Public Competition Assessment

4 December 2020

Mylan – proposed combination with Pfizer's Upjohn Inc. division

The ACCC's decision

1. On 8 September 2020, the ACCC announced its decision not to oppose the proposed merger of Mylan N.V. (**Mylan**) and Pfizer's Upjohn Inc. division (**Upjohn**) (the **proposed transaction**), after accepting section 87B divestiture undertakings from Mylan, Upjohn and Pfizer Inc. (**Pfizer**) (the **Undertakings**).

2. The Undertakings required the divestment of the following products supplied to pharmacies and hospitals:

    - Amlodipine/Atorvastatin (Brand name: Caduet) – a lipid-regulating cardiovascular treatment
    - Latanoprost (Brand name: Xalatan) – an anti-glaucoma treatment
    - Latanoprost/Timolol (Brand name: Xalacom) – an anti-glaucoma treatment

    (together, the **divestiture package**).

3. The ACCC considers that the Undertakings sufficiently address its competition concerns such that the proposed transaction is unlikely to contravene section 50 of the *Competition and Consumer Act 2010* (the **Act**). Section 50 prohibits acquisitions that would have the effect, or be likely to have the effect, of substantially lessening competition in any market.

4. The ACCC considers that, without the divestiture package, the proposed transaction would be likely to substantially lessen competition in the supply, to hospitals and pharmacies, of each of the relevant products, which are used to treat cardiovascular conditions and certain types of glaucoma.

5. This Public Competition Assessment outlines reasons for the decision by the ACCC not to oppose the proposed transaction, after accepting the Undertakings.

6. ACCC public competition assessments are subject to the following qualifications:

- The ACCC considers each transaction on a case-by-case basis, so the analysis and decision outlined in one assessment will not necessarily reflect the ACCC's view of another transaction.

- As assessments are relatively brief and do not refer to confidential information, assessments do not necessarily set out all of the issues and information considered by the ACCC.

The parties and the transaction

Mylan

7. Mylan is incorporated under the laws of the Netherlands, publicly traded on the NASDAQ Global Select Market and a global pharmaceutical company that develops, manufactures, markets and sells generic and branded products, biosimilar medicines and over-the-counter (**OTC**) remedies.

8. In Australia, Mylan supplies a portfolio of approximately 350 generic pharmaceutical drugs and over 450 branded, biosimilar medicines and OTC remedies to pharmacies and hospitals. Mylan runs its Australian operations through Alphapharm Pty Ltd, trading as Mylan Australia, which is a wholly-owned subsidiary of Mylan.

Pfizer Inc. and Upjohn

9. Pfizer is a global pharmaceutical company that develops, manufactures, markets and sells prescription medicines and OTC products.

10. Upjohn is a wholly-owned and solely controlled subsidiary of Pfizer and conducts its Australian operations through Upjohn Australia Pty Ltd (Upjohn Australia). Upjohn manufactures and supplies branded and generic off-patent medicines.

11. Globally, Upjohn supplies a portfolio of 21 off-patent pharmaceutical products, 18 of which are sold in Australia through Upjohn Australia across the following key therapeutic areas: Cardiovascular, Neurology and Pain, Psychiatry, Urology and Ophthalmology.

The transaction

12. On 29 July 2019, Mylan and Pfizer entered into a transaction which involves the separation of Upjohn from Pfizer through a spin-off and its combination with Mylan. Upon closing of the transaction, Upjohn will be the ultimate parent entity of the combined group and be renamed 'Viatris'.

Market inquiries

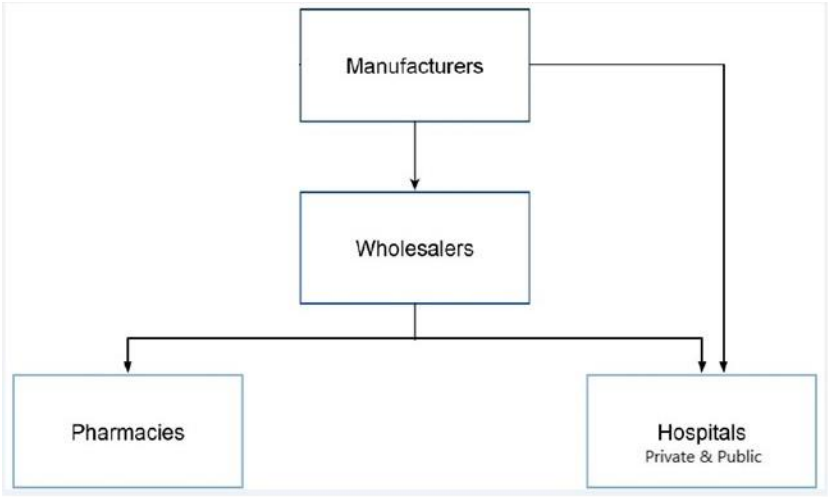
13. The ACCC conducted market inquiries with a range of industry participants, including manufacturers, wholesalers, retailers, competitors and government health departments. The ACCC consulted on the substantive competition issues and the Undertakings.

Industry background

Supply of prescription pharmaceuticals in Australia

14. The prescription pharmaceutical supply chain in Australia operates across three levels:

Diagram 1: Australian prescription pharmaceutical supply chain



15. **Manufacturing**: pharmaceuticals are manufactured either in-house by manufacturers or contracted to third party manufacturers (or a combination of both). Manufacturers contract directly with pharmacies and hospitals to supply pharmaceutical products. Manufacturers use wholesale distributors to distribute the pharmaceutical products to pharmacies and hospitals (there is limited direct distribution from manufacturers, but only to hospitals).

16. **Wholesale distributors**: stock and distribute pharmaceutical products to pharmacies. Some distributors are eligible as National Distributors for the Community Service Obligation (**CSO**) funding pool. The CSO requires wholesale distributors to stock a full range of Pharmaceutical Benefits Scheme (**PBS**) listed medicines for delivery to community pharmacies within 24 hours (or 72 hours in remote areas). Wholesale distributors also stock and distribute biosimilar medicines, OTC products and other fast-moving consumer goods (**FMCG**). Wholesale distributors also distribute pharmaceuticals to hospitals, on behalf of manufacturers.

Branded and generic pharmaceuticals

17. An originator or innovator product is the first new medicine to the market based on an active ingredient or using that active ingredient for a particular indication. These pharmaceutical products are typically patent-protected for a period of time (in Australia, the standard patent term is 20 years) and typically identified by their brand name. Pharmaceutical products, known as the branded, innovator or originator product, and typically identified by active ingredient, are protected.

18. When a patent expires, the branded pharmaceutical product will potentially face competition from other suppliers producing generic bioequivalent copies of the originator product. Generic products are typically identified by active ingredient.

19. Pharmacies typically stock a branded and, once available, a generic version of each prescription pharmaceutical product (with the same active ingredient). Unless the prescribing doctor prohibits substitution, pharmacists can recommend either a branded or generic product and patients can choose between the branded or generic product when having their prescription filled.

PBS pricing

20. The Pharmaceutical Benefits Pricing Authority sets the initial PBS List Price of a branded product that is listed on the PBS. The initial PBS List Price for a generic product, once the branded product is off-patent, is set by reference to the PBS List Price of the branded originator product. The generic product PBS List Price may be the same as or less than that of the branded originator product. A price premium or brand premium, may apply to some branded products and is an additional charge payable for the branded product. Over time, the PBS List Price for both the branded and generic product typically decreases in line with statutory anniversary price reductions. In effect, the PBS List Price acts as a price cap on the price paid by patients for pharmaceutical products purchased in a pharmacy.

Supply arrangements for generic and branded active ingredients

Pharmacies

21. Pharmacies/pharmacy groups enter into supply arrangements with manufacturers for a portfolio of generic products based on active ingredients, but typically contract on an individual active ingredient basis with each manufacturer that supplies a branded product.

22. Generic product manufacturers typically offer incentives to pharmacies to encourage consumers to substitute a generic product for the equivalent branded product. These incentives include the offer of volume rebates applied across the portfolio of generic products.

Hospitals

23. Hospitals typically procure pharmaceutical products through tender processes for each active ingredient. As a result, hospitals typically enter into supply arrangements for a particular active ingredient, rather than acquiring a portfolio of products from a single supplier.

Anatomical Therapeutic Chemical classes

24. The Anatomical Therapeutic Chemical (**ATC**) Classification system is a drug classification system (consisting of five levels) that classifies the active ingredients of drugs according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties. It is developed and maintained by the European Pharmaceutical Market Research Association (EphMRA).

25. The ATC system classifies products into cascading levels, generally according to their anatomical site of action, and their therapeutic, pharmacological and chemical composition. The following table provides an example of the ATC system using the cascading levels outlined above:

Level	Basis of classification	Example
1st level (ATC1)	Anatomical group	C – Cardiovascular System
2nd level (ATC2)	Therapeutic group	C10 – Lipid modifying agents
3rd level (ATC3)	Pharmacological/Therapeutic treatment subgroup	C10A – Lipid modifying agents, plain
4th level (ATC4)	Chemical/pharmacological/therapeutic subgroup	C10A1 – Statins (HMG-CoA reductase inhibitors)

Market definition

26. The ACCC's starting point for considering which markets will be affected by a proposed transaction is to identify the areas of overlap between the products actually or potentially supplied by the merger parties. The ACCC then considers other actual or potential suppliers of those products, as well as what other products constitute sufficiently close substitutes to provide a significant source of constraint on the merged entity.

27. The parties overlap in the supply of 12 active ingredients in Australia across a broad range of therapeutic treatments (ATC3 class) as outlined below:

Table 1: Overlapping active ingredients

Active ingredient	Product name Upjohn/Mylan	Pharmacological / Therapeutic treatment subgroup	ATC3 class
Amlodipine/Atorvastatin	Caduet/Cadivast	Lipid-regulating Cardiovascular Combinations	C11A
Amlodipine	Norvasc/Nordip	Calcium channel blockers	C8A
Atorvastatin	Lipitor/Lorstat	Lipid modifying agents, plain	C10A
Celecoxib	Celebrex/Celaxib	Anti-rheumatics, non-steroidal	M1A
Eplerenone	Inspra/Inpler	Low-ceiling Diuretics, thiazides	C3A
Gabapentin	Neurontin/Nupentin	Anti-epileptics	N3A
Latanoprost/Timolol	Xalacom/Xalamol 50/5	Anti-glaucoma preparations and Miotics	S1E
Latanoprost	Xalatan/Xalaprost	Anti-glaucoma preparations and Miotics	S1E
Pregabalin	Lyrica/Lyzalon	Anti-epileptics	N3A
Sertraline	Zoloft/Eleva	Anti-depressants	N6A
Sildenafil	Viagra/Vedafil	Erectile dysfunction products	G4E

Active ingredient	Product name Upjohn/Mylan	Pharmacological / Therapeutic treatment subgroup	ATC3 class
Venlafaxine	Effexor/Venlofex	Anti-depressants	N6A

28. For the purposes of assessing the proposed transaction, the ACCC considers it is appropriate to define separate markets for each active ingredient, or combination of active ingredients, rather than a market for a broader group of different active ingredients in the same ATC3 class.

29. Market inquiries indicated that different active ingredients in the same ATC3 class were not close substitutes for each other for the following reasons:

    - pharmacies and hospitals purchase pharmaceutical products on the basis of the active ingredient, rather than products within the same ATC3 class;

    - pharmacies cannot substitute prescriptions from one active ingredient to another active ingredient within the same ATC3 class without the patient obtaining a new prescription from their prescribing doctor; and

    - active ingredients within an ATC3 class may differ in their efficacy in treating a patient for a particular medical condition, limiting substitution opportunities for an individual patient.

30. Both Mylan and Upjohn contract to supply products to pharmacies (distributed via wholesalers) and hospitals on a national basis, as do their competitors. As a result, the ACCC considers that the appropriate geographic market definition is a national market for the supply of pharmaceutical products based on their active ingredient to pharmacies and hospitals.

Competition analysis

31. The ACCC analysed a range of information, including internal documents from Mylan and Upjohn, and industry data. The ACCC also conducted extensive market inquiries with, and collected information from, interested third parties.

32. The ACCC considers that due to the number and strength of competitors, the proposed transaction was unlikely to raise concerns for the supply of products with the following active ingredients: Amlodipine, Atorvastatin, Celecoxib, Eplerenone, Gabapentin, Pregabalin, Sertraline, Sildenafil, and Venlafaxine.

33. The ACCC identified competition concerns (outlined in detail below) in the supply of products with the active ingredients:

    - Latanoprost

    - Latanoprost/Timolol, and

    - Amlodipine/Atorvastatin.

Latanoprost

34. Latanoprost is used in the treatment of open-angle glaucoma and ocular hypertension, and is delivered in the form of an eye drop.

35. The proposed transaction would result in a reduction of competitors from three to two, with Viatris (post-transaction) holding a significant share of supply to pharmacies and hospitals. The only other supplier of Latanoprost would have a significantly smaller market share than Viatris, post-transaction.

36. The ACCC considers that, for supply of Latanoprost to pharmacies, the only remaining competitor has a minimal market share and would not provide a sufficient competitive constraint on the merged entities' price and service decisions. For the supply of Latanoprost to hospitals, while the remaining competitor has a more material presence, the ACCC considers that, taking into account market feedback and the manufacturing constraints outlined in the paragraph below, it may not provide a sufficient competitive constraint on the merged entities' price and service decisions.

37. Latanoprost must be manufactured in sterile production facilities. The ACCC understands that there are only a limited number of manufacturers globally who have the appropriate facilities, and that new entry into the supply of Latanoprost in Australia is unlikely to occur in response to an increase in price.

38. In response to these concerns, Mylan/Upjohn offered to divest the Upjohn off-patent branded product (Xalatan) to an ACCC approved purchaser.

39. Xalatan is a strong brand with a significant share of the market and capable of being supplied by a manufacturer without a large portfolio of other products. The divestment is intended to enable a new supplier of anti-glaucoma treatments to replace the competitive constraint that would have been lost as a result of the proposed transaction.

Latanoprost/Timolol

40. Latanoprost/Timolol is a combined active ingredient product used in the treatment of open-angle glaucoma and ocular hypertension, and is delivered in the form of an eyedrop.

41. The proposed transaction would have combined the two largest suppliers of the combination Latanoprost/Timolol to hospitals and pharmacies in Australia, and resulted in a significant reduction in competition.

42. The only other supplier of Latanoprost/Timolol – Novartis/Sandoz – has a significantly smaller market share than Viatris will have post transaction. Taking into account market feedback and the manufacturing constraints outlined in the paragraph below, the ACCC considers that Novartis/Sandoz would be unlikely to provide a sufficient competitive constraint on Viatris' price and service decisions.

43. As with Latanoprost, Latanoprost/Timolol must be manufactured in sterile production facilities. The ACCC understands that there are only a limited number of manufacturers globally which have the appropriate facilities, and that new entry into the supply of Latanoprost/Timolol in Australia is unlikely to occur in response to an increase in price.

44. To remedy the ACCC's concerns, Mylan/Upjohn offered to divest the Upjohn off-patent branded product (Xalacom) to an ACCC approved purchaser.

45. Xalacom is a strong brand with a significant share of the market and capable of being supplied by a manufacturer without a large portfolio of other active ingredients. The divestment is intended to enable a new supplier of anti-glaucoma treatments to replace the competitive constraint that would have been lost as a result of the proposed transaction.

Amlodipine/Atorvastatin

46. Amlodipine/Atorvastatin is a combined active ingredient product used in the treatment of hypertension and/or angina, treats cholesterol for those with high blood pressure and coronary heart disease, and hypercholesterolaemia.

47. Upjohn and Mylan are currently the only suppliers of Amlodipine/Atorvastatin to hospitals and pharmacies in Australia. Mylan and Upjohn are the sole competitive constraints on each other's price and service decisions in relation to the supply of the active ingredient. Following the transaction, there would be no remaining competitive constraints for the supply of the active ingredient.

48. The ACCC considers that products containing the constituent Amlodipine and Atorvastatin active ingredients (purchased separately) would not closely constrain Viatris' price and service decisions for the supply of the combined Amlodipine/Atorvastatin. When patients are prescribed the combined Amlodipine/Atorvastatin, they are unable to substitute to the constituent active ingredients separately without a new prescription. This was confirmed by market inquires, and it was noted that the combination product is often prescribed to improve patient compliance in taking the prescribed dosage.

49. Market inquiries also identified the reduced cost to patients of the combination Amlodipine/Atorvastatin combination product. If a patient were to purchase the Amlodipine product and Atorvastatin product separately, a second dispensing fee would need to be paid.

50. Accordingly, the ACCC considers that products containing the individual constituent active ingredients are not close substitutes for the combination product.

51. To remedy the ACCC's concerns, Mylan/Upjohn offered to divest the Upjohn off-patent branded product (Caduet) to an ACCC approved purchaser.

52. Caduet is a strong brand with a significant share of the market and capable of being supplied by a manufacturer without a large portfolio of other active ingredients. The divestment is intended to enable a new supplier of cholesterol and triglyceride regulators to replace the competitive constraint that would have been lost as a result of the proposed transaction.

Competition conclusions

53. The ACCC considers that the concerns raised in relation to pharmaceutical products based on the active ingredients Latanoprost, Latanoprost/Timolol, and Amlodipine/Atorvastatin will be remedied by the divestiture package after Mylan and Upjohn gave the Undertakings pursuant to section 87B of the Act to divest

the brands: Xalatan; Xalacom; and Caduet and Pfizer gave a supporting Undertaking.

54. The ACCC accepted a divestment of the branded off-patent products rather than its generic equivalent, as branded products are supplied to pharmacies on an individual basis. In contrast, generic products are supplied to pharmacies on a portfolio basis and, as such, any potential purchaser of the equivalent generic products would need to have a significant existing portfolio of generic products in order to be a viable and effective future source of competitive constraint.

The Undertakings

55. Mylan, Upjohn and Pfizer offered court enforceable undertakings pursuant to section 87B of the Act to address the ACCC's competition concerns.

56. The ACCC spoke to a range of market participants about the Undertakings, which related to divestments of pharmaceutical products based on the active ingredients Latanoprost, Latanoprost/Timolol, and Amlodipine/Atorvastatin.

57. The ACCC concluded that the Undertakings addressed its competition concerns with the proposed combination. A copy of the Undertakings are available on the ACCC mergers register and undertakings register.

The Mylan/Upjohn Undertaking

58. The key elements of the Mylan/Upjohn Undertaking are set out below:

- Mylan and Upjohn will divest the brands Caduet, Xalatan, and Xalacom, and the licences, agreements, assets, inventory and intellectual property, as well as certain rights in relation to Pfizer's XAL-Ease eye dropper that is used to administer Xalacom and Xalatan (the **Divestiture Business**), required to facilitate the operation of the Divestiture Business in Australia.

- At the time the Undertaking was accepted, the ACCC approved Aspen Global Incorporated (**AGI**) as the Approved Purchaser of the Divestiture Business. Approval of AGI included approval of:

    - the Asset Purchase Agreement in the form of Confidential Schedule 8 of the Undertaking as the approved Sale and Purchase Agreement, and

    - the Supply and Technology Transfer Agreement in the form of Confidential Schedule 9 of the Undertaking as the Approved Transitional Supply Agreement and Approved Transitional Technical Assistance Agreement.

- Mylan and Upjohn must appoint an ACCC approved independent auditor to monitor Mylan and Upjohn's compliance with the Mylan/Upjohn Undertaking.

- In the event the business is not sold, the ACCC has the discretion to direct Mylan and Upjohn to appoint an ACCC approved independent manager to

manage the Divestiture Business until the Divestiture Business is sold to an ACCC approved purchaser.

The Pfizer Undertaking

59. To support the Mylan/Upjohn Undertaking, the ACCC also accepted an Undertaking from Pfizer. Pfizer's consent is needed in order for Mylan and Upjohn to transfer or licence certain intellectual property rights, manufacturing technology and scientific and regulatory materials to the Approved Purchaser.

60. The objective of the Pfizer Undertaking is to support the operation of the Mylan/Upjohn Undertaking by ensuring that Pfizer enables and facilitates, and does not hinder or prevent, Mylan and Upjohn from complying with the Mylan/Upjohn Undertaking.

Divestment of Divestiture Business to Aspen

61. The ACCC has approved AGI as the purchaser of the Divestiture Business. Aspen Pharmacare Australia Pty Ltd (**Aspen Australia**) is a 100% owned subsidiary of AGI. Aspen Australia will distribute the products in Australia under a distribution agreement between Aspen Australia and AGI.

62. Aspen Australia is currently the third largest pharmaceutical supplier by volume in Australia. Aspen Australia has significant experience marketing off-patent branded pharmaceutical products in Australia, and provided evidence that demonstrated its intention to become an effective long-term competitor in the supply of these active ingredients.

63. There is no overlap between the brands to be divested and any of the products currently marketed by Aspen Australia in Australia either at the molecular active ingredient level or at the therapeutic class level.

Conclusion

64. Based on the above analysis, the ACCC considers that the proposed combination of Mylan and Upjohn, taking into account the Undertakings, would not be likely to have the effect of substantially lessening competition in any relevant market in Australia.