PARTIES' RESPONSE TO COMMERCE COMMISSION'S STATEMENT OF ISSUES

1. Introduction and executive summary

1.1 This submission sets out Mylan and Upjohn's (the **Parties**') response to the Commerce Commission's (**Commission**'s) Statement of Issues dated 27 March 2020 (**SOI**) published in relation to the proposed merger between the Parties (**Proposed Transaction**).

1.2 The Commission is currently of the view that competition concerns cannot, at this stage, be ruled out in relation to:

(a) celecoxib;

(b) gabapentin;

(c) pregabalin;

(d) atorvastatin;

(e) venlafaxine;

(f) sildenafil

(g) latanoprost; and

(h) ziprasidone,

(the **SOI Products**).

1.3 The Parties do not agree that the Proposed Transaction is likely to substantially lessen competition in any market in New Zealand.

1.4 In particular, there are some products for which there is no competitive overlap in New Zealand. For example, Mylan no longer has a registered ziprasidone product in New Zealand (with registration having lapsed as at 25 February 2020) [ ]. There is therefore no meaningful overlap regarding this molecule between Upjohn and Mylan and no way in which competition could be harmed.

1.5 In addition, the Parties maintain that no concerns should arise in relation to the remaining SOI Products for the reasons set out in the remainder of this response.

2. No unilateral effects (in public or private markets)

Parties are not close competitors

2.1 As an initial point, the Parties consider that the Commission's concern set out in the SOI that Upjohn might be a particularly strong or close competitor to Mylan is not supported by the facts.

2.2 Upjohn markets branded originator products that now are off patent; while those products are exposed to generic competition, Upjohn is not a typical generic supplier. [ ]

2.3 That means that in public markets in New Zealand, Upjohn is not a close competitor to Mylan. For most overlaps called out by the Commission in the public market, Upjohn is not the funded supplier [ ]. And, while Upjohn is the funded supplier for two of the SOI Products, those products (celecoxib and pregabalin) are some of the most recent in Upjohn's portfolio to lose

patent protection. Products that have been off patent for longer tend to attract more and more competition from generics. Accordingly, as PHARMAC issues new tenders for subsequent sole supply periods, prices tend to drop. [ ] The fact that Upjohn currently is or previously was the funded supplier for certain molecules is not a meaningful basis to claim that it will be a significant competitor in the future, or that it is a close competitor to Mylan for future tenders.

2.4 In private markets, the Parties are not close competitors given that Mylan's products generally enjoy little brand recognition and their wholesale price is set by reference to the PHARMAC contract price.

Ability of "new entrants" to compete in PHARMAC tenders

2.5 As a separate point, the Commission sets out in its SOI the elements that it considers make suppliers stronger or weaker competitors at a tender (SOI paragraphs 38 to 41). In general, the Parties consider that the elements identified by the Commission (existing registration, competitive cost of supply, reliability of supply) are indeed relevant elements. However, they consider that the SOI may overstate the difficulty that generics suppliers face in meeting these elements, including where they do not have an existing registration.

2.6 Indeed, it is not the case that previous experience of supplying PHARMAC is necessary and it is not uncommon to seek registration of a product in conjunction with a bid. For example, as recently as March 2020, a supplier previously unknown to Mylan (Phebra New Zealand Limited, a subsidiary of an Australian supplier (**Phebra**)) was awarded the PHARMAC tender for benzatropine mesylate (in competition against Mylan and, possibly, other suppliers). Phebra will be listed on the PHARMAC Schedule from 1 July 2020 for supply of this product. The Medsafe website lists its registration as being granted on 3 October 2019.

2.7 Prior to this tender win, Phebra supplied only one product to PHARMAC, being a phosphorus product. Despite this, it has six products registered with Medsafe, all of which appear to have been approved since the beginning of 2018. While there are many other examples, Phebra is a prime example of a relatively unknown supplier in New Zealand obtaining Medsafe registration for products and shortly after successfully competing for PHARMAC tenders against more established suppliers (such as Mylan).

2.8 As another example, Juno won the pemetrexed PHARMAC tender in 2017. This was a high profile product for treating mesothelioma and non-small cell lung cancer that was only available privately prior to the tender being awarded. At the time of winning the tender, although Juno had established a relatively small but growing business in Australia, the Parties believe that Juno was an unknown supplier in New Zealand.[1]

Ziprasidone

2.9 Neither Party is funded for this product. Further, Mylan no longer has a current registration for the ziprasidone molecule in New Zealand, [ ]. Mylan applied to Medsafe to have all of its ziprasidone products (being Zaprone capsules 20mg, 40mg, 60mg and 80mg) deregistered as of 25 February 2020 (being the notification date to Medsafe). The product status change request form is attached as **Annexure 1**, which confirms that all ziprasidone product has been depleted from the New Zealand market (although in fact the product was never sold in New Zealand so no stock has ever been available) and the registration status should be changed from "not available" to "approval lapsed". This status change has now occurred, as can be viewed on Medsafe's website.[2]

2.10 [ ] This decision was made some time ago (independently of the Proposed Transaction) and has already been implemented by Mylan.

[1] See https://www.pharmac.govt.nz/news/notification-2017-08-18-pemetrexed/; and https://www.thepharmaletter.com/article/approval-of-funding-for-juno-pemetrexed-for-the-treatment-of-mesothelioma-and-nsclc-in-nz.

[2] See https://www.medsafe.govt.nz/regulatory/ProductDetail.asp?ID=14474.

2.11 [ ]

2.12 There is therefore no meaningful overlap between the Parties for ziprasidone in New Zealand and indeed any future reduction in the number of potential suppliers in future PHARMAC tenders is not merger specific.

2.13 Rather, Douglas as the current PHARMAC funded provider of ziprasidone is a strong competitor for ziprasidone. In addition:

(a) [ ]; and

(b) any number of generic pharmaceutical suppliers active in New Zealand could establish a supply of ziprasidone and obtain Medsafe registration to enable them to supply in New Zealand. Dr Reddy's Laboratories Limited was the supplier of the API for the Mylan product and could readily supply any other manufacturer (or, given its strong manufacturing capability and significant New Zealand presence, Dr Reddy's could establish this supply itself). To this end, Mylan [ ]

2.14 Given there is, and will be, no meaningful overlap between the Parties for this product, the Parties submit that ziprasidone should no longer be a product of concern for the Commission.

Latanoprost

2.15 Neither Party is funded for this product. Further, [ ]

2.16 [ ]

2.17 [ ]

2.18 There is therefore no meaningful overlap between the Parties for latanoprost in New Zealand and indeed any future reduction in the number of potential suppliers in future PHARMAC tenders is not merger specific.

2.19 Rather, Teva as the current PHARMAC funded provider of latanoprost in New Zealand is a strong competitor for latanoprost. [ ].

2.20 Given there is no meaningful overlap between the Parties for this product, the Parties submit that this should no longer be a product of concern for the Commission.

Sildenafil

2.21 The Parties submit that there is no meaningful overlap between the Parties for sildenafil, given Mylan focuses on PHARMAC tenders, and Upjohn on private sales.

<u>Public market</u>

2.22 As Upjohn has advised the Commission[3] [ ]. The Commission has [ ] in the SOI, by acknowledging that suppliers which are generating high sales in the private channel may choose not to bid for PHARMAC tenders to avoid having to charge a lower price for their product (SOI at paragraph 42).

2.23 In any event, there remain a number of competitors which will constrain the merged entity in future as it considers tendering for sildenafil. These include:

(a) Dr Reddy's, who is a strong competitor with its sildenafil product in other countries and has Medsafe registration for a sildenafil product in New Zealand. Given Dr Reddy's strong

[3] Response to the Commission's request for information dated 17 February 2020.

presence and long history in New Zealand, including participation in PHARMAC tenders, it could readily bring its sildenafil product to market here;

(b) Teva, [ ], retains an active registration for this product which it could use to compete;

(c) Douglas, [ ]; and

(d) a range of other suppliers internationally which could readily enter the New Zealand market (many of whom already supply numerous other pharmaceuticals here).

2.24 [ ] Further, Mylan [ ] is much more likely to consider potential bids from other registered suppliers, and any other potential entrants, in setting the price it bids for the PHARMAC supply of sildenafil, than it is to consider an unlikely tender from Upjohn, or Upjohn's pricing in the private channel.

2.25 It is not the case that Upjohn's activities in the private channel have any impact on the price at which Mylan responds to PHARMAC tenders for sildenafil. Rather, when determining the price at which it will bid, Mylan [ ] does not know which other suppliers will also be participating in that tender process, or how low these competitors will be able to price their own products.

Private market

2.26 The Proposed Transaction will not have any meaningful impact on the price at which the merged entity supplies Viagra in the private market, given the substantial differential between the relative margins of Mylan and Upjohn's products. As noted in the clearance application, Upjohn prices Viagra based on the very substantial brand equity it enjoys. It would not be worth the merged entity increasing the price of Viagra by any meaningful amount in the hope that lost Viagra sales, and therefore margin, might be recouped through additional sales of Vedafil. [ ]. As a demonstration, [ ]

2.27 Rather, the competitive constraints that currently impact the pricing of Viagra in the private market will remain. A substantial amount of lost Viagra sales arising from an increase in Viagra pricing would be likely to divert to other strong competitors, including:

(a) Douglas, which is a strong, branded competitor in this space. Douglas is the only New Zealand owned and operated business that is active in this market, has a long history with New Zealand pharmacy and commands significant ongoing loyalty from New Zealand pharmacists;

(b) Teva, as a potential competitor for sildenafil in this channel (both in respect of future PHARMAC tenders and the private market);

(c) erectile dysfunction products with different active ingredient molecules but the same therapeutic indication as sildenafil, including tadalafil (Cialis) and vardenafil (Levitra), given in the private market customers do not focus on the molecule make-up of a product, but rather its brand and its intended use. [ ] Generic versions are likely to enter the market over the next five years and will add additional competition to this product category; and

(d) other possible new entrants to the New Zealand market for sildenafil (and tadalafil and vardenafil in due course).

Venlafaxine

2.28 The Parties submit that there is no meaningful overlap between the Parties for venlafaxine, given Mylan focuses on the public market, and Upjohn on the private market.

Public market

2.29 [ ]

2.30 [ ]

2.31 [ ] The Commission has [ ] in its statement in the SOI that suppliers which are generating high sales in the private channel may not choose to bid for PHARMAC tenders to avoid having to charge a lower price for their product (SOI at paragraph 42).

2.32 In any event, there remain a number of competitors which will constrain the merged entity in future as it considers tendering for venlafaxine. These include:

(a) REX Medical, who is a strong competitor;

(b) Teva, [ ]; and

(c) other possible new entrants to the New Zealand market for venlafaxine.

2.33 As for sildenafil, it is not the case that Upjohn's activities in the private channel have any impact on the price at which Mylan responds to PHARMAC tenders for venlafaxine. Rather, [ ] it does not know what other suppliers will also be participating in that tender process, or how low they will be able to price their own product to win the supply away from Mylan (or any other sole-supply holder).

Private market

2.34 The Proposed Transaction will not have any impact on the price at which Upjohn supplies its venlafaxine product in the private market. [ ]

2.35 This would not change if the Mylan and Upjohn products were held by one entity, given the relative margins of Mylan and Upjohn's products. [ ] [ ] [ ], it would not be worth the merged entity increasing the price of Efexor in the expectation that lost sales (and therefore margin) may be recouped on the Mylan Enlafax product. As a demonstration, [ ]

2.36 Rather, the competitive constraints that currently impact the pricing of Upjohn's venlafaxine product in the private market will continue, including:

(a) Teva, which is a strong competitor, especially when considering only sales via the private market. [ ];

(b) REX Medical is currently registered for the product and could begin supplying in the private market; and

(c) other possible new entrants to the New Zealand market for venlafaxine.

Atorvastatin

2.37 The Proposed Merger will not give rise to a substantial lessening of competition for atorvastatin at future PHARMAC tenders for this molecule.

2.38 [ ]

2.39 [ ]

2.40 [ ]

2.41 [ ]

2.42 In any event, [ ], a variety of strong, viable competitors will remain in the public market for the supply of atorvastatin Post-Transaction. These include:

(a) CARSL Consulting;

(b) API Consumer Brands;

(c) Dr Reddy's; and

(d) other possible new entrants to the New Zealand market for atorvastatin.

2.43 The merged entity will not know which of these (or other suppliers) will decide to respond to PHARMAC's tender and how aggressively they will price that response. The merged entity will therefore need to offer as low a price as possible based on its cost of goods and security of supply at that time.

Celecoxib, gabapentin, pregabalin

2.44 The Parties also disagree that there will be a substantial lessening of competition for celecoxib, gabapentin and pregabalin. Competitors will remain in the market at the next tender to challenge the merged entity. [ ] Further, the pregabalin molecule was only first funded for supply by PHARMAC in 2017; as noted above, [ ].[4] [ ][5] [ ].

2.45 [ ]

3. **No coordinated effects**

3.1 The Proposed Transaction will not give rise to coordinated effects.

3.2 While the Commission considers it unlikely that firms could coordinate over the price or conditions of competition for a single market, it is still assessing whether firms could coordinate to agree which molecules to compete for.

3.3 The Parties consider that it would simply not be possible to reach an understanding between pharmaceutical suppliers as to who would bid for what contract. This is because:

(a) pharmaceutical companies have quite different portfolios of products, with differing strengths, weaknesses, cost base and geographic focus. In addition, there will be dozens of suppliers responding to aspects of the annual PHARMAC tenders. There would be no practical way that this number of competitors with different portfolios of products and asymmetric cost bases could reach a tacit understanding as to who would bid for which product at a given time. They would also have no incentive to do so, given their widely varying sizes, structures and cost bases, and global commercial strategies;

(b) compounding this issue (and as noted by the Commission), the varying length and value of contracts would destabilise any attempt at coordination – competitors are highly incentivised to win sole supply of the large contracts in particular, as this guarantees a substantial revenue stream for a three year period;

(c) because prices of sole supply contracts are set for the duration of the contract, there is no effective punishment strategy – attempting to punish a competitor by bidding on a product that was ostensibly "allocated" to that competitor would completely destabilise any

[4] See PHARMAC "Decision to fund pregabalin, and change the funded brand of gapapentin and listing restrictions" (7 December 2017), accessed 7 April 2020. Available at: https://www.pharmac.govt.nz/news/notification-2017-12-07-pregabalin-gabapentin/.
[5] [ ]

attempted coordination. While a normal punishment strategy might see prices dropped for a short period to punish a competitor, with prices subsequently raised again, such a 'drop and revert' strategy is not possible when bidding for a three year contract; and

(d) PHARMAC has complete discretion over the operation of its tenders and has many procurement options outside of its tender process (see below). It frequently enters negotiations with suppliers on products ahead of tenders or outside of tenders and does not need to guarantee sole supply. It could readily use these tools to destabilise any attempt at coordination.

3.4 For similar reasons, coordination on an international level would be impossible. Once a supplier has an established supply chain for a generic pharmaceutical, it is incentivised to maximise sales of that product globally. In doing so, it will face multiple competitors for each product. It would simply not be feasible to reach a broad, tacit understanding encompassing a large number of suppliers, each with many products and each selling into many regions. In any event, Upjohn with its relatively limited portfolio of primarily branded products is not a significant or close generic competitor, and the combination with Mylan is unlikely to substantially change market dynamics in a manner that would be conducive to a greater risk of coordination.

4. No conglomerate effects

4.1 The Proposed Transaction does not give rise to a plausible conglomerate effects theory of harm:

(a) neither Party supplies a "must have" product to PHARMAC – all of Upjohn's and Mylan's products are exposed to generic competition and the nature of generic pharmaceuticals is that they are interchangeable with other suppliers' products who manufacture the same molecule (in the same strength and galenic form);

(b) even if any of the Parties' products were considered to be a "must have" product, given Mylan's current broad portfolio of generic products in New Zealand, to the extent that it were profitable to bundle or tie sets of products to exclude competitors, this would already occur today. However, this does not occur today and nothing about the Proposed Transaction would change the merged entity's ability or incentive to bundle or tie such products;

(c) in particular, as set out in the Commission's merger guidelines and noted in the SOI, conglomerate effects issues might arise where merging parties sell "complementary" products. Even where the Parties sell products to the same purchasers (primarily PHARMAC) their products are not economic complements; and

(d) as noted by the Commission, most suppliers to PHARMAC compete with a portfolio of products such that they are highly unlikely to be reliant on only one product to effectively compete in New Zealand.

5. Countervailing power of PHARMAC

5.1 The Commission has indicated some concern regarding the ability of PHARMAC to exercise its countervailing power when there are two firms competing at tender, and one firm has existing supply and the other may have barriers which discourage it from competing.

5.2 However, this assumes that parties tendering have perfect and complete information as to who will tender for the relevant products, which is instead not the reality. Each supplier will be aware of which of its competitors is registered with Medsafe. The supplier preparing a bid generally would anticipate that each of these competitors might participate in the tender, although this might not prove to be the case. In addition, it is not uncommon for a new supplier to enter without an existing registration (as set out in the Clearance Application). Accordingly, a supplier planning to bid can never be "complacent" about the level of competition when going into a tender, in particular where losing the tender can result in forgoing a substantial amount of revenue over a three year period.

5.3 Furthermore, PHARMAC's "toolbox" is not limited to the sole-supply tender process. As acknowledged in *Pfizer, Inc and Hospira, Inc [2015] NZCC 19*, PHARMAC has a number of strategies it uses to promote competition and manage its budget, including direct negotiation, "Alternative Commercial Proposals" (which allow PHARMAC to negotiate with suppliers across a bundle of products, therefore potentially leveraging its strong bargaining position in one product to obtain a better offer on another) and RFP processes.[6] As recognised in *Mylan and Abbott Laboratories' Established Pharmaceuticals Division [2014] NZCC 40,* PHARMAC can, in some instances, use tools to manage patient demand for a product in order to exert its countervailing power.[7]

5.4 In Upjohn's view, [ ]

5.5 Accordingly, the Parties do not consider that the conditions necessary for effective competition with two tenderers (as set out in paragraph 41 of the SOI) reflect the reality of suppliers bidding for a PHARMAC tender. The reality is that such suppliers will always be driven to submit a competitive price due to the uncertainty of who else will bid and the ability of PHARMAC to take alternative approaches when it considers prices to be uncompetitive.

6. Conclusion

6.1 The Parties remain confident that the Proposed Transaction will not give rise to a substantial lessening of competition in relation to any product market in New Zealand.

6.2 The Parties trust this submission satisfies the Commission regarding the issues identified in the SOI. Both Mylan and Upjohn remain happy to discuss any of the points above further with the Commission, if useful.

[6] Paragraph 43.
[7] Paragraph 80.