ISBN 978-1-869458-06-5

Statement of Issues

Mylan / Upjohn

27 March 2020

Introduction

1. On 18 December 2019, the Commerce Commission registered an application (the Application) from Mylan N.V. (Mylan) and Upjohn Inc. (Upjohn) (the Parties) seeking clearance to combine Upjohn's global portfolio of off-patent branded products with Mylan's global portfolio of generic pharmaceutical products (the Proposed Merger).[1] The Application relates to the Proposed Merger to the extent it affects markets in New Zealand.

2. We have been unable to reach a decision on the Application within the initial 40 working day statutory timeframe provided under the Commerce Act 1986 (the Act).

3. This Statement of Issues (SoI) sets out our concerns about the potential competition issues we have identified following our initial investigation so that the Parties and interested parties can provide us with submissions relating to those concerns. This SoI is accompanied by a confidential attachment that has been provided to external counsel under confidentiality undertakings.

4. In reaching the preliminary views set out in this SoI, we have considered information provided to date by the Parties and other industry participants. We have not yet made any final decisions on the issues outlined below (or any other issues) and our views may change, and new competition issues may arise, as the investigation continues.

The concerns we are testing

5. The main focus of this SoI is whether the Proposed Merger would substantially lessen competition due to unilateral effects for the supply of a number of medicines in response to Pharmaceutical Management Agency (PHARMAC) procurement processes. We are testing whether the Proposed Merger could give the merged entity the ability to profitably raise prices and/or reduce service or quality in the supply of relevant products.

6. We are also continuing to consider whether the Proposed Merger is likely to substantially lessen competition due to:

[1] A public version of the Application is available on our website at: http://www.comcom.govt.nz/business-competition/mergers-and-acquisitions/clearances/clearances-register/.

6.1 horizontal unilateral effects for medicines that are supplied outside PHARMAC's procurement processes;

6.2 coordinated effects, for example by enhancing the prospects for market allocation, or by generally making coordination more likely, more complete or more sustainable; and

6.3 conglomerate effects where the merged entity is able to leverage "must-have" products in its dealings with PHARMAC to foreclose rivals.

7. At this time, we are not investigating further and do not require any further information from the Parties or interested parties in respect of the potential for the Proposed Merger to result in vertical effects.

8. If we identify any further issues during our analysis of the Proposed Merger that are not discussed in this SoI, we will update the Parties and other interested parties through an updated SoI.

Process and timeline

9. We have agreed with the Parties an extension of time until 11 May 2020 in which to make a decision.

10. The Commission would like to receive submissions and supporting evidence from the Parties and other interested parties on the issues raised in this SoI. We request responses by close of business on 14 April 2020, including a public version of any submission.

11. All submissions received will be published on our website with appropriate redactions.[2] All parties will have the opportunity to cross-submit on the public versions of submissions from other parties by close of business on 21 April 2020.

12. The Commission acknowledges that some interested parties may face a range of challenges during New Zealand's COVID-19 lockdown. This may impact their ability to submit in a meaningful way within these timeframes. If you would like to make a submission but face difficulties in doing so within the timeframe, please ensure that you register your interest with the Commission at **registrar@comcom.govt.nz** so that we can work with you to accommodate your needs where possible.

Industry background

Medicine categories

13. The Proposed Merger relates to the supply of off-patent and generic medicines. One method to classify medicines is the Anatomical Therapeutic Chemical (ATC)

[2] Confidential information must be clearly marked (by highlighting the information and enclosing it in square brackets). Submitters must also provide a public version of their submission with confidential material redacted. At the same time, a schedule must be provided which sets out each of the pieces of information over which confidentiality is claimed and the reasons why the information is confidential (preferably with reference to the Official Information Act 1982).

classification system. The system has five levels which get progressively more specific in terms of describing the medicine. For example, ATC1 groups medicines broadly according to the part of the body that they act on. ATC5 lists the specific molecule which is the active ingredient that pharmaceutical companies develop and patent, and which later becomes available as a generic.

14. The main groups that we refer to below are ATC5 (the specific molecule) and ATC4. ATC4 includes a wider range of molecules with the same therapeutic use or similarities in their class, formulation or mode of action.[3]

Medsafe registration

15. Pharmaceutical products supplied in New Zealand must be approved by the New Zealand Medicines and Medical Devices Safety Authority (Medsafe).[4] Medsafe's role is to ensure that medicines and medical devices have acceptable efficacy, quality and safety. Medsafe-approved products are referred to below as being "registered" and the process to get approval is referred to as "the registration process".

16. The Application notes that the registration process can take between 15 and 18 months but it can be quicker in some circumstances.[5]

The public and private channels

17. There are two main channels through which firms can supply registered medicines in New Zealand, which we refer to in turn as "the public channel" and "the private channel".

    17.1 In the public channel, PHARMAC decides which medicines to subsidise for use in New Zealand's public healthcare system and (usually) procures them by running tenders for supply contracts. District Health Boards (DHBs) then pay the PHARMAC contract price for the subsidised medicines that doctors prescribe, and pharmacists dispense. Patients with prescriptions for subsidised medicines pay only the prescription charge. Dispensing pharmacists are reimbursed for their procurement costs from public funds held by DHBs.

    17.2 In the private channel, firms compete to supply medicines outside the PHARMAC process. PHARMAC does not subsidise these products and so the price will normally be higher than the same or similar medicine that is PHARMAC funded. Pharmacies and final consumers are the main decision makers on what medicines are purchased in this channel.

18. Some medicines are sold in both public and private channels. For example, paracetamol is publicly funded (procured by PHARMAC through tenders), as well as sold in pharmacies and supermarkets without funding.

---

3 The Application at [12.7]

4 Subject to certain exceptions such as those provided in sections 25 and 29 of the Medicines Act 1981.

5 The Application at [11.4]-[11.5].

The relevant markets

19. 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 still impose some degree of competitive constraint on the merged entity.

20. As noted above, the key areas of overlap between the Parties are in the supply of off-patent medicines in response to PHARMAC procurement processes,[6] as well as supply of medicines to consumers outside of PHARMAC processes in the private channel.

21. In the Application, the Parties provided product information that was broken down into several categories:[7]

    21.1 product overlaps at molecule (ATC5) level where competition is driven by PHARMAC tenders (being atorvastatin, celecoxib, gabapentin, and venlafaxine);

    21.2 product overlaps at molecule level for indications that are not publicly funded (being sildenafil); and

    21.3 "notional" product overlaps at ATC4 level (which, being one level above ATC5, can include a range of different molecules) where competition is driven by PHARMAC tenders (being anti-epileptic products, diuretics, calcium antagonists, selective serotonin reuptake inhibitors, and miotics and anti-glaucoma products).

22. The Parties submitted that regardless of the approach the Commission takes to market definition, the Proposed Merger will not raise competition issues.

Supply chain level market definition

23. We agree with the Parties that there are separate channels for public and private supply of pharmaceuticals in New Zealand.[8]

24. We are of the view that for the purposes of assessing the Proposed Merger there are likely to be separate public and private markets for each relevant pharmaceutical product. This is because competition for sales takes place differently in each channel:

    24.1 In the public channel, suppliers respond to tenders or requests for proposals (RFPs) in order to win PHARMAC contracts. PHARMAC sets the terms of the tenders and RFPs, and is the sole decision maker as to the winner. PHARMAC

6 See [14] of our Statement of Preliminary Issues for more information on PHARMAC's role.
7 The Application at [1.12] and following.
8 The Application at [1.5]-[1.6].

will normally seek bids for a specific molecule. PHARMAC evaluates bids with consideration to the level of need, health benefits, suitability, and costs and savings.[9] These contracts are typically for sole-supply status at a set price for a three-year term. As PHARMAC partly subsidises these products, and the price a pharmacist can charge is fixed (for funded indications), the subsidised products are available at a much lower price than an equivalent medicine in the private channel.

24.2 In the private channel, suppliers compete to sell branded pharmaceuticals to final consumers that have a prescription. Factors that might determine that decision are the price at which the product is being offered, the support that the supplier is offering for the product, and patient demand for the product. Brand can be an important factor in determining patient demand. Unlike in the public channel, suppliers can regularly change their price as they respond to competitive pressures.

25. As the competition assessment for the public and private markets differ, we have set out these analyses separately for each of the relevant pharmaceutical products. While we are treating these as separate markets, we are continuing to consider whether, in specific instances, PHARMAC-funded medicines provide a constraint on equivalent or similar medicines sold in the private channel, or vice versa. Where relevant, we identify this in the analyses below.

Product market definition

26. Our preliminary view is that, for most of the relevant products, the closest substitutes are products that have the same active ingredient molecule. As such, so far we have been considering separate markets at a molecule (ATC5) level.

27. However, for each product we are continuing to assess whether other products that have different active ingredient molecules are close substitutes. As our investigation continues, we may find that some of the relevant products are better assessed as being part of a broader product market that includes other molecules.

28. The molecules that we have assessed so far are:

28.1 amlodipine;

28.2 atorvastatin;

28.3 celecoxib;

28.4 doxazosin;

28.5 eplerenone;

28.6 gabapentin;

[9] See for example <www.pharmac.govt.nz> “Factors for consideration”.

28.7 latanoprost;

28.8 phenytoin;

28.9 pregabalin;

28.10 sildenafil;

28.11 tolterodine;

28.12 venlafaxine; and

28.13 ziprasidone.

Geographic market definition

29. We consider that the relevant markets are likely to be national in scope, given that:

29.1 pharmaceuticals are distributed nationwide; and

29.2 competitive conditions do not seem to differ regionally.

The factual and counterfactual

30. Assessing whether a substantial lessening of competition is likely requires us to compare the likely state of competition if the Proposed Merger proceeds (the scenario with the merger, often referred to as the factual) with the likely state of competition if it does not (the scenario without the merger, often referred to as the counterfactual) and to determine whether competition is likely to be substantially lessened by comparing those scenarios.

31. With the Proposed Merger, Upjohn's global portfolio of off-patent branded products will be combined with Mylan's global portfolio of generic pharmaceutical products.

32. At this stage we consider that the likely counterfactual is the status quo. That is, the Parties would continue to operate as independent businesses.

Competition assessment: unilateral effects

33. Unilateral effects arise when a firm merges with or acquires a competitor that would otherwise provide a significant competitive constraint (particularly relative to remaining competitors) such that a market participant can profitably increase prices above the level that would prevail without the merger (and/or reduce quality). We have set out our analyses for the public and private markets separately below.

Public markets

34. The Proposed Merger would combine two major suppliers of off-patent pharmaceuticals to PHARMAC in New Zealand. This means that the Proposed Merger would result in a reduction in the number of competitors that could participate in a PHARMAC procurement process for any of the molecules in which the Parties overlap for supply in New Zealand.

35. We are considering whether the reduction in competitors would substantially lessen competition in any of the public product markets due to unilateral effects. The loss of competition between the Parties could, for example, result in the merged entity:

    35.1 raising its bid prices in the next tender; and/or

    35.2 reducing its product range (such as pack size or presentation type) for a molecule in the next tender; and/or

    35.3 providing a poorer service to PHARMAC (such as by reducing the volumes of medicines it is prepared to hold in New Zealand, eg, a three-month supply instead of a four-month supply).

36. In the Application, the Parties submitted that the Proposed Merger would not be likely to substantially lessen competition in any of the relevant markets due to unilateral effects. Although the Parties identified a range of molecules that they both supply, they submitted that:

    36.1 there are other competitors for each of the products, in particular those competitors that already have a registered product in New Zealand;[10]

    36.2 barriers to entry are low, and suppliers of the products in other countries could easily enter New Zealand markets to participate in the tenders;[11] and

    36.3 PHARMAC exerts substantial countervailing power due to its position as a monopsonist for funded pharmaceuticals such that even the presence of only two players would be sufficient to ensure a competitive outcome.[12]

Competition in the public markets

37. In public markets, competition takes place through tenders or RFPs that PHARMAC runs periodically. There is a single supplier and the price is fixed over the term of the PHARMAC contract. To assess the impact of the Proposed Merger, we therefore need to assess who is likely to compete in the next tender or RFP and how strong each offer is likely to be. The impact of the Proposed Merger will depend on how strong the Parties are likely to be as competitors compared to other participants.

38. The Parties submitted that all firms that have a registered product could compete for the next tender and that suppliers of the product in other countries could also compete for future tenders. Although we agree that it is possible that all such firms could compete in tenders, our investigation has indicated that these firms are not necessarily all equally well-placed to compete for the tenders. We set out the reasons for this preliminary view below.

---

10 See for example the Application at [17.9].

11 The Application at [26].

12 The Application at [11.20]-[11.22], [17.11], [27].

39. First, having a registered product is just one (required) element of a firm's ability to compete. Other important factors are a firm's ability to source the product at a competitive price and to obtain a reliable supply to avoid running out of stock.

    39.1 The firms that compete to supply PHARMAC often source their products from overseas-based generic manufacturers. The evidence we have viewed so far indicates that the manufacturing cost is an important part of the overall cost of supplying a medicine, and that this can differ materially from one supplier to another. This cost is likely to materially affect whether a registered competitor bids, as well as the price that they can offer.

    39.2 Reliability of supply is also an important factor. Under a PHARMAC contract, the contract holder must be able to supply the product on demand. Where the contract holder is unable to supply on demand, it must use its best endeavours to find an alternative source. The contract holder may have to buy from a rival at a higher price than it can sell the product under the PHARMAC contract, and it may have to indemnify PHARMAC for its costs or pay PHARMAC liquidated damages. We understand that a firm that cannot be sure of maintaining a regular supply is likely to factor that risk into the price it offers PHARMAC, or otherwise not submit a bid at all. Reliability of supply is also an important factor for PHARMAC, and so PHARMAC is less likely to award a tender to a firm if it considers that firm is likely to experience supply issues.

    39.3 All else being equal, our current view is that the firms that are likely to have the most confidence in maintaining a regular supply in New Zealand are those firms that already supply the medicine in New Zealand (for example, as the funded supplier or outside the PHARMAC tender) or have recently supplied the medicine (for example, as a past contract holder). It is possible that a firm that is currently supplying (or recently supplied) a different molecule to PHARMAC might also have some confidence to supply a given molecule compared to one with no presence in New Zealand. We continue to investigate whether registered suppliers for the relevant products are likely to be less competitive at the next tender due to reliability of supply issues.

40. Secondly, firms that do not have a registered product in New Zealand face an additional barrier. We agree with the Parties' submission that obtaining Medsafe registration seems relatively straightforward for parties where their products are already registered overseas by Medsafe-recognised regulators.[13] However, we are still considering whether this additional barrier means overseas suppliers are less likely to be a strong competitor compared to those already present in New Zealand. The process still incurs a cost in respect of time for those parties compared to those with an already registered product.

[13] The Application at [26].

41. Taking these factors into account, to date our investigation has indicated that, in general, firms can be viewed as stronger or weaker competitors depending on which of the following categories they fall into:

    41.1 the firm has a competing product registered with Medsafe and is already making sales in New Zealand to PHARMAC or outside of the PHARMAC process (since this indicates an ability to maintain a regular supply);

    41.2 the firm has a competing product registered with Medsafe which it is not currently supplying in New Zealand but has done so recently;

    41.3 the firm has a competing product registered with Medsafe but has not recently supplied in New Zealand;

    41.4 the firm has a competing product registered with a Medsafe-recognised overseas regulator, but is not registered in New Zealand;

    41.5 the firm has never registered or supplied a competing product in New Zealand, but has a competing product registered globally; or

    41.6 the firm does not have a competing product in its global portfolio.

42. We note that some firms we have spoken to have specific circumstances that will affect their ability to compete in future tenders. We have taken these into account in assessing competition for each molecule. Another possible exception to the list above is for medicines where suppliers are generating high sales in the private channel. We are considering whether such firms may choose not to bid for PHARMAC tenders to avoid having to charge a much lower price for their product than in the private channel.

Countervailing power – public markets

43. The Parties submitted in the Application that PHARMAC exerts substantial countervailing power due to its position as a monopsonist for funded pharmaceuticals. The Parties claimed that, due to this power, even the presence of only two firms would be sufficient for PHARMAC to drive a competitive outcome.[14]

44. We agree with the Parties' submission that PHARMAC has some countervailing power, being the monopsonist buyer. However, it is not clear that PHARMAC can constrain price rises through its countervailing power even if competition is weak.

45. First, although PHARMAC can design its tender process, the principle that "two firms would be sufficient" for a competitive outcome only applies under certain conditions. These are:[15]

[14] The Application at [11.20]-[11.22] and [17.11].

[15] See for example Paul Klemperer "Competition Policy in Auctions and 'Bidding Markets" in P Buccirossi (ed) *Handbook of Antirust* (MIT Press, 2008).

45.1 competition is “winner take all”;

45.2 competition is lumpy so that each contest is large relative to a suppliers’ total sales in a period;

45.3 competition begins afresh for each contract; and

45.4 entry of new suppliers into the market is easy.

46. It is unclear to us that these conditions are met.

46.1 First, as noted above, we consider that there is an advantage for those firms with an existing supply (particularly as an incumbent) and there are some barriers that might discourage a supplier from competing. As such, at least two conditions may not be satisfied. If two suppliers are insufficient, then the Proposed Merger could reduce competition and shift the balance of power away from PHARMAC in a such a way that price rises may be viewed as a substantial lessening of competition.

46.2 Secondly, although PHARMAC could take action to encourage or assist other firms, it still requires good options to impose that threat. For example, in principle it may be able to:

46.2.1 find an alternative molecule to the one it is tendering that could provide the same or similar treatment; or

46.2.2 approach an overseas firm to become the funded supplier (subject to it being registered).

However, these alternatives are only likely to impose a competitive threat if they do not impose a material cost on PHARMAC. If they do (for example, because there are greater risks switching to alternatives or the alternative is only available at a higher price), then PHARMAC may be prepared to accept higher prices before switching to those alternatives.

47. We are considering whether PHARMAC would face particularly high costs to switch to alternatives (and therefore have weaker countervailing power) against suppliers that have market power over particularly important products, or multiple products. This question relates not just to our concerns about horizontal effects but also to our concerns, below, about the potential conglomerate effects of the merger. Some potential issues are as follows.

47.1 PHARMAC might be less able to resist a price increase effectively from a firm with market power over a ‘must-have’ product that treats a widespread or severe condition. In such a case, PHARMAC would face particularly high risks in trying to secure alternative supply, since a break in continuity or reduction in manufacturing quality could be critical.

47.2 A supplier with multiple products and market power over a 'must-have' product might be able to leverage the latter to obtain higher prices for its other products, by making a credible and powerful threat to withhold supply of the 'must-have' product unless granted higher prices at other tenders. As explained further in the section on conglomerate effects below, we are assessing whether the merged entity could gain such a position.

47.3 PHARMAC might also be less able to resist price increases effectively from firms that have market power over multiple products than from firms that have market power over just one or two. PHARMAC would have fewer opportunities to punish a firm that is dominant in multiple markets for raising prices at a tender in other markets and would face higher costs if it tried to secure alternative supply.

48. We continue to assess the extent to which PHARMAC could use its position to mitigate the effects of any lost competition as a result of the Proposed Merger, and we invite submissions on this point.

Products for which we have identified potential competition concerns

49. Using the approach above, we consider the evidence to date shows that:

49.1 absent the Proposed Merger, Mylan and Upjohn are likely to be strong competitors (or potential competitors) for future tenders for several molecules. This competition would be lost with the Proposed Merger. We consider each firm may be a strong competitor, either because:

49.1.1 it is currently funded for this product;

49.1.2 it previously held the contract;

49.1.3 it previously bid; and/or

49.1.4 it supplies the product in the private channel;

49.2 it is unclear that all of the firms that the Parties identify in the Application (including registered and non-registered suppliers) will be sufficiently strong competitors in future tenders (and in some cases there are doubts whether they will participate at all) to replace that lost competition; and

49.3 it is unclear yet whether PHARMAC has sufficient countervailing power to replace that lost competition.

50. The products that raise the greatest competition concerns in public markets on this basis are set out in Table 1, along with some brief comments on why we think the Parties are strong rivals in the market.

Table 1: Products that raise the most concerns in public markets*

Product	Position of the Parties and rivals
celecoxib	• Upjohn is funded for this product. • Mylan participated in the last tender and, based on the Application, was the only other firm supplying celecoxib in New Zealand in 2018. • Apotex and Teva are the other firms that are registered to supply celecoxib in New Zealand.
gabapentin	• Apotex is funded for this product. • Mylan, Upjohn, Douglas and Teva are the other firms that are registered to supply gabapentin in New Zealand.
pregabalin	• This was not identified as an overlap or potential overlap in the Application. • Upjohn is funded for this product. • Mylan and Apotex are the only other firms that are registered to supply pregabalin in New Zealand.
atorvastatin	• Mylan is funded for this product. • Upjohn/Pfizer was the previous supplier to PHARMAC. • Te Arai BioFarma is listed as a registered supplier of atorvastatin, and is noted being able to compete with the Merged Entity at the next tender. However, Te Arai Biofarma's product is a combination capsule containing aspirin, atorvastatin and ramipril, and may not be an equivalent product.
venlafaxine	• Mylan is funded for this product. • Upjohn is registered and was previously a PHARMAC supplier. Upjohn is currently selling its Efexor XR product in the private channel. According to the Application, Upjohn and Teva were the only other firms supplying venlafaxine in New Zealand in 2018. • Teva and REX Medical are the other suppliers that are registered to supply venlafaxine in New Zealand. The Application states that Apotex is registered to supply venlafaxine with Medsafe and could compete at the next tender. However, Apotex is not listed as registered on the Medsafe website.

Note:* The information in this table is based on the firms listed in the market share tables for 2018 in the Application, the accompanying information, and publicly available information including PHARMAC's historical New Zealand Pharmaceutical Schedule.

51. We are also considering other molecules for which both Parties are registered, and which may impose a constraint on one another. These are set out in Table 2. However, our initial evidence indicates that the Parties may not compete as closely for these products as for the products in Table 1, and therefore any competition

concerns may not be as significant. We are continuing to gather information on these products.

Table 2: Other molecules we are considering that may raise concerns in public markets

Product	Position of the Parties and rivals
sildenafil	• Mylan is funded for this product. • According to the Application, Upjohn does not participate in PHARMAC tenders. However, Upjohn supplies Viagra in the private market and therefore may be a potential competitor for PHARMAC tenders. • The other registered suppliers are Teva, Douglas, Dr Reddy's, and Apotex.
latanoprost	• Latanoprost was not identified as a molecular overlap in the Application. • Teva is funded for this product. • The other registered suppliers are Mylan, Upjohn, Apotex and Douglas.
ziprasidone	• Ziprasidone was not identified as a molecular overlap in the Application. • Douglas is funded for this product. • The other registered suppliers are Mylan (as at 1 February 2020), Upjohn and Teva.

52. In addition, we have also considered the molecules below (which were not listed in the Application) but at this stage we do not consider they raise competition concerns and do not require any further information from the applicants:

    52.1 amlodipine;

    52.2 doxazosin;

    52.3 eplerenone;

    52.4 phenytoin; and

    52.5 tolterodine.

53. We welcome any further information or submissions on these molecular overlaps, including about:

    53.1 the strength of competitors in each of the relevant markets post-merger; and/or

53.2 the ability of PHARMAC to exercise any countervailing power.

Private markets

54. We are considering the effect of the Proposed Merger on certain products mentioned in the Application which are sold in the private channel. As noted above, competition in private markets differs from that in public markets. Instead of competing to win PHARMAC tenders, firms compete on price and brand to make sales to pharmacies and final consumers.

55. We have identified two private product markets which are of concern: sildenafil and venlafaxine.

56. In these markets, Upjohn sells its branded sildenafil (Viagra) and venlafaxine (Efexor XR) products.[16] Mylan does not sell its sildenafil or venlafaxine products in the private channel but is instead the current supplier to PHARMAC for both products.

57. We are considering whether Mylan's funded pharmaceuticals impose some constraint on Upjohn's privately marketed products, such that the Proposed Merger could substantially lessen competition in the private markets for these products due to horizontal unilateral effects. We discuss each product in turn below.

Sildenafil

58. We understand that most sales of sildenafil in New Zealand are likely to be private market sales to customers seeking to treat erectile dysfunction. PHARMAC currently funds Mylan's Vedafil for other uses, ie treatment of pulmonary arterial hypertension, Reynaud's Syndrome, and erectile dysfunction for patients with spinal cord injuries.

59. While PHARMAC does not fund Vedafil for typical cases of erectile dysfunction, we understand that pharmacists are able to:[17]

59.1 source Vedafil from Mylan at the PHARMAC-negotiated price for the purposes of supplying in the private market; and

59.2 sell to patients in the private market with no retail price restrictions as an alternative to selling Viagra and other privately marketed versions of sildenafil.

60. On this basis we understand that some portion of Vedafil sales are effectively private sales to customers that may otherwise have purchased Viagra or other sildenafil products.

61. In the Application, the Parties submitted that there is no "ongoing price competition between Vedafil and other erectile dysfunction products as the Vedafil price can only change at the next tender round".[18] At this point of our investigation we consider

16 The Application at [20.9] and [21.15]-[21.21].
17 The Application at [21.14].
18 The Application at [21.15].

that Vedafil could provide a degree of ongoing price constraint on Viagra. Although it may not have the brand strength of Viagra, Vedafil is a much lower cost alternative and so may be attractive for Viagra customers. We therefore consider it possible that Upjohn takes into account the threat of losing some customers to Vedafil when setting the price of Viagra.

62. As noted in the Application, the price of the funded product is set at tender. Providing the Proposed Merger does not adversely affect competition for the funded product, then we might expect the price of the funded product to remain at a similar level. However, the identity of the supplier of the funded product might still make a difference. At present, Upjohn will consider the potential loss of sales to Mylan when setting the price of Viagra. Post-merger it would internalise those losses when setting the price of Viagra, which might make a price increase worthwhile. That would not be the case if another firm supplied the funded product.

63. We continue to assess whether other constraints could replace lost competition between Upjohn and Mylan, including:

    63.1 the constraint that Douglas imposes as a current competitor and Teva as a potential competitor; and

    63.2 the extent to which privately marketed sildenafil products are constrained by other erectile dysfunction products such as Cialis and Levitra, which are supplied by other firms and use different active ingredient molecules (tadalafil and vardenafil respectively).

64. We welcome any further information or submissions on competition in the private market for sildenafil products.

Venlafaxine

65. Venlafaxine is funded by PHARMAC to treat anxiety and depression. Mylan's Enlafax XR is currently the funded product. We understand that Upjohn was a funded supplier before Mylan became the sole supplier in 2017.[19] Upjohn is currently supplying its Efexor XR product in the private market.

66. As with the private market for sildenafil, the key question we are considering is the extent to which Mylan's funded Enlafax XR imposes a competitive constraint on Upjohn's privately marketed Efexor XR product. For example, we are considering whether the merged entity would be able to increase the price of Efexor XR on the basis that it would recapture some revenues from the customers that might divert to the funded Enlafax XR product.

67. We continue to assess whether other constraints could replace the lost competition between Upjohn and Mylan, including:

---

[19] 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>.

67.1 the constraint that other market participants could impose (including those with a product registered in New Zealand or overseas); and

67.2 the extent to which venlafaxine is constrained by other molecules.

68. We invite any further information or submissions on competition in the private market for venlafaxine products.

Non-molecular overlaps

69. As stated above, our preliminary view is that the products supplied by the Parties most closely compete with competitors' products that have the same active ingredient molecule. However, we are still considering whether any of the medicines supplied by the Parties are close competitors despite containing different molecules.

70. We note that, in the Application, the Parties present several non-molecular overlaps where Mylan and Upjohn supply medicines that share the same ATC4 class, and where competition takes place in the public market for PHARMAC contracts. The Parties describe these overlaps as "notional", on the basis that PHARMAC generally procures products separately on a molecular basis.

71. We have fewer concerns in relation to the potential overlaps where the Parties may compete with products that use different molecules. As above, we consider the closest substitutes for a given medicine will be medicines that use equivalent active ingredient molecules. Also, markets that include multiple molecules are naturally wider in scope. This means that there are likely to be more competitors, such as:

71.1 third party suppliers of each relevant molecule supplied by the Parties; and

71.2 third parties that supply other competing molecules which are not supplied by the Parties but nonetheless impose a constraint in the same market.

72. We are assessing whether the Parties supply any products that compete closely despite using different molecules, such that the Proposed Merger would substantially lessen competition in a broader market containing different pharmaceuticals that are substitutable from a doctor or patient perspective.

Competition assessment: coordinated effects

73. 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 which can arise from the merged entity acting on its own, coordinated effects require some or all of the firms in the market to be acting in a coordinated way.[20]

[20] *Mergers and Acquisitions Guidelines* above n **Error! Bookmark not defined.** at [3.84].

74. In the Application, the Parties submitted that the Proposed Merger will not increase the likelihood of coordinated effects in the relevant markets, because:[21]

    74.1 prices in the generic pharmaceuticals industry are not transparent (until such time as a tender is awarded);

    74.2 PHARMAC strongly constrains pricing;

    74.3 competitors would quickly disrupt any attempt to coordinate;

    74.4 there are strong out of market competitors that could easily enter in response to increased prices;

    74.5 the products are not homogenous; and

    74.6 the Proposed Merger does not remove an aggressive competitor.

75. We have considered two ways in which coordination might occur in the markets that the firms compete:

    75.1 First, whether the firms might be able to coordinate over the price or condition of competition for a single market.

    75.2 Secondly, where the firms coordinate to agree which molecules to compete for.

76. At this point we consider that the Proposed Merger is unlikely to give rise to coordinated effects in any single product market. The private markets affected by the Proposed Merger are more likely to raise unilateral concerns due to the merged entity's high market share. We consider that coordination within individual PHARMAC tenders for specific molecules is unlikely because contracts are "winner takes all". There is no incentive for bidders to coordinate on price because only the winner benefits from the high price.

77. We continue to consider whether the Proposed Merger could make it easier for suppliers to coordinate in respect of the allocation of contracts, with suppliers either not bidding competitively or not at all on each other's allocations. We are considering whether this could take place by allocating contracts within New Zealand or across countries.

78. There are some factors that might help facilitate such coordination within New Zealand. For example:

    78.1 assuming an allocation could be established, it would be easy to monitor adherence to the understanding since it would be clear who won the contract and at what price;

[21] The Application at [29].

78.2 there would be a reduction in the number of players with whom to coordinate;[22] and

78.3 there may be barriers to entry for a firm to start supplying in New Zealand.

79. However, we are also considering whether other factors may make such coordination harder to sustain.

79.1 First, in order to reach an understanding of this nature there would need to be a relatively easy way to allocate contracts. However, the PHARMAC contracts are of greatly different sizes[23] and typically last for three years. This may make it harder to maintain a stable allocation, without some parties trying to cheat and win one of the few most valuable contracts. We are still considering whether there would be an effective punishment strategy that would discourage cheating.

79.2 Secondly, we are assessing whether PHARMAC could disrupt such coordination. For example, for the products where it does have good alternatives, PHARMAC could change the format of the tender or negotiate directly with a rival supplier to displace the incumbent. It may be worthwhile for PHARMAC to accept this cost if the coordination was taking place across a large number of products.

80. We are also continuing to consider whether coordination could occur on an international level.[24] For example, a reduction in the number of players could make it easier to reach an understanding not to compete in certain territories.

81. We invite submissions on this topic.

Competition assessment: conglomerate effects

82. 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 merging parties have complementary products. The merged entity may provide bundled discounts (where customers buy the product together rather than separately) or may refuse to sell one product unless the customer buys another product (tying). This can harm competition because it may mean a competitor is denied access to sufficient market demand to achieve competitive scale and is foreclosed from the market.

---

22 The range of products that the coordination takes place over will affect how significant the impact of the Proposed Merger would be. For example, if the coordination was believed to be taking place over all PHARMAC contracts, there would be many suppliers active in New Zealand and the loss of one player is unlikely to have a major effect.

23 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.

24 We note that former executives at some pharmaceutical companies active in New Zealand have recently been prosecuted in the United States for price-fixing and market-sharing. See for example Ben Remaly "Former Sandoz exec pleads guilty to price-fixing" *GCR* (18 February 2020).

83. A possible way that such conglomerate effects could occur in these markets is that:

83.1 the merged entity ties or bundles a group of medicines in such a way that makes it attractive to the buyer;

83.2 other rivals are not able to match the tie or bundle because only the merged entity can supply a certain product or products (that is, it has a "must have" product);

83.3 a rival supplier is unable to supply any of the medicines in the bundle or tie, which means it does not have sufficient revenues to justify a New Zealand presence (for example, because there is a fixed cost to operate an office) or it becomes an inefficient operator;

83.4 the rival becomes a less effective competitor or exits New Zealand; and

83.5 there is a substantial lessening of competition for the medicines that the rival no longer competes for or where it is a less effective competitor.

84. We are continuing to assess whether the Proposed Merger could result in such an outcome. We are assessing whether:

84.1 the merged entity would have any must-have products which rivals cannot supply, which it could leverage in its negotiations with PHARMAC to foreclose rivals; and

84.2 whether it is plausible that foreclosure of this nature could result, given most firms seem to have a wide portfolio of products (so are unlikely to be reliant on any particular molecule or molecules to compete effectively in New Zealand).

85. We invite submissions on this topic.

Next steps in our investigation

86. The Commission is currently scheduled to decide whether or not to give clearance to the Proposed Merger by 11 May 2020. However, this date may change as our investigation progresses.[25] In particular, if we need to test and consider the issues identified above further, the decision date may extend.

87. As part of our investigation, we will continue to identify and contact parties that we consider will be able to help us assess the issues identified above.

Making a submission

88. We are continuing to undertake inquiries and seek information from industry participants about the impact of the Proposed Merger. We welcome any further

[25] The Commission maintains a clearance register on our website at http://www.comcom.govt.nz/clearances-register/ where we update any changes to our deadlines and provide relevant documents.

evidence and other relevant information and documents that the Parties or any interested parties are able to provide regarding the issues identified in this SoI.

89. If you wish to make a submission, please send it to us at registrar@comcom.govt.nz with the reference "Mylan / Upjohn" in the subject line of your email, or by mail to The Registrar, PO Box 2351, Wellington 6140. Please do so by close of business on 14 April 2020.

90. As above, if in the current COVID-19 lockdown environment this deadline will be difficult for you to meet, please register your interest with the Registrar so that we can work with you to accommodate your needs where possible.

91. All information we receive is subject to the Official Information Act 1982 (OIA), under which there is a principle of availability. We recognise, however, that there may be good reason to withhold certain information contained in a submission under the OIA, for example in circumstances where disclosure would be likely to unreasonably prejudice the commercial position of the supplier or subject of the information.