCC 40; *Pfizer, Inc and Hospira, Inc* [2015] NZCC 19.

PHARMAC's countervailing power will depend on the characteristics of each medicine.

76.1 Although PHARMAC has other ways to procure supply, this does not necessarily give PHARMAC the ability to resist a price increase or consistently extract competitive outcomes. In particular, PHARMAC still needs good alternatives to turn to, and for some of the medicines that we have concerns about there would be few registered players.

76.2 If PHARMAC looks for supply beyond firms that are already registered and supplying in New Zealand, this may present costs and risks. For example, a supplier that does not have a registered medicine will not have a track record of supplying that product in New Zealand. It is possible that the reason the supplier has not already applied for registration is because it faces some other disadvantage that would hinder its ability to supply effectively (for example, lack of physical presence in New Zealand or high supply costs). PHARMAC may be less likely to incur such costs where the value or volume of a registered medicine is low.

76.3 PHARMAC may be able to manage patient demand for medicines in some cases but doing so would have to be justified on a clinical basis. PHARMAC may not be prepared to manage patient demand if it might put patients' health at risk. PHARMAC willingness to manage patient demand is likely to differ depending on the characteristics of each medicine.

Conclusion

77. In summary, the principles that underpin our analysis of the public markets that are relevant to the Proposed Merger are as follows.

77.1 For a given product where the Parties overlap, the strongest competitors in future PHARMAC tenders are those that currently have registered medicines, and particularly those that have previously held a PHARMAC contract for that medicine.

77.2 While it is possible that a new player might compete without a registration, the evidence suggests that this is uncommon and that it is even less common for such a player to win a contract. As such, we consider that registered suppliers will in general view such potential rivals as lesser threats.

77.3 While PHARMAC does have some countervailing power, there are some limits. The extent of any such countervailing power will depend on the characteristics of the particular molecule.

77.4 As noted in the market definition section, other molecules are unlikely to pose a significant constraint.

78. Below we set out our analysis using these principles.

Markets in which we did not have concerns

79. Table 2 below sets out the relevant public markets in which we are satisfied that the Proposed Merger would not be likely to substantially lessen competition, and summarises the main reasons for this conclusion. For the reasons given above, we also take into account that the merged entity will face some constraint from PHARMAC's countervailing power and from the threat of unregistered players.

Table 2: Public markets where we do not have competition concerns

Product	Funded supplier	Main reasons we are satisfied the Proposed Merger is unlikely to cause an SLC
amlodipine	Apotex	Many players with registered medicines
atorvastatin	Mylan	Many players with registered medicines
doxazosin	Apotex	Neither of the Parties' products are registered
eplerenone	Upjohn	Mylan product not registered Another player with a registered medicine
latanoprost	Teva	Other players with registered medicine [ ]
phenytoin	Upjohn	Mylan product not registered
sildenafil	Mylan	Other players with registered medicine Upjohn does not participate in Pharmac tenders[44] [ ]
tolterodine	Teva	Mylan product not registered
venlafaxine	Mylan	Other players with registered medicine [ ]
ziprasidone	Douglas	Mylan product no longer registered Other players with registered medicine

Markets in which we have competition concerns

80. We are not satisfied that the Proposed Merger will not have, or would not be likely to have, the effect of substantially lessening competition in the public markets for:

[44] The Application at [21.15].

80.1 celecoxib;

80.2 gabapentin; and

80.3 pregabalin.

81. We outline our reasons for this view below.

The public market for celecoxib

82. Celecoxib is used to treat pain and inflammation caused by diseases like arthritis. There are only three firms with Medsafe registration for celecoxib: Upjohn, Mylan and Teva. In 2018 celecoxib sales in New Zealand were approximately [ ].[45]

83. We consider that in the counterfactual Upjohn and Mylan are likely to impose a significant competitive constraint on one another for celecoxib in future PHARMAC tenders and RFPs. This is because:

83.1 Upjohn has been funded for celecoxib since 2017; and

83.2 while Mylan is not actively supplying celecoxib in New Zealand at present, it maintains a registration.
[ ][46]

84. This competitive constraint would be lost if the Proposed Merger proceeds.

85. We are not satisfied that other constraints would be sufficient to replace this lost competition with the Proposed Merger.

85.1 [
]47

85.2 The Parties submitted that the merged entity would continue to be constrained by the possibility that unregistered firms could compete in the next tender.[48] However, we are not able to rely heavily on such constraints because [ ].

85.2.1 Zentiva does not appear to supply any medicines (or have any presence) in New Zealand or Australia, and therefore does not appear to be a likely competitor.[49]

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45 The Application at Table 5.

46 [ ]

47 [

]

48 The Application at [18.10].

49 See Zentiva's website, https://www.zentiva.com/contact/export-countries. Zentiva does not sponsor any medicines registered with Medsafe in New Zealand or the Therapeutic Goods Administration in Australia.

85.2.2 [ ].[50]

85.3 We are not satisfied that PHARMAC would be likely to take the necessary actions to prevent a substantial lessening of competition in this market.

85.3.1 [ ][51]

85.3.2 There are relatively few suppliers registered for celecoxib, which could make it more difficult for PHARMAC to exercise any countervailing power it has. For example, we consider PHARMAC may face risks switching to a supplier that does not have a registered medicine.

86. As such, we are not satisfied that the Proposed Merger will not have, or would not be likely to have, the effect of substantially lessening competition in this market. However, as discussed below, the Parties have offered a divestment that remedies our concerns.

The public market for gabapentin

87. Gabapentin is used to treat epileptic seizures and neuropathic pain. The firms with Medsafe registration for gabapentin are Mylan, Upjohn, Apotex, Teva and Douglas. According to Medsafe's website, Ipca Pharma (NZ) Pty Limited (Ipca) has applied for registration.[52] In 2019 gabapentin sales in New Zealand were approximately [ ].[53]

88. We consider that in the counterfactual Upjohn and Mylan are likely to impose a significant competitive constraint on one another for gabapentin in future PHARMAC tenders and RFPs. This is because Upjohn and Mylan both have registered medicines and are previous suppliers of gabapentin to PHARMAC.

89. We are not satisfied that other constraints would be sufficient to replace that lost competition.

89.1 The constraint from other registered players is uncertain:

89.1.1 Apotex is currently funded for gabapentin. Apotex will exit the New Zealand market in 2021, and as a result will not be competing for future tenders or RFPs.

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50 [ ]

51 [ ].

52 Medsafe website "Medicines: Product/Application search", https://www.medsafe.govt.nz/regulatory/DbSearch.asp.

53 The Application at Table 7.

89.1.2 [ ].[54]

89.1.3 [ ].[55]

89.2 The Parties submitted that the merged entity would continue to be constrained by the possibility that unregistered firms would compete.[56] However, we are not able to rely heavily on such constraints because [ ].

89.2.1 Servier has a gabapentin medicine, but does not supply it in New Zealand or Australia.

89.2.2 [ ]

89.2.3 [ ]

89.2.4 Ipca has applied to register a gabapentin product with Medsafe. However, it is not clear whether Ipca's application will be successful.

89.3 We are not satisfied that PHARMAC would be likely to take the necessary actions to prevent a substantial lessening of competition in this market.

89.3.1 PHARMAC may face risks switching to a supplier that does not have a registered medicine.

89.3.2 As gabapentin is used to treat neuropathic pain and epilepsy, it may be a relatively critical medicine from a clinical perspective, and we consider PHARMAC may not wish to manage patient demand where it is working effectively for that patient.

90. As such, we are not satisfied that the Proposed Merger will not have, or would not be likely to have, the effect of substantially lessening competition in this market. However, as discussed below, the Parties have offered a divestment that remedies our concerns.

The public market for pregabalin

91. Pregabalin is used to treat epileptic seizures and neuropathic pain. Mylan, Upjohn and Apotex have registered medicines for pregabalin. In 2018 pregabalin sales in New Zealand were approximately [ ].[57]

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54 [ ]
55 [ ]
56 The Application at [18.10].
57 The Application at Table 8.

92. We consider that Upjohn and Mylan are likely to impose a significant competitive constraint on one another for pregabalin in future tenders and RFPs. This is because Upjohn has been funded for pregabalin since 2017 and Mylan has a registered medicine.

93. We are not satisfied that other constraints would be sufficient to replace that lost competition with the Proposed Merger.

93.1 Apotex is the only other competitor with a registered medicine. However, Apotex is exiting the New Zealand market in 2021, and as a result will not be competing for future tenders or RFPs.

93.2 The Parties submitted that other suppliers could register a product with Medsafe and compete for pregabalin. However, we were not able to rely heavily on such constraints, because:

93.2.1 [ ][58]

93.2.2 [ ][59]

93.3 We are not satisfied that PHARMAC would be likely to take the necessary actions to prevent a substantial lessening of competition in this market.

93.3.1 [ ][60]

93.3.2 There are relatively few suppliers registered for pregabalin, which could make it more difficult for PHARMAC to exercise any countervailing power it has. For example, PHARMAC may face risks switching to a supplier that does not have a registered medicine.

93.3.3 As pregabalin is used to treat neuropathic pain and epilepsy, it may be a relatively critical medicine from a clinical perspective, and we consider PHARMAC may not wish to manage patient demand where it is working effectively for that patient.

94. As such, we are not satisfied that the Proposed Merger will not have, or would not be likely to have, the effect of substantially lessening competition in this market. However, as discussed below, the Parties have offered a divestment that remedies our concerns.

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58 [ ]

59 [ ]

60 [ ]

Horizontal unilateral effects in private markets

95. We considered the effect of the Proposed Merger on certain products mentioned in the Application that are sold in the private channel. As noted above, competition plays out differently in private markets. Instead of competing to win PHARMAC tenders, firms compete on price and brand to make sales to pharmacies and final consumers.

96. We identified that the Proposed Merger might affect competition in two private product markets:

    96.1 sildenafil; and

    96.2 venlafaxine.

The private market for sildenafil

97. Sildenafil is sold in the private market as a treatment for erectile dysfunction. Customers can purchase sildenafil from a pharmacy with a prescription from a doctor or (in some cases) a pharmacist. In 2018 sildenafil sales in New Zealand were approximately [ ].[61]

98. Upjohn's Viagra is the originator product and is the most well-known brand of sildenafil.

99. Mylan's sildenafil product is called Vedafil. Vedafil is currently funded by PHARMAC in the public market for certain rare conditions,[62] but not for general erectile dysfunction. However, pharmacies can obtain Vedafil at the PHARMAC contract wholesale price and then sell it (at any retail price they wish) for the treatment of general erectile dysfunction.[63]

100. The evidence we have seen suggests that Vedafil imposes a strong competitive constraint on Viagra. Viagra's retail price is set high compared to Vedafil as result of brand strength.[64] However, pharmacies can source Vedafil at the PHARMAC contract price, and therefore it represents a low-cost alternative to Viagra. The degree of competition that Vedafil imposes on Viagra is evidenced by:

    100.1 the high revenue and volume share of sildenafil that the merged entity would hold compared to its next largest rival;[65] and

    100.2 the views of pharmacists, for example:

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61 The Application at Table 11.

62 Vedafil is funded for the treatment of pulmonary arterial hypertension, Reynaud's Syndrome, and erectile dysfunction caused by spinal-cord injuries.

63 The Application at [21.14].

64 See Mylan and Upjohn, Submission on Statement of Issues, 14 April 2020 at [2.26] (14 April 2020).

65 Based on 2019 revenue and volume figures, we understand the merged entity would hold around [ ]% of revenues (with the Proposed Merger leading to an increment of [ ]%) and [ ]% of volumes (with an increment of [ ]%).

100.2.1 [ ];[66]
and

100.2.2 [ ] told us:

(a) that patients using Viagra are most likely to switch to Vedafil, as it is the cheapest option and has the same active ingredient; and

(b) [ ].[67]

101. The Parties submitted that the following constraints exist in the private market for sildenafil:[68]

101.1 Douglas, as an existing supplier with its sildenafil product Silvasta;

101.2 potential entrants such as Teva and Dr Reddy's which already have Medsafe registration for their sildenafil products; and

101.3 other erectile dysfunction products that use different active ingredients, for example Cialis (an Eli Lilly-owned tadalafil product) and Levitra (a Bayer-owned vardenafil product).

102. We are not satisfied that these constraints would be sufficient to replace the competition lost from the Proposed Merger.

102.1 Douglas' Silvasta appears to be a less close alternative to Viagra than Vedafil on the basis that it has a lower share of the private market by volume. [ ] told us that it does not stock Silvasta as it is less popular than other sildenafil products, because it is more expensive than Vedafil but does not have the same brand recognition as Viagra.[69]

102.2 We could not rely on potential entry to constrain the merged entity, because although
[
].

102.3 Other alternatives (such as tadalafil and vardenafil) are weaker constraints, even though they may be equally effective treatments of erectile dysfunction.[70]

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66 [ ]

67 [ ]

68 See Mylan and Upjohn submission at [2.27] (14 April 2020).

69 [ ]

70 For example, Gong et al (2017) carried out a meta-analysis comparison of tadalafil and sildenafil for the treatment of erectile disfunction. It found that tadalafil and sildenafil had similar efficacies and overall adverse event rates. Gong B, Ma M, Xie W, et al. "Direct comparison of tadalafil with sildenafil for the

102.3.1 Patients will tend to use a medicine they are familiar with and that works for them. Sildenafil customers more frequently switch between brands of sildenafil before switching to another medicine.[71]

102.3.2 Sildenafil is the only erectile dysfunction medicine that can be purchased through a pharmacy prescription and a large proportion of sales are made this way.[72] Customers that wish to switch to tadalafil or vardenafil need to go to the additional cost and effort of visiting a doctor to get a prescription.

103. As such, we are not satisfied that the Proposed Merger will not have, or would not be likely to have, the effect of substantially lessening competition in this market. However, as discussed below, the Parties have offered a divestment that remedies our concerns.

The private market for venlafaxine

104. Venlafaxine is funded by PHARMAC to treat anxiety and depression. Mylan's Enlafax has been funded since 2017.[73] Patients can obtain Enlafax with a prescription, paying only the prescription fee.

105. Upjohn's Efexor was the funded product before Mylan became the sole supplier in the public market in 2017. Upjohn is currently supplying its Efexor product in the private market to patients that prefer it over Enlafax.

106. We considered the extent to which Enlafax currently constrains the price of Efexor in the private market. On balance we concluded that the price of Enlafax is unlikely to materially affect the price of Efexor. This was because:

106.1 the evidence we received from pharmacies suggested that customers typically prefer one product or the other, and that very few customers switch between them;[74] and

106.2 an analysis of the likelihood of customers switching, combined with the relative margins on Efexor and Enlafax, did not suggest that the Proposed Merger would incentivise the merged entity to raise prices of Efexor.

107. As such, we are satisfied that the Proposed Merger will not have, or would not be likely to have, the effect of substantially lessening competition in this market.

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treatment of erectile dysfunction: a systematic review and meta-analysis." *Int Urol Nephrol*. 2017;49(10):1731-1740.

71 [ ]

72 [ ]

73 See previous PHARMAC schedules. For example, Upjohn's Efexor XR is listed in Pharmaceutical Management Agency: New Zealand Pharmaceutical Schedule August 2016 https://www.pharmac.govt.nz/2016/07/27/Sched.pdf.

74 [ ].

Coordination

108. An acquisition can substantially lessen competition if it increases the potential for the merged entity and all or some of its remaining competitors to coordinate their behaviour and collectively exercise market power such that output reduces and/or prices increase in the relevant market. Unlike a substantial lessening of competition that arises from the merged entity acting on its own, coordinated effects require some or all of the firms in the market to act in a coordinated way.[75]

109. We have considered whether the Proposed Merger might change conditions in private or public markets so as to facilitate coordination, ie, so as to make coordination "more likely, more complete or more sustainable" as per the test in the Commission's *Mergers and Acquisitions Guidelines*.[76]

Private markets

110. In the private markets that we have considered – for the supply of sildenafil and venlafaxine – we consider that the Proposed Merger would be unlikely to facilitate coordination for the following reasons.

    110.1 In respect of sildenafil, as noted above, without the Divestment Undertaking the merged entity would have the two strongest sildenafil brands – Viagra and Vedafil – and a market share greater than [ ] by volume and revenue. It would be only weakly constrained by Douglas (which supplies Silvasta) and by suppliers of the tadalafil and vardenafil molecules. In such a strong position, it would have no clear incentive to coordinate with rivals. In the small part of the market remaining, Douglas would likely be in a stronger position than suppliers of the other molecules, and so would have no clear incentives to coordinate with them.

    110.2 In respect of venlafaxine, the merged entity would supply the only venlafaxine medicines making sales in New Zealand (Efexor in the private market and Enlafax in the public market in accordance with the PHARMAC contract). No other firms supply venlafaxine products in the private market, and so there would be no competitors for the merged entity to coordinate with following the Proposed Merger.

Public markets

111. In the public markets, PHARMAC tenders are awarded by sealed-bid auctions and are not typically split between suppliers. Therefore, suppliers seeking to coordinate would need to find a mutually satisfactory way to allocate contracts between themselves. They would then need to rig their bids to enable each coordinating supplier to hold its allocated contract(s) at inflated prices.

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75 *Mergers and Acquisitions Guidelines* above n [2] at [3.84].

76 Ibid, at [3.85].

112. We have focused our analysis on the following types of possible coordinated contract allocation:

112.1 allocations of PHARMAC contracts between suppliers coordinating only within New Zealand, achieved by:

112.1.1 sharing out contracts between coordinating suppliers, with each participating supplier being allocated one or more contracts to hold indefinitely, and other parties to the allocation not bidding competitively on contracts not allocated to them;

112.1.2 rotating contracts between coordinating suppliers, who would take turns to win each contract covered by the allocation (presumably PHARMAC's largest, most attractive contracts), with other parties to the allocation not bidding competitively against the one currently selected to win at a high price;

112.2 an allocation of all PHARMAC contracts to one or more participants in an arrangement to allocate public markets internationally, with each participant or group being allocated one or more whole geographic regions to operate in without genuine competition.

113. For each of these scenarios we have tested whether coordinated effects might arise by asking:

113.1 whether the markets in which the Parties compete have features that make it easy to reach, and then to sustain, an agreement and so make any of those markets vulnerable to coordination;[77] and

113.2 whether the Proposed Merger will make coordination significantly more likely, complete or sustainable (for example, by removing an aggressive competitor).

Our assessment of coordination

114. Some factors may make PHARMAC's tender and RFP processes somewhat vulnerable to coordination. For example:

114.1 if markets could be allocated, it would be easy to monitor adherence since it would be clear who had won contracts and at what prices; and

114.2 as noted at paragraphs [68]-[73], there are costs and risks involved in registering a product that may inhibit new entrants to the relevant markets.

115. However, other factors may make PHARMAC contracts less vulnerable to coordination. For example:

[77] For more details on these features see *Mergers and Acquisitions Guidelines* above n 2 at [3.84].

115.1 contracts are of highly variable sizes,[78] and typically last for three years. This may make it hard for suppliers to reach and maintain an agreement on how to allocate them; and

115.2 PHARMAC could disrupt coordination by changing the format of tenders or by negotiating directly with suppliers if it suspected bid rigging.

116. We did not need to conclude on whether public markets are vulnerable to coordination as we are satisfied that the Proposed Merger would not make coordination significantly more likely, complete or sustainable. Although the Proposed Merger would reduce the number of competitors for some products, it would have no material impact on the total number of pharmaceutical companies that supply PHARMAC, most of which would need to be involved in an anticompetitive allocation for it to be sustainable.

117. We reached a similar conclusion for the potential impact of the Proposed Merger on coordination at an international level. Given the number of international suppliers, we are satisfied that the Proposed Merger would not make coordination significantly more likely, more complete or more sustainable.

Overall conclusion on coordination

118. As such, we are satisfied that the Proposed Merger will not have, or would not be likely to have, the effect of substantially lessening competition due to coordinated effects.

Conglomerate effects

119. A merger between suppliers (or buyers) who are not competitors but who operate in related markets can result in a substantial lessening of competition due to conglomerate effects. This can occur where the parties supply (or buy) complementary products.

120. We considered whether the merged entity would gain the ability and incentive to harm competition by using anticompetitive bundling or tying strategies. However, we are satisfied that the prospect of this is remote for the following reasons.

120.1 At present, we are not aware of tying or bundling in public or private markets, even though some suppliers, including the Parties, may already have market power over some products that could be deemed "must-have". This may be because, in the context of New Zealand's markets, any anticompetitive tying or bundling strategy would be an extreme move liable to damage a supplier's international reputation for little immediate gain.

120.2 While we consider the merged entity would gain market power over a number of products absent the Divestment Undertaking, it would not gain any clear incentive to begin attempting anticompetitive tying or bundling

[78] For example, in 2018, funded [ ] revenues were $[ ] while funded revenues for some other products in the Application were less than $[ ], and there are many smaller products.

strategies. Each of the Parties already supplies large portfolios of products in New Zealand, and has degrees of power in various markets. Since the Parties and other suppliers seem to find the prospect of anticompetitive tying or bundling unattractive, most likely for the reasons given above, we consider that the merged entity would also.

120.3 Neither the Parties' rivals nor PHARMAC have expressed any concerns about conglomerate effects.

121. As such, we are satisfied that the Proposed Merger will not have, or would not be likely to have, the effect of substantially lessening competition as a result of conglomerate effects.

The Divestment Undertaking

Introduction

122. As outlined above, the Commission considers that the Proposed Merger will have, or would be likely to have the effect of substantially lessening competition in:[79]

122.1 the public markets for:

122.1.1 gabapentin;

122.1.2 celecoxib;

122.1.3 pregabalin; and

122.2 the private market for:

122.2.1 sildenafil.

123. The Parties proposed to divest Upjohn's versions of these products in the Divestment Undertaking.

124. In accordance with the Divestment Undertaking, the merged entity would divest certain assets to Aspen Pharmacare Australia Pty Ltd (Aspen) to enable Aspen to compete to supply the following Upjohn medicines in New Zealand:

124.1 Neurontin (gabapentin);

124.2 Celecoxib Pfizer (celecoxib);

124.3 Pregabalin Pfizer (pregabalin); and

124.4 Viagra (sildenafil)

[79] In our Statement of Issues, we identified potential concerns with some other medicines, namely: atorvastatin, latanoprost and ziprasidone. However, further investigation led us to be satisfied that the Proposed Merger would not substantially lessen competition for these medicines. See Table 2.

(together, the Divestment Products).

125. This divestment would only apply in New Zealand. The merged entity would continue to be able to supply the Divestment Products outside of New Zealand.

126. For the reasons set out in paragraphs [131]-[174], we are satisfied that as a result of the Divestment Undertaking the Proposed Merger will not have, or would not be likely to have, the effect of substantially lessening competition in the markets identified in paragraphs [122.1] and [122.2].

Main elements to divestment

127. The Parties proposed to give effect to the Divestment Undertaking through a number of agreements, including:

127.1 An asset purchase agreement which transfers, assigns, licenses or sub-licenses to the Proposed Purchaser all of the assets, licenses, agreements, and other tangible and intangible property which are required to allow the Proposed Purchaser to compete in the markets for the Divestment Products (the APA). The APA will transfer all necessary IP, Medsafe approvals and necessary product information, and (where applicable) PHARMAC contracts that Upjohn currently holds in relation to the Divestment Products.

127.2 A long term [ ] supply and technology transfer agreement (the SA) to ensure continuity of supply to the Proposed Purchaser. The SA includes an option for the Proposed Purchaser to carry out a "technology transfer" with respect to manufacture for the Divestment Products at any time during the term of the SA, and for a period after expiration or termination.

127.3 Other ancillary arrangements, including an intellectual property assignment, a pharmacovigilance agreement, and a quality agreement.

128. The nature of the SA is such that it imposes behavioural requirements on the Parties (as opposed to requiring a structural divestment). The Commission is unable to accept behavioural undertakings in the context of its consideration of a merger. However, the Commission can take into account agreements that would exist in the factual (placing the appropriate weight of the likelihood of such agreements being entered into).

129. In assessing whether the Divestment Undertaking will remedy our competition concerns, we have taken into account the likely implications of the Parties entering into the SA with the Proposed Purchaser. As such, where relevant, we refer to the likely impacts of the SA in our analysis below.

130. As part of offering the undertaking, the Parties have identified Aspen as the proposed purchaser (the Proposed Purchaser).

Our approach to considering the Divestment Undertaking

131. We have assessed the Divestment Undertaking having regard to:

131.1 our own guidelines;[80]

131.2 international best practice as set out in the International Competition Network Merger Remedies Guide 2016;[81] and

131.3 practices of other jurisdictions.[82]

132. We considered whether the Divestment Undertaking will remedy our competition concerns. For this to happen, we must be satisfied that the divestment would result in sufficient competitive constraint on the merged entity so that a substantial lessening of competition is no longer likely.

133. In testing this proposition, we assessed three kinds of risk associated with divestment undertakings:

133.1 purchaser risk – the risk that there may not be a purchaser acceptable to the Commission available and/or the risk that the applicant has an incentive to sell to a weak competitor.

133.2 asset risk – the risk that the competitive effectiveness of a divestment package will deteriorate prior to completion of the divestment.

133.3 composition risk – the risk that the scope of a divestment undertaking may be too constrained, or not appropriately configured, to attract a suitable purchaser, or that the contents of a divestment would not sufficiently restore competition.

Purchaser risk

134. We have assessed whether Aspen is an acceptable purchaser based on the following criteria:

134.1 whether it is independent of the merged entity;

134.2 whether it possesses or has access to the necessary expertise, experience, and resources to be an effective long-term competitor in the market; and

134.3 whether its acquisition of the divested assets raises competition concerns.

Independence of the Proposed Purchaser

135. We are satisfied that Aspen will be sufficiently independent of the Parties.

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80 *Mergers and Acquisitions Guidelines* above n 2 at Attachment F.

81 Merger Remedies Guide 2016, Merger Working Group, International Competition Network.

82 Richard Feinstein, Negotiating Merger Remedies: Statement of the Bureau of Competition of the Federal Trade Commission (January 2012); The FTC's Merger Remedies 2006-2012, A Report of the Bureaus of Competition and Economics, January 2017; and Notice on remedies acceptable under Council Regulations, European Commission, 2008.

136. There is no ownership relationship between Aspen and the Parties or any of their affiliates.

137. Under the divestment as proposed, Aspen will initially rely on the SA for supply of the Divestment Products from the merged entity (and may continue to do so if it does not exercise the option to carry out a technology transfer). However, we are satisfied that the SA allows Aspen sufficient flexibility in terms of setting its competitive strategy, including [ ], such that Aspen can remain an independent competitor while being supplied by the merged entity.

Necessary expertise, experience and resources

138. We are satisfied that Aspen is a viable operator in New Zealand and has the necessary expertise, experience and resources to be an effective competitor to the merged entity.

139. Aspen has operated in New Zealand since 2003. It claims to be a major pharmaceutical company in New Zealand.[83] [ ].

140. Evidence suggests Aspen has the experience and expertise to supply the divested molecules:

    140.1 Aspen is experienced in bidding for PHARMAC tenders and currently supplies 37 products subject to a PHARMAC agreement.

    140.2 Industry players in general viewed Aspen as capable of supplying the divested molecules.

        140.2.1 [ ] told us Aspen is large and has been represented in NZ for a long time and should therefore face no difficulties with this transaction.

        140.2.2 [

            (a)

            (b)

            (c)

        ]

[83] For example, in Pharmacy Today it claimed to be the "14th or 15th largest pharmaceutical distributor in New Zealand". See Jonathan Chilton Towle "Pharmaceutical distributor aims high with move to upmarket location" *Pharmacy Today* (online ed, 3 July 2019).

140.3 [ ]

140.3.1 Aspen appears to be sufficiently reliable to supply pharmaceuticals in New Zealand;

140.3.2 Aspen's reliability as a supplier would in principle be equivalent to Upjohn's for as long as Aspen is supplied under the SA; and

140.3.3 [ ]

Acquisition by Aspen does not raise competition concerns

141. We consider that the acquisition of the Divestment Products by Aspen does not raise any competition concerns.

Unilateral conduct

142. There is no overlap between Aspen's current portfolio and the products being acquired, and so does not raise any horizontal concerns.

Coordinated conduct

143. Aspen has recently offered settlements in the European Union and the United Kingdom in response to alleged competition law breaches in those jurisdictions.[84] We considered whether Aspen's acquisition of the assets would make coordination in New Zealand markets more likely.

144. Despite the alleged breaches, we are satisfied that it is unlikely that Aspen's acquisition of the Divestment Products would make coordination in New Zealand markets more likely, for the following reasons:

144.1 Aspen has told us that it is committed to competition law compliance and has provided evidence of its compliance program (including implementation in New Zealand); and

144.2 Aspen is already present in New Zealand. It is unlikely the acquisition of these additional molecules would make coordination more likely.

---

[84] On 9 July 2020 the Competition and Markets Authority found that Aspen, among others, entered into an anticompetitive agreement in relation to the supply of fludrocortisone acetate 0.1mg tablets in the United Kingdom. Aspen admitted to breaching competition law by entering into this agreement, and paid a fine of £2.1m, as well as making a payment of £8m to the NHS.

The European Commission (EC) is also currently investigating whether Aspen Pharmacare Holdings Limited and its related entities' pricing practices in respect of certain cancer medicines amounts to abuse of a dominant position. Aspen has submitted commitments to address the EC's concern, which would reduce the prices of the relevant medicines by 73% on average and would also commit Aspen to continuous supply of the medicines for a significant period. The EC is market testing these proposed commitments.

Conclusion

145. We consider that Aspen is a suitable purchaser of the Divestment Products. It is sufficiently independent, and has the necessary experience, expertise and resources to be an effective competitor to the merged entity. In addition, we do not consider that the investigations into conduct overseas increases the likelihood of coordination in New Zealand.

Asset risk

146. Asset risk is the risk that the competitiveness of a divested business will deteriorate prior to completion of the divestment, such that the divestment will not restore competition to the relevant markets sufficiently. This could occur if there are insufficient arrangements for holding a divestment business separate during the divestment period.

147. The Parties submitted to us that the asset risks are limited, as:

147.1 the short divestment period [ ] means that there is no need for a formal hold-separate arrangement or a divestment manager;

147.2 the APA requires the Parties to preserve the Divestment Products before the divestment is completed, including using reasonable best efforts to preserve relevant relationships and conduct business in the ordinary course;

147.3 the products that are being supplied under PHARMAC contracts would not deteriorate because the merged entity would be required to continue supplying according to PHARMAC contract terms until novation of the contracts to Aspen is completed; and

147.4 in the private market for sildenafil, where marketing is important to the competitive strength of the Divestment Product, Viagra has a strong brand which would not be impeded by a reduction of marketing activity during the divestment period (and marketing will continue in the ordinary course).

148. We agree with the Parties' submission that there are limited asset risks. We take this view because of:

148.1 the short transition period;

148.2 the limited scope to alter the supply of Upjohn products that are subject to PHARMAC contracts (being celecoxib and pregabalin);

148.3 the fact that Upjohn's gabapentin product is not currently funded by PHARMAC, and is therefore unlikely to be making material sales in New Zealand; and

148.4 Viagra's strong brand, [ ]. This suggests that sales will persist during the divestment period.

149. We are therefore satisfied that the asset risk is low.

Composition risk

150. Composition risk is the risk that a divestment proposal may be too limited in scope, or not appropriately configured, to attract either a suitable purchaser or to allow a successful business to be operated in competition with the merged entity.

151. We considered whether the Divestment Undertaking, given effect to through the APA, includes all of the assets that Aspen would need to successfully compete with the merged entity. We also considered whether:

151.1 we can be confident the APA and the SA will be executed and carried out;

151.2 the merged entity and Aspen are likely to carry out technology transfers (so that Aspen will be fully independent from the merged entity); and

151.3 if not, whether Aspen would be able to compete effectively by relying on the SA.

152. On balance we are satisfied that the composition of the divestment will allow Aspen to operate a successful business in competition with the merged entity.

Determining whether the SA will be executed and carried out

153. The merged entity will initially have to supply the Divestment Products to Aspen to allow it to fulfil supply to PHARMAC, and to compete in PHARMAC tenders. This is because Medsafe approval is linked to a specific manufacturing site. Aspen will not be able to supply the Divestment Products itself until it receives Medsafe approval for its chosen manufacturing site.

154. The SA forms part of the divestment package to Aspen. As noted above at paragraph [128], we cannot accept a behavioural undertaking that the Parties will enter into and adhere to the terms of the SA. However:

154.1 the Parties provided us with an executed copy of the (conditional) SA (and APA) before clearance was granted; and

154.2 we consider it likely that the Parties would adhere to the terms of the SA for the following reasons.

154.2.1 Aspen is likely to have the incentive to enforce the APA and SA. Under the Divestment Undertaking Aspen will purchase the assets [ ] to enable it to earn revenue from the Divestment Products. Aspen will be incentivised to challenge any breaches of the agreements in order to protect that investment.

154.2.2 The Parties are likely to have sufficient incentives to meet their obligations under the Divestment Undertaking.

(a) As we describe in further detail below, the SA includes provisions that will help Aspen to enforce the agreements. These include provisions that allow Aspen to [ ].

(b) Failure of the Parties to meet their SA obligations would amount to a breach of contract, and may have an adverse reputational impact on the Parties', and the merged entity's:

(i) existing and ongoing relationships with PHARMAC;

(ii) supply arrangements with Aspen in other countries; and

(iii) reputation as a supplier to other firms.

155. Some industry participants are sceptical about the strength of these reputational factors.[85] However, taking into account all factors, we are satisfied that they, combined with the SA obligations, would incentivise the Parties (and the merged entity) to adhere to the SA.

It is unclear whether Aspen will perform the technology transfers

156. We would typically prefer for divestments to be configured so that the purchaser is completely independent from the divesting party(ies). As such we considered whether Aspen would be likely to move away from the SA to manufacture the Divestment Products itself.

157. The SA includes an option for the Aspen to carry out a "technology transfer" at any time during the term of the SA and for a period after expiration or termination. This requires the merged entity to provide all technical data and know-how reasonably necessary to enable Aspen to set up a manufacturing process for the Divestment Products at a different plant. Implementing the technology transfer would allow Aspen, or a third-party manufacturer, to manufacture the Divestment Products instead of the merged entity.

158. We considered whether Aspen will have the ability and incentive to undertake the technology transfers for the Divestment Products. In our view, it is unclear whether Aspen would carry out technology transfers for each of the Divestment Products.

158.1 Although the SA creates some obligations on both Aspen and the Parties to put plans in place for technology transfers, there is ultimately no requirement on Aspen to request or execute a technology transfer.

158.2 Aspen has expressed confidence that it can carry out a technology transfer for these products. However, we understand that technology transfers take time and are costly.

[85] [ ]

[
] This is reflected in [ ] term for the SA.

158.3 Given the time and cost, a technology transfer may not currently be economically sensible for some of the Divestment Products since:

158.3.1 it is not guaranteed that Aspen will win future PHARMAC tenders or RFPs for any of the Divestment Products (in particular celecoxib and pregabalin, for which Upjohn currently holds the PHARMAC contracts);

158.3.2 [ ]; and

158.3.3 [
].

159. Since it is unclear whether Aspen will carry out technology transfers for the Divestment Products, we have not relied on them occurring to reach our decision. We have instead considered whether Aspen would be a sufficiently effective competitor if it supplied the Divestment Products sourced under the SA in the medium term. We consider that it would, for the reasons set out below.

Aspen would be an effective competitor to the merged entity while relying on the SA

160. As outlined above, Aspen will source the Divestment Products from the merged entity under the SA (until and unless it completes technology transfers). We have considered whether the SA will allow Aspen to be an effective competitor despite that, under its terms, Aspen would rely on a rival for supply. Specifically, we considered whether:

160.1 the SA's pricing mechanism will enable Aspen to compete effectively;

160.2 Aspen has sufficient protections around supply security; and

160.3 the merged entity knowing Aspen's costs and wholesale prices will adversely affect competition.

161. On balance, we are satisfied that the terms of the SA are sufficient to ensure that Aspen will be an effective competitor. We set out our analysis in more detail below.

<u>Pricing mechanism</u>

162. We considered whether the pricing mechanism in the SA will enable Aspen to compete effectively against the merged entity.

163. The main pricing terms of the SA are:

163.1 [

163.2

163.3]

163.4 Aspen has the option to [ ]

164. We consider that the SA's pricing mechanism will allow Aspen to compete effectively.

165. First, if Aspen pays [ ] for the Divestment Products, then it ought to be [ ].

166. Second, it is likely that Aspen will continue to pay the [ ] price over the term of the SA, which will allow it to compete on price in PHARMAC tenders and in the private markets:

166.1 Aspen has conducted its own assessment of the prices set in the SA and is satisfied that the prices are [ ].

166.2 [

166.2.1

166.2.2

166.2.3

(a)

(b)

].

Supply security

167. We considered whether the SA provides adequate protections for Aspen in the event of any supply issues or failures. On balance we are satisfied there are sufficient protections for Aspen.

168. Where the merged entity fails to supply Aspen under the SA, the merged entity must [ ]. This means that the merged entity [ ] in the event of a supply break.

169. There are some restrictions on what amounts to a "failure to supply". For example, a failure to supply only occurs where supply is [ ] past the due date for delivery

or [ ] past the due date [ ]. However, speaking to other market participants we understand that it is not uncommon to have supply breaks for the periods specified in the SA.[86] Firms deal with potential supply breaks by holding sufficient inventory. Aspen ought to be able to do the same.

170. In a situation where the supply of any Divestment Product is constrained, under the SA the merged entity must
[
].

171. The Parties submitted that the merged entity will have important reputational and relational incentives to ensure supply to Aspen is maintained under the SA. For example, supply breaks may adversely affect the merged entity's relationship with PHARMAC, and also with Aspen (who the merged entity will have contractual relationships with in other countries). While this incentive may not be as sharp as the financial incentives outlined above, it may still add some weight to the latter.

Whether the merged entity's knowledge of Aspen's costs and wholesale prices will adversely affect competition

172. As a result of supplying the Divestment Products to Aspen under the SA, the merged entity will know the costs and wholesale prices of the Divestment Products. We have considered:

172.1 whether this knowledge would likely be shared with the merged entity's staff who set prices for the products that would compete with Aspen in New Zealand; and

172.2 the implications for competition of the merged entity knowing Aspen's costs and wholesale prices when bidding against it for PHARMAC tenders.

173. On balance we consider that there are reasonable safeguards against the merged entity's staff sharing knowledge of Aspen's wholesale prices inappropriately, and that competition is unlikely to be substantially lessened even if the merged entity's commercial staff in New Zealand could infer Aspen's wholesale prices under the SA.

173.1 First, the SA contains safeguards to [ ]. The SA requires the merged entity to take all actions necessary to [ ].

173.2 Second, even if the merged entity's commercial staff in New Zealand could infer Aspen's costs, on balance competition is not likely to be substantially lessened.

173.2.1 A potential concern is that data from a range of bidders at PHARMAC tenders shows that the cost of goods sold (COGS) can account for a significant part of suppliers' bids, typically [ ]. This raises the

[86] [ ]

question of whether the merged entity could adapt its bidding behaviour anticompetitively when facing Aspen at tenders if its commercial staff knew Aspen's costs.

173.2.2 However, the merged entity will not know other key determinants of Aspen's bid prices, such as Aspen's overheads and margin requirements. Since there is a wide variation in the ratios of suppliers' COGS to their bid prices (even if COGS is usually significant, as noted above), the drivers of Aspen's bidding will remain unknown to the merged entity. Overall, this means that Aspen should remain an effective constraint on the merged entity.

173.3 Finally, in most of the markets that we are considering Aspen is not the only constraint on the merged entity. For example, there are other registered players for gabapentin and sildenafil. Aspen's bid price is not the only factor to consider and the merged entity would risk losing the bid or market share if it relied entirely on Aspen's price to determine its own bidding behaviour.

Conclusion on composition risk

174. We are satisfied that Aspen will be able to compete effectively under SA, and the composition of the divestment is likely to remedy our concerns.

Determination on notice of clearance

175. We are satisfied that the Proposed Merger along with the Divestment Undertaking dated 8 September 2020 will not have, or would not be likely to have, the effect of substantially lessening competition in a market in New Zealand.

176. Pursuant to section 66(3)(a) of the Act, the Commerce Commission determines to give clearance to Mylan N.V. and Upjohn Inc. to merge subject to the Divestment Undertaking dated 8 September 2020 provided by the Parties and Upjohn New Zealand ULC under section 69A of the Act.

Dated this 9th day of September 2020

Anna Rawlings
Chair

Attachment A – Divestment Undertaking

Deed

relating to

the divestment of the right, title and interest, including the right to develop, manufacture and use with a view to sales in New Zealand, that will be held by Mylan in the following Upjohn products that are registered in New Zealand:

> All Upjohn products based on the molecule celecoxib, with the main brand "Celecoxib Pfizer" (together referred to as "**Celecoxib Pfizer**" except as otherwise stated);
>
> All Upjohn products based on the molecule gabapentin, with the main brand "Neurontin" (together referred to as "**Neurontin**" except as otherwise stated);
>
> All Upjohn products based on the molecule pregabalin, with the main brand "Pregabalin Pfizer" (together referred as "**Pregabalin Pfizer**" except as otherwise stated); and
>
> All Upjohn products based on the molecule sildenafil, with the main brand "Viagra" (together referred to as "**Viagra**" except as otherwise stated); and

as further defined in Schedule 3 (together, the **Divestment Products**), including ancillary trademarks as set out in Schedule 1.

Given by Mylan N.V. and **Upjohn Inc. and Upjohn New Zealand ULC** (together, **Upjohn Parties**)**.**

in favour of the Commerce Commission

Date **8 September 2020**

This **Deed** is made on 8 September 2020

and is given by:

(a) Mylan N.V. (**Mylan**)**;** and

(b) Upjohn Inc. (**Upjohn**) and its subsidiary Upjohn New Zealand ULC (together referred to as the **Upjohn Parties** in this undertaking),

(together referred to as the **Undertaking Parties**)

in favour of **the Commerce Commission** (the **Commission**)

Introduction

A. The Commission is considering an application for clearance of a proposed merger between Mylan and Upjohn (the **Proposed Transaction**) pursuant to section 66 of the Act. That application was registered on 18 December 2019.

B. The Undertaking Parties consider that the Proposed Transaction is unlikely to substantially lessen competition in any market. However, in order to address any Commission concern and facilitate prompt completion of the Proposed Transaction, the Undertaking Parties undertake to carry out the Divestment of the Divestment Assets pursuant to section 69A of the Commerce Act 1986.

C. On 24 August 2020 Mylan entered into an Asset Purchase Agreement under which the Divestment Assets will be divested to the Proposed Purchaser (as set out in Schedule 2), subject to Commission approval, (**Asset Purchase Agreement**).

It is agreed

1. DEFINITIONS

1.1 In this Deed:

(a) **Act** means the Commerce Act 1986.

(b) **Affiliate** has the meaning as set out in the Asset Purchase Agreement.

(c) **Approved Purchaser** means a purchaser of the Divestment Assets approved by the Commission pursuant to clause 5 of this Deed.

(d) **Asset Purchase Agreement** means the Agreement entered into between Mylan and the Proposed Purchaser, dated 24 August 2020 for the sale of the Divestment Assets.

(e) **Business Day** excludes Saturday, Sunday, and public holidays. A Business Day starts at 8:30am and ends at 5pm.

(f) **Control Date** means the date on which the Proposed Transaction is completed.

(g) **Divestment** means the completion of the transaction(s) effecting divestment of the Divestment Assets in accordance with this Deed.

(h) **Divestment Assets** means, for each of the Divestment Products, the assets set out in Schedule 1 to this Deed.

(i) **Divestment Period** means the Initial Divestment Period *[redacted].*

(j) **Divestment Undertakings** means clause 2.1.

(k) **Initial Divestment Period** starts on and includes the Control Date and ends at midnight on the date that is *[redacted]* after the Control Date.

(l) **Medsafe Registration** means authorisation by the New Zealand Medicines and Medical Devices Safety Authority to market a product in New Zealand.

(m) **Mylan** means Mylan N.V.

(n) **Pfizer** means Pfizer Inc.

(o) **Pricing Information** has the meaning as set out in the Asset Purchase Agreement.

(p) **Proposed Purchaser** means the Party identified in Schedule 2.

(q) ***[Redacted]***

(r) **Supply Agreement** means the supply and technology transfer ancillary agreement to the Asset Purchase Agreement, entered into between Mylan and the Proposed Purchaser on 24 August 2020, for Mylan to manufacture and supply the Divestment Products to the Proposed Purchaser on a transitional basis.

(s) **Upjohn** means the Upjohn business being spun-off from Pfizer and combined with Mylan. Upjohn is made up of (a) a portfolio of 21 established brands organized across the following key therapeutic areas: (i) Cardiovascular, (ii) Central Nervous System/Psychiatry, (iii) Pain/Neurology, (iv) Urology and (v) Ophthalmology; and (b) Greenstone LLC (**Greenstone**), a US-focused generics business. Greenstone sells non-branded authorised generic versions of Pfizer branded products (and a very small number of authorised generics licensed from Allergan) exclusively in the US.

1.2 References to dates and time in this Deed are references to New Zealand Standard Time or Daylight Savings Time as applicable.

1.3 This Deed will be governed by, and construed in accordance with, the laws of New Zealand.

1.4 A right or obligation of any two or more people comprising a single party confers that right, or imposes that obligation, as the case may be, on each of them severally and each two or more of them jointly, except that any such right or obligation of any Upjohn Parties will not be taken to be joint with Mylan until on and from the Control Date.

1.5 Any notice or communication that is given or served under or in connection with this Deed must be given in writing in the following manner:

(a) if addressed to the Commission, by hand delivery or email to the following address:
Commerce Commission
Level 9, 44 The Terrace, Wellington 6011
Attention: Tania Pringle (tania.pringle@comcom.govt.nz)

(b) if addressed to the Undertaking Parties, by hand delivery or email to the following addresses:
C/- Bell Gully

Level 21, Vero Centre, 48 Shortland Street, Auckland 1010
Attention: Torrin Crowther (torrin.crowther@bellgully.com) / Glenn Shewan (glenn.shewan@bellgully.com)

and

C/- Chapman Tripp
Level 14, 10 Customhouse Quay, Wellington 6011
Attention: Lucy Cooper (lucy.cooper@chapmantripp.com)

2. DIVESTMENT

2.1 The Undertaking Parties undertake to the Commission that they will, upon completion of the Proposed Transaction:

(a) procure the divestment of the Divestment Assets to an Approved Purchaser within the Divestment Period in accordance with the terms of this Deed; and

(b) within 3 Business Days inform the Commission in writing that the Proposed Transaction has completed.

2.2 The Undertaking Parties acknowledge that the Divestment Undertakings:

(a) form part of any clearance given by the Commerce Commission for the Proposed Transaction under section 66(3)(a) of the Commerce Act 1986; and

(b) impose legal obligations on them, and the Undertaking Parties hereby irrevocably submit to the jurisdiction of the New Zealand courts for the purposes of any proceedings brought by the Commerce Commission under the Commerce Act 1986 in relation to this Deed.

3. COMMENCEMENT AND TERM

3.1 The Divestment Undertakings come into effect when signed by the Undertaking Parties and accepted by the Commission under section 69A of the Commerce Act.

3.2 The Undertaking Parties' obligations under this Deed are discharged when, either:

(a) the sale of the Divestment Assets to an Approved Purchaser has completed; or

(b) the Commission has accepted in writing the Undertaking Parties' submission that the Proposed Transaction will no longer proceed to completion.

4. PRESERVATION OBLIGATIONS

4.1 At all times before completion of the Divestment, the Undertaking Parties will (either directly or via their Affiliates), in relation to the Divestment Assets, use all reasonable endeavours to:

(a) preserve their reputation and goodwill; and

(b) preserve their economic viability, marketability and competitiveness.

4.2 During the Divestment Period neither the Undertaking Parties nor their Affiliates will:

(a) carry out any act upon their own authority that might have a significant adverse impact on the value or competitiveness of the Divestment Assets or that might alter the nature and scope of activity, or the industrial or commercial strategy in relation to the Divestment Assets;

(b) sell or transfer any of the Divestment Assets to any person other than an Approved Purchaser in accordance with this Deed or where the sale or transfer is in respect of inventory disposed of in accordance with the ordinary course of business; or

(c) cease any marketing or promotion of the Divestment Assets to the extent such marketing or promotion was occurring at the commencement of the Divestment Period.

4.3 At the request of an Approved Purchaser, the Undertaking Parties will provide reasonable information regarding the Divestment Products to the Approved Purchaser for the purposes of obtaining any Medsafe Registration, or other information necessary to enable the Approved Purchaser to participate in any PHARMAC tender in relation to the Divestment Products ahead of completion of the Divestment. The Undertaking Parties shall in such case make clear that any tender offer submitted by the Approved Purchaser in relation to the Divestment Products ahead of completion of the Divestment shall be subject to completion of the Proposed Transaction and the Divestment.

5. PURCHASER APPROVAL

5.1 Mylan has entered into an Asset Purchase Agreement with the Proposed Purchaser. At the time of accepting the Divestment Undertaking the Commerce Commission approves the Proposed Purchaser as an Approved Purchaser by reference to the criteria set out at clause 5.3 below.

5.2 The Undertaking Parties acknowledge that the Commerce Commission may revoke a purchaser's status as an Approved Purchaser if the Commission becomes aware that any information provided to it was incorrect, inaccurate or misleading. In such case, the Undertaking Parties will notify the Commission in writing of the identity of an alternative proposed purchaser (or where negotiations are ongoing with more than one potential purchaser, the potential purchasers) of the Divestment Assets as soon as practicable and no later than 20 Business Days before the anticipated closing of the Divestment.

5.3 The Undertaking Parties must satisfy the Commission (acting reasonably) that any alternative proposed purchaser of the Divestment Assets identified pursuant to clause 5.2 above:

(a) is not associated with, or an interconnected body corporate of, the Undertaking Parties or any of their Affiliates;

(b) has the financial resources, proven expertise and incentive to viably operate and develop the Divestment Assets in competition with Mylan in the relevant market(s);

(c) is not likely to create competition concerns that may result in a contravention of section 47(1) of the Commerce Act 1986; and

(d) is not likely to give rise to a risk that the implementation of the Divestment will be unduly delayed, and must, in particular, reasonably be expected to obtain all necessary approvals from the relevant authorities for the acquisition of the Divestment Assets.

5.4 The Undertaking Parties will ensure that final binding agreements provide that settlement of the Divestment is conditional on obtaining the Commission's approval of the proposed purchaser based on the criteria set out in clause 5.3.

6. RING-FENCING OF PRICING INFORMATION

6.1 From the Control Date, the Undertaking Parties shall take all actions necessary and appropriate to prevent access to, and the disclosure or use of, the Pricing Information by or to any person not authorised to access, receive or use such information and shall implement and maintain a system of controls with respect to protecting and segregating the Pricing Information otherwise than as provided for by clause 7 or where such disclosure is strictly necessary for one or more of the purposes of:

(a) progressing the Divestment;

(b) reporting to the Commission pursuant to clause 7; and

(c) complying with legal, reporting and regulatory obligations (including obligations relating to taxation, accounting, financial reporting or stock exchange disclosure requirements) or to progress any legal dispute,

and provided such information is disclosed only to those persons who have signed a confidentiality undertaking and need to know the information in order to carry out the purposes listed at clause 6.1(a)-(c) above, provided that where the person is an external advisor it is sufficient for the firm which that person represents to sign on behalf of its representatives.

7. MONITORING COMPLIANCE WITH THIS DEED

7.1 The Undertaking Parties will, at the Commission's request, provide to the Commission any information and documents reasonably required:

(a) about the Divestment and the Undertaking Parties' progress towards carrying out the Divestment; and

(b) demonstrating that the Undertaking Parties' conduct during the Divestment Period complies with the Divestment Undertakings.

7.2 If requested, the Undertaking Parties will attend the Commission at a time and place appointed by the Commission to answer any questions the Commission may have (including by telephone if more convenient).

7.3 Without limiting clause 7.1, the Undertaking Parties will provide to the Commission a copy of any transaction documents relating to the Divestment within 3 Business Days of their execution.

7.4 Nothing in this Deed requires the Undertaking Parties to provide legally privileged information or documents to the Commission or any other party.

8. EXECUTION

Executed as a deed. This document may be executed in counterparts.

Mylan N.V.

	Thomas D. Salus
Authorised Signatory	Authorised Signatory
John Miraglia	Thomas D. Salus
Print Name	Print Name
Amanda J. Beamon	Amanda J. Beamon
Witness	Witness
Amanda J. Beamon	Amanda J. Beamon
Print Name	Print Name
Senior Counsel	Senior Counsel
Occupation	Occupation
[*Redacted*]	[*Redacted*]
Address	Address

Upjohn Inc.

Authorised Signatory	Authorised Signatory
Print Name	Print Name
Witness	Witness
Print Name	Print Name
Occupation	Occupation
Address	Address

8. EXECUTION

Executed as a deed. This document may be executed in counterparts.

Mylan N.V.

Authorised Signatory	Authorised Signatory
Print Name	Print Name
Witness	Witness
Print Name	Print Name
Occupation	Occupation
Address	Address

Upjohn Inc.

DocuSigned by: 260B654401644FD... Authorised Signatory	DocuSigned by: FF981C452A1344A... Authorised Signatory
Alison L.M. O'Neill	Stephen P. Diamond, Jr.
Print Name	Print Name
DocuSigned by: D4FCAF65A093498... Witness	DocuSigned by: D4FCAF65A093498... Witness
Sean F. Kelley	Sean F. Kelley
Print Name	Print Name
Manager	Manager
Occupation	Occupation
[*Redacted*]	[*Redacted*]
Address	Address

SCHEDULE 1 – Divestment Assets

<table>
<tr>
<td>Divestment Assets</td>
<td>The Divestment Assets comprise the right, title and interest, including the right to develop, manufacture, package and sell in New Zealand that will be held by the Undertaking Parties in the following Upjohn products that are registered in New Zealand (as further described in Schedule 3):
<table>
<tr><th>Main Divestment Product</th><th>Molecule</th></tr>
<tr><td>Neurontin</td><td>Gabapentin</td></tr>
<tr><td>Pregabalin Pfizer[1]</td><td>Pregabalin</td></tr>
<tr><td>Celecoxib Pfizer[2]</td><td>Celecoxib</td></tr>
<tr><td>Viagra</td><td>Sildenafil[3]</td></tr>
</table>
and as accompanied by the assets, licences, agreements and other tangible and intangible property listed in this Schedule 1 and necessary to enable an Approved Purchaser to be a sustainable, effective, stand-alone, independent, long-term and viable competitor in New Zealand.</td>
</tr>
</table>

[*Redacted*]

[1] Note that Upjohn's pregabalin product, which is currently marketed under the trade name Pregabalin Pfizer, was initially registered with Medsafe as Lyrica. The registered trade name was subsequently changed to Pregabalin Pfizer
[2] Note that Upjohn's celecoxib product, which is currently marketed under the trade name Celecoxib Pfizer, was initially registered with Medsafe as Celebrex. The registered trade name was subsequently changed to Celecoxib Pfizer, however Upjohn also has separate registrations under the trade name Celebrex with Medsafe.
[3] For the avoidance of doubt, the divestiture does not impact Revatio and its respective indications.

Schedule 2: Identity of Proposed Purchaser

Mylan has entered into an Asset Purchase Agreement with Aspen Pharmacare Australia Pty Ltd (ABN 51 096 239 985) with Aspen New Zealand of Level 3, 7 Falcon Street, Parnell, Auckland 1052 appointed as agent for the service of process in New Zealand in relation to any matter arising out of the Asset Purchase Agreement (the **Proposed Purchaser**).

Schedule 3: Product Registrations

The below table lists the relevant marketing authorisations and sponsorship details for the Upjohn products included in the Divestment Assets as registered by Medsafe.

Active molecule	Product details	Medsafe File Reference	Sponsor	Status	Approval date
Celecoxib[4]	Celecoxib 100 mg capsules in pack size of a 2, 10 and 60 capsule blister packs	TT50-5892/1	Upjohn New Zealand ULC	Consent given	9/09/1999
	Celecoxib 200 mg capsules in pack size of a 2, 10 and 30 capsule blister packs	TT50-5892/1a	Upjohn New Zealand ULC	Consent given	9/09/1999
	Celecoxib 100 mg capsules in pack size of a 60 capsule blister pack	TT50-10509	Upjohn New Zealand ULC	Not available	10/01/2019
	Celecoxib 200 mg capsules in pack size of a 60 capsule blister pack	TT50-10509a	Upjohn New Zealand ULC	Consent given	10/01/2019
	Celecoxib 400 mg capsules in pack size of a 30 capsule blister pack	TT50-5892/1b	Upjohn New Zealand ULC	Not available	4/05/2006
Gabapentin	Gabapentin 100 mg capsules in pack size of a 100 capsule blister pack	TT50-4285/1b	Upjohn New Zealand ULC	Consent given	4/08/1994
	Gabapentin 300 mg capsules in pack sizes of a 4, 20 and 100 capsule blister packs	TT50-4285/1	Upjohn New Zealand ULC	Consent given	4/08/1994
	Gabapentin 400 mg capsules in pack size of a 100 capsule blister pack	TT50-4285/1a	Upjohn New Zealand ULC	Consent given	4/08/1994

[4] Note that Upjohn's celecoxib product was initially registered with Medsafe as Celebrex. The registered trade name was subsequently changed to Celecoxib Pfizer for those products appearing with the brand name Celecoxib Pfizer in the table above.

Active molecule	Product details	Medsafe File Reference	Sponsor	Status	Approval date
	Gabapentin 600 mg film coated tablets in pack sizes of a 20 and 100 tablet blister pack and 100 and 500 tablet bottles	TT50-4285/2	Upjohn New Zealand ULC	Consent given	19/10/2000
	Gabapentin 800 mg film coated tablets in pack sizes of a 100 tablet blister pack and 100 and 500 tablet bottles	TT50-4285/2a	Upjohn New Zealand ULC	Not available	19/10/2000
Pregabalin[5]	Pregabalin 150 mg capsules in pack sizes of various 14, 20, 56 and 60 capsule blister packs and 14, 20, 56 and 60 capsule bottles	TT50-7184d	Upjohn New Zealand ULC	Consent given	24/11/2005
	Pregabalin 25 mg capsules in pack sizes of various 14, 20, 56 and 60 capsule blister packs and 14, 20, 56 and 60 capsule bottles	TT50-7184	Upjohn New Zealand ULC	Consent given	24/11/2005
	Pregabalin 300 mg capsules in pack sizes of various 14, 20, 56 and 60 capsule blister packs and 14, 20, 56 and 60 capsule bottles	TT50-7184g	Upjohn New Zealand ULC	Consent given	24/11/2005
	Pregabalin 75 mg capsules in pack sizes of various 14, 20, 56 and 60 capsule blister packs and 14, 20, 56 and 60 capsule bottles	TT50-7184b	Upjohn New Zealand ULC	Consent given	24/11/2005
	Pregabalin 100 mg capsules in pack sizes of	TT50-7184c	Upjohn New Zealand ULC	Not available	24/11/2005

[5] Note that Upjohn's pregabalin product was initially registered with Medsafe as Lyrica. The registered trade name was subsequently changed to Pregabalin Pfizer.

Active molecule	Product details	Medsafe File Reference	Sponsor	Status	Approval date
	various 14, 20, 56 and 60 capsule blister packs and 14, 20, 56 and 60 capsule bottles				
	Pregabalin 200 mg capsules in pack sizes of various 14, 20, 56 and 60 capsule blister packs and 14, 20, 56 and 60 capsule bottles	TT50-7184e	Upjohn New Zealand ULC	Not available	24/11/2005
	Pregabalin 225 mg capsules in pack sizes of various 14, 20, 56 and 60 capsule blister packs and 14, 20, 56 and 60 capsule bottles	TT50-7184f	Upjohn New Zealand ULC	Not available	24/11/2005
	Pregabalin 50 mg capsules in pack sizes of various 14, 20, 56 and 60 capsule blister packs and 14, 20, 56 and 60 capsule bottles	TT50-7184a	Upjohn New Zealand ULC	Not available	24/11/2005
Sildenafil	Sildenafil 100 mg film coated tablet in the pack sizes of 1, 4, 8 and 12 tablet blister packs and 4, 8 and 12 tablet bottles	TT50-6069b	Upjohn New Zealand ULC	Consent given	29/10/1998
	Sildenafil 25 mg film coated tablet in the pack sizes of 1, 4, 8 and 12 tablet blister packs and 4, 8 and 12 tablet bottles	TT50-6069	Upjohn New Zealand ULC	Consent given	29/10/1998
	Sildenafil 50 mg film coated tablet in the pack sizes of 1, 4, 8 and 12 tablet blister packs and 4, 8	TT50-6069a	Upjohn New Zealand ULC	Consent given	29/10/1998

Active molecule	Product details	Medsafe File Reference	Sponsor	Status	Approval date
	and 12 tablet bottles				
	Sildenafil 25 mg film coated tablet in the pack sizes of 4, 8 and 12 tablet blister packs and 4, 8, 12 and 24 tablet bottles	TT50-8602	Upjohn New Zealand ULC	Not available	24/02/2011
	Sildenafil 50 mg film coated tablet in the pack sizes of 1, 4, 8 and 12 tablet blister packs and 4, 8, 12 and 24 tablet bottles	TT50-8602a	Upjohn New Zealand ULC	Not available	24/02/2011
	Sildenafil 100 mg film coated tablet in the pack sizes of 1, 4, 8 and 12 tablet blister packs and 4, 8, 12 and 24 tablet bottles	TT50-8602b	Upjohn New Zealand ULC	Not available	24/02/2011

Schedule 4: Funding approvals

The below table lists the relevant agreements with PHARMAC for the community funding of the Divestment Products.

Trade name	Product details	Agreement	Purpose
Celecoxib Pfizer	Celecoxib 100 mg capsules in a 60 capsule blister pack	Agreement between PHARMAC and Pfizer New Zealand Limited for Terms of Listing Celecoxib Pfizer on the Pharmaceutical Schedule dated 28 October 2016	Community Funding and DHB Hospital Funding
Celecoxib Pfizer	Celecoxib 200 mg capsules in a 30 capsule blister pack	Agreement between PHARMAC and Pfizer New Zealand Limited for Terms of Listing Celecoxib Pfizer on the Pharmaceutical Schedule dated 28 October 2016	Community Funding and DHB Hospital Funding
Pregabalin Pfizer	Pregabalin 25 mg capsules in pack size of 56 capsules blister pack	Agreement between PHARMAC and Pfizer New Zealand Limited for Terms of Listing of Pregabalin Pfizer on the Pharmaceutical Schedule dated 16 October 2017	Community Funding and DHB Hospital Funding
Pregabalin Pfizer	Pregabalin 75 mg capsules in pack size of 56 capsules blister pack	Agreement between PHARMAC and Pfizer New Zealand Limited for Terms of Listing of Pregabalin Pfizer on the Pharmaceutical Schedule dated 16 October 2017	Community Funding and DHB Hospital Funding
Pregabalin Pfizer	Pregabalin 150 mg capsules in pack size of 56 capsules blister pack	Agreement between PHARMAC and Pfizer New Zealand Limited for Terms of Listing of Pregabalin Pfizer on the Pharmaceutical Schedule dated 16 October 2017	Community Funding and DHB Hospital Funding
Pregabalin Pfizer	Pregabalin 300 mg capsules in pack size of 56 capsules blister pack	Agreement between PHARMAC and Pfizer New Zealand Limited for Terms of Listing of Pregabalin Pfizer on the Pharmaceutical Schedule dated 16 October 2017	Community Funding and DHB Hospital Funding

(a) **CONFIDENTIAL SCHEDULE: *[redacted]***