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FOLLITROPIN ALFA (GONAL-f®), Merck Serono Australia Pty Ltd

- 1.1 The submission requested that follitropin alfa not be 'a-flagged' to Bemfola® or any future follitropin alfa biosimilar.
- 1.2 The PBAC noted the submission as part of its consideration of follitropin alfa (Bemfola).

Correspondence from the Pharmacy Guild of Australia

1 Purpose of Item

- 1.1 The Minister (delegate) requested that the PBAC provide advice on the following matter(s) matters under section 101(3) of the *National Health Act, 1953*:
 - Correspondence from The Pharmacy Guild of Australia (the Guild) to the PBAC Chair (dated 17 December 2015)
 - Correspondence from the Guild to the Minister for Health (dated 25 January 2016);
 - Correspondence from The Consumer Health Forum to the PBAC Chair (dated 16 February 2016)
 - Correspondence from Pain Australia to the Minister for Health (dated 13 January 2016)
- 1.2 In the letter to the PBAC Chair dated 17 December 2015, the Guild requested that the PBAC review its recommendation to delist certain medicines that are also available over the counter (OTC) from general availability on the Pharmaceutical Benefits Scheme (with a particular emphasis on the paracetamol 665 mg and Panadol Osteo®), and raised concerns about the operation of various section 100 programs.
- 1.3 In the letter to the Minister for Health dated 25 January, the Guild raised similar matters in relation to de-listing Panadol Osteo® including Quality Use of Medicine concerns, and also a request to review the eligibility criteria for oral liquid paracetamol Panamax Elixir, to allow access for people with swallowing difficulties.
- 1.4 Pain Australia and the Consumer Health Forum raised concerns about the clinical and financial implications of de-listing Panadol Osteo®.

For more detail on PBAC's view, see section 3 "PBAC outcome"

2 Background

Over the counter de-listings

- 2.1 On 1 January 2016, following receipt of PBAC advice, 17 low-cost OCT medicines were delisted from general Pharmaceutical Benefits Scheme (PBS) availability, as

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part of measures agreed under the PBS Access and Sustainability Package. This represented less than 15 per cent of all OTC products subsidised on the PBS.

2.2 In April 2015 the PBAC advised, and in July 2015 it confirmed, the following guiding principles for removal of PBS subsidy:

- the medicine is available over the counter without a prescription;
- it has a low PBS-approved ex-manufacturer price where access is unlikely to change appreciably in the absence of PBS subsidy;
- no specialist prescriber involvement is required; and
- any clinical evidence considered by the PBAC did not conclusively support current subsidy arrangements.

2.3 In July 2015 the PBAC gave the following principles for retaining medicines on the PBS:

- high ex-manufacturer price, likely to prevent access by patients in the absence of PBS subsidy;
- drugs for urgent or emergency situations where there should be the fewest possible barriers
- drugs technically considered ‘over the counter’, but only because they are not ‘Scheduled Poisons’ – they are unlikely to be purchased over the counter (eg, I.V. glucose or sodium chloride)
- Palliative Care Schedule, and access for Aboriginal and Torres Strait Islander patients (and for some other small programs, eg, Paraplegic and Quadriplegic access)
 - Aboriginal and Torres Strait Islander people who have or are at risk of chronic disease can receive their medicines without payment of the co-payment, with no requirement to reach a safety net threshold. This initiative was part of the Close the Gap health policy, so PBS subsidised access was retained.
 - Palliative Care availability is intended to retain significant flexibility for supply of medicines that may be required at the end of life. It was considered that this flexibility was best managed for relevant medicines through continued PBS subsidy.

These principles resulted in a number of OTC medicines being retained for full PBS subsidy – including emergency drugs, nicotine replacement therapy, nutritional products, intravenous drugs, enzyme replacements and vitamin supplements.

2.4 The PBAC developed a guide for considering medicine affordability. It indicated that medicines with an approved ex-manufacturer price above the PBS concessional co-payment should remain on the PBS. The approved ex-manufacturer price is a per pack price – the comparison to the concessional co-payment amount of \$6.10 was not being made for the cost of a PBS supplied quantity. The PBAC comparison to the concessional co-payment amount also did not account for any potential mark-ups. This is because the PBAC approach was not intended to be a comparison of the cost before and after removal from the PBS, but a guide used to assess affordability.

2.5 At its July 2015 meeting, the PBAC provided further advice as to specific OTC drugs that were listed on the PBS and advised which of those items it may be appropriate to remove from general availability on the PBS. In providing this advice, the PBAC took into account submissions from suppliers and consumer groups. In the Overview prepared for the PBAC, the Secretariat highlighted those drugs where the maximum quantity was greater than the pack size. The PBAC considered that since these

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products would remain available to Australian patients at a reasonable cost in the absence of PBS subsidy, the arguments made in these submissions were not sufficient to justify the required Commonwealth expenditure.

- 2.6 All of the OTC medicines removed from general availability on the PBS on 1 January 2016 had an ex-manufacturer price per pack below the 2015 PBS concessional co-payment.
- 2.7 While some consumers will not be able to access delisted OTC products free of charge (once they reach their safety net), and may pay more for some OTC medicines, it is understood by the PBAC that other measures, such as allowing pharmacies to discount the PBS co-payment and other changes to prices (e.g. encouraging greater access to generics) will make many medicines more affordable.

Delisting of Panadol Osteo®

- 2.8 In this context, in July 2015 the PBAC gave specific advice that, taking into consideration the overall cost of the PBS subsidy, paracetamol 665 mg tablets should be restricted from general PBS availability. The PBAC recommended that the product only remain listed for palliative care and Aboriginal and/or Torres Strait Islander patients with persistent pain associated with osteoarthritis.
- 2.9 In making its recommendation in July 2015, the PBAC considered submissions from the Panadol Osteo® sponsor and the Australian Rheumatology Association that said the over-the-counter price for the PBS quantity of two packs would be higher than the PBS cost to concessional patients.
- 2.10 The Guild correspondence dated 17 December 2015 argued that patients who were previously prescribed two packs with a single payment of \$7.52 (co-payment \$6.10 + brand premium \$1.42) will be financially disadvantaged by pharmacies charging more than this for two packs of Panadol Osteo® OTC.
- 2.11 Following notice of the recommendation to tighten the PBS listing, rather than maintain listing on the Palliative Care Schedule and for Aboriginal and/or Torres Strait Islander patients with persistent pain associated with osteoarthritis, the sponsor of Panadol Osteo® decided to completely delist this product from the PBS and increase its OTC wholesale price by around 50 per cent.
- 2.12 The market dominant brand of paracetamol 665 mg on the PBS was Panadol Osteo®. The sponsor of the brand remaining on the PBS, Osteomol®, would not have expected to be requested to supply its product in the same high quantities as Panadol Osteo®. The company that produces Osteomol® is dealing with increasing supply requirements.
- 2.13 Price agreements are made under section 85AD of the *National Health Act 1953* (the Act) at the ex-manufacturer price level.
 - Price agreements are made for the pricing quantity of a pharmaceutical item which is the lowest of any pack quantity of any listed brand of the pharmaceutical item (Section 84AK of the Act).
 - For Panadol Osteo® the pricing quantity was 96 tablets (1 pack). The maximum quantity was 192 tablets (2 packs).

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- The approved ex-manufacturer price for Panadol Osteo® prior to 1 January 2016 was \$3.47.
- The ex-manufacturer price claimed by GSK for Panadol Osteo® prior to 1 January 2016 was \$4.13. The 66 cents difference between the approved and claimed prices reflects the per pack premium charged by GSK at the ex-manufacturer level. This equates to a premium of \$1.42 at the Dispensed Price for Maximum Quantity (DPMQ) level. This means a concessional patient was paying \$7.52 for 2 packs (\$6.10 co-payment plus \$1.42 premium).
- When the maximum quantity of 192 tablets is dispensed, the PBS subsidised amount allowed the manufacturer, wholesaler and pharmacist the amounts detailed in Table 1 (for Panadol Osteo® this refers to the period immediately before the 1 January 2016 de-listing).

Table 1: Distribution of DPMQ by recipient for maximum quantity of 2 packs (192 tablets)

Recipient	Panadol Osteo® (GSK)	Osteomol® (Pharmacor)
Manufacturer	\$8.26	\$6.94
Wholesaler	\$0.62	\$0.52
Pharmacist	\$10.43	\$10.43
DPMQ	\$19.31*	\$17.89

*Claimed DPMQ, including brand premium of \$1.42.

- 2.14 Panadol Osteo® 665 mg sustained release tablets contain the same active ingredient as the 500 mg immediate release tablet, paracetamol. The Therapeutic Relativity Sheets (1 February 2016), based on previous PBAC statements, say that “Paracetamol modified release tablet 665 mg was recommended on the basis that 6 x 665 modified release tablets = 8 x 500 mg immediate release tablets of paracetamol.”
- 2.15 Panadol Osteo® is possibly a more convenient form of paracetamol due to the less frequent dosing; it is generally taken three times per day whereas the 500 mg product is generally taken four times per day. However, the 500 mg immediate release tablet is significantly less expensive than Panadol Osteo® – a box of 100 tablets can be bought for as little as \$2.
- 2.16 The price at which Panadol Osteo® is sold in pharmacy will now depend on a number of factors, including the choices made by GSK on de-listing its product from the PBS entirely. Further, the OTC price for all medicines varies widely from pharmacy to pharmacy. Anecdotally, Panadol Osteo® is available at some pharmacies for \$7.50 for 2 boxes, but does cost more than that at other pharmacies. A consideration of availability at a particular price OTC in pharmacy compared with the co-payment amount was not previously adopted by the PBAC.
- 2.17 The sponsor, in its submission to the July 2015 PBAC meeting, argued that the PBAC has previously accepted that there is a distinction between Panadol Osteo® and standard immediate-release oral paracetamol. This referred to the April 2008 consideration of criteria relevant to exempt item status when the PBAC advised that the product is particularly advantageous for use by the subgroup of patients with osteoarthritic pain who are institutionalised. The specific exempt item criteria and the current approach to those criteria under the Act are not currently matters before the PBAC. There is no current legal exempt item determination based on the April 2008 PBAC recommendation, and any request for exempt item status would be returned to

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the PBAC. The correspondence requested the PBAC to consider afresh the paracetamol 665 mg item, its place in therapy and relevance for the OTC measure.

For more detail on PBAC's view, see section 3 "PBAC outcome"

3 PBAC Outcome

- 3.1 The PBAC noted that the Guild requested "that the PBAC undertake its own analysis of OTC prices of the delisted medicines and if it is confirmed that these products are not available at prices below the price paid by Concessional Card holders under the PBS, the decision to delist should be reviewed in consultation with relevant consumer groups...". The PBAC noted that this request had a particular emphasis on paracetamol 665 mg.
- 3.2 The PBAC noted the correspondence received from the Consumers Health Forum and Pain Australia which raised similar issues.
- 3.3 The PBAC recalled the guiding principles it used in recommending which drugs to remove from general PBS availability, and for retaining drugs on the PBS (as per paragraphs 2.2-2.3).
- 3.4 The PBAC further recalled that it recommended amending the circumstances under which paracetamol 665 mg was listed on the PBS. Specifically, the PBAC recommended continued listing for palliative care and Aboriginal and/or Torres Strait Islander patients with persistent pain associated with osteoarthritis. Following notice of the recommendation to tighten the PBS listing, the sponsor of Panadol Osteo® (one of the then two listed brands of paracetamol 665 mg) decided to delist this product from the PBS and increase its OTC wholesale price by around 50 per cent. The PBAC noted that the other brand of paracetamol 665 mg, Osteomol®, remains listed on the PBS for the restricted populations.
- 3.5 The PBAC assessed the issues raised in the correspondence, but did not consider that there was any basis to revisit its earlier recommendations in this regard. The PBAC noted that it had considered the ex-manufacturer price as a guide to assess affordability, but that this cost had not been the only guiding principle adopted under its previous advice. The PBAC considered that it would not be informative to review market prices, noting that it is up to the free market to set prices, which will be affected by supply, demand and competition.
- 3.6 The PBAC noted that paracetamol 665 mg sustained release tablets contain the same active ingredient as the 500 mg immediate release form of paracetamol. In this regard, the PBAC recalled that it previously considered that six paracetamol modified release 665 mg tablets are therapeutically equivalent to eight paracetamol 500 mg tablets. However, the 500 mg immediate release tablet is significantly less expensive than Panadol Osteo® – a box of 100 tablets can be bought for as little as \$2.
- 3.7 The PBAC noted the Quality Use of Medicines concerns raised in the correspondence; specifically, that patients previously using PBS-listed Panadol Osteo® may now seek alternative PBS-listed therapies with poorer safety profiles such as non-steroidal anti-inflammatory drugs (NSAIDs) or opioids. The PBAC will monitor the utilisation of these drugs.

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- 3.8 The PBAC did not recommend the restoration of PBS subsidised paracetamol 665 mg for persistent pain associated with osteoarthritis (or restoration of the other OTC medicines for which restrictions were modified in January 2016) beyond the current listings.
- 3.9 The PBAC noted that the Guild correspondences also raised issues regarding the availability of liquid paracetamol (Panamax Elixir®) and the operation of Section 100 programmes. The PBAC deferred consideration of these matters until a future meeting.

Correspondence from the Consumer Health Forum

- 1.1 The Consumer Health Forum (CHF) wrote to the PBAC Chair on 16 February 2016, regarding the delisting of Panadol Osteo® from the PBS, and its impact on patient affordability.
- 1.2 The PBAC considered this correspondence in conjunction with *Correspondence from the Pharmacy Guild of Australia*.

Correspondence from Pain Australia

- 1.1 Pain Australia wrote to the Minister for Health on 13 January 2016, regarding the delisting of Panadol Osteo® from the PBS, and its impact on patient affordability. Pain Australia raised related Quality Use of Medicine concerns and broader issues concerning chronic pain management in Australia. The Minister (delegate) referred this correspondence to the PBAC.
- 1.2 The PBAC considered this correspondence in conjunction with *Correspondence from the Pharmacy Guild of Australia*.