

8.01 PARACETAMOL, Suppositories 500 mg, 10, Panadol[®], GlaxoSmithKline Australia Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission requested a Restricted Benefit listing of a new pack size of paracetamol suppositories 500 mg (referred to as Panadol[®] 10 from herein) under the same eligibility criteria as the current presentation (referred to as Panadol[®] 24 from herein). Panadol 24 is available in pack quantities of 24 and a maximum quantity of 4 packs (96 suppositories). The submission requested listing of Panadol 10 with an increased maximum quantity of 10 packs (100 suppositories) and a 15% increase in AEMP.

2 Background

Registration status

- 2.1 Panadol 24 is a grandfathered product and predates the *Therapeutic Goods Act 1989*. The date this product was entered into the Australian Register of Therapeutic Goods is considered to be 10 October 1991.
- 2.2 Panadol 10 was registered by the TGA on 27 March 2020.
- 2.3 Both brands are approved for the following indication:
“For fast effective temporary relief of pain and discomfort associated with headache, muscular aches, period pain, arthritis/osteoarthritis, toothache, migraine headache, cold & flu symptoms, tension headache, sinus pain/headache and backache. Reduces fever.”

For more detail on PBAC’s view, see section 6 PBAC outcome.

3 Requested listing

- 3.1 Panadol 24 is currently listed on the PBS as a Restricted Benefit for the treatment of analgesia or fever in patients intolerant to alternate therapy and undergoing palliative care.
- 3.2 The submission requested the same listing conditions to the existing listing (see tables below).

Add new pack size as follows:

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Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Proprietary name and manufacturer	
PARACETAMOL Suppositories 500 mg, 24	5319Y	4	4	3	Panadol®	GlaxoSmithKline Australia Pty Ltd
PARACETAMOL Suppositories 500 mg, 10	New	10	10	3	Panadol®	GlaxoSmithKline Australia Pty Ltd

Restriction Summary [6167] / Treatment of Concept [6167]

Concept ID	Category / Program: GENERAL – General Schedule Palliative Care (Code PL)
	Prescriber type: <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
	Restriction Level / Method: <input type="checkbox"/> Unrestricted benefit <input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input type="checkbox"/> Authority Required - Streamlined
[13954]	Indication: Analgesia or fever
[8229]	Clinical criteria:
[8228]	Patient must be receiving palliative care
	AND
[13956]	Clinical criteria:
[13955]	Patient must be intolerant to alternative therapy

For more detail on PBAC's view, see section 6 PBAC outcome.

4 Comparator

4.1 The minor submission nominated Panadol 24 as the main comparator. This was considered appropriate.

For more detail on PBAC's view, see section 6 PBAC outcome.

5 Consideration of the evidence

Clinical evidence

- 5.1 The Sponsor did not submit data to establish superiority over the comparator.
- 5.2 In its submission, the Sponsor explained that the changes were requested due to planned closure of their current manufacturing site in Sydney, Australia and a decision to source supply from a site located in France. The change in pack size was due to the packaging agreement with the French manufacturer, and additional supply chain costs were cited as the reason for the higher requested AEMP.
- 5.3 The production of Panadol 24 is expected to cease in July 2020 and should Panadol 10 not be PBS listed, paracetamol suppositories would only be available to the Australian market privately.

Pricing considerations

5.4 The proposed price for Panadol 10 is shown in comparison to Panadol 24 in Table 1.

Table 1: Current and proposed prices for paracetamol suppositories

Product	PBS code	AEMP	Price to pharmacy	DPMQ
Panadol 24	5319Y	\$16.50	\$17.74	\$82.43
Panadol 10	new	\$7.91	\$8.49	\$96.48

5.5 The submission requested a 15% increase in the AEMP for Panadol 10 citing increased costs following a move to an international manufacturing site, increased cost of raw materials and health related inflation rate as reasoning. The Sponsor commented that the current pricing is not sustainable, however, did not provide information on the cost of goods for Panadol 24 or Panadol 10.

5.6 The Sponsor anticipated that Panadol 10 would account for 50% of the PBS supply of this item in Year 1 of launch, increasing to 100% by Year 2. Given the proposal to have both brands subsidised by the PBS simultaneously and based on the current price of Panadol 24, a proportional ex-manufacturer price for Panadol 10 of \$6.88 would be required under Section 85D of the *National Health Act 1953* ('the Act').

Estimated PBS usage & financial implications

5.7 The submission provided that the number of PBS claims for Panadol 24 in 2019 was 1,794. The Sponsor estimated an average growth rate of this market of 4% annually and anticipated no increase in the overall size of the market. The Sponsor expected that Panadol 10 would replace Panadol 24 and supply 100% of the PBS demand by Year 2 of listing. The minor submission estimated a total net cost to the PBS/RPBS of \$160,768 over the first six years of listing. This is summarised in the table below.

5.8 Based on historical PBS script data, the Department estimated an average annual growth rate of the paracetamol suppository market of -1.15%, however it was noted that the majority of the cost was driven by the proposed price increase.

Table 2: Summary of Net Impact of listing Panadol 10 at an AEMP of \$7.91

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use (as scripts dispensed)						
New listing ^a	933	1,940	2,018	2,099	2,183	2,270
Existing listing	933	0	0	0	0	0
PBS						
New listing	\$75,388	\$156,792	\$162,988	\$169,554	\$176,322	\$183,393
Existing listing	\$63,658	-\$132,396	-\$137,628	-\$143,172	-\$148,887	-\$154,858
Additional cost to PBS	\$11,730	\$24,396	\$25,360	\$26,382	\$27,435	\$28,535
RPBS						
New listing	\$9,003	\$18,742	\$19,568	\$20,303	\$21,130	\$21,957
Existing listing	\$7,626	-\$15,875	-\$16,576	-\$17,198	-\$17,899	-\$18,599
Additional cost to RPBS	\$1,377	\$2,867	\$2,992	\$3,105	\$3,231	\$3,358
Estimated net financial implications						
Net cost to PBS/RPBS	\$155,675	\$175,534	\$182,556	\$189,857	\$197,452	\$205,350
Net additional cost to PBS/RPBS	\$13,107	\$27,263	\$28,352	\$29,487	\$30,666	\$31,893

^a Assuming number of scripts per patient per year as estimated by the submission.

Source: Table 7,8,9, Part 3 of the submission

5.9 As a minor submission, the financial estimates have not been independently evaluated.

For more detail on PBAC's view, see section 6 PBAC outcome.

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of Panadol 10 on the condition that it only be supplied through the Palliative Care schedule, on the same conditions as the current Panadol 24.
- 6.2 The PBAC noted the importance of continued access to paracetamol suppository products for a small, targeted group of palliative care patients for whom the product is currently subsidised.
- 6.3 The PBAC noted additional correspondence received from the Sponsor advising that the increased cost of goods for Panadol 10 compared with Panadol 24 was due to manufacturing costs and increased warehouse and distribution costs.
- 6.4 The PBAC noted additional correspondence received from the Sponsor also stated Australian manufacture of Panadol 24 was anticipated to cease in December 2020 and supply of Panadol 24 was anticipated to be exhausted in January 2021.
- 6.5 The PBAC noted the submission did not present evidence of an improved clinical outcome between Panadol 24 and Panadol 10 to justify the increased proposed price.
- 6.6 Taking into account all of the submissions made to it, the PBAC considered that it was not possible to ascertain a cost-effectiveness premium for Panadol 10 over Panadol 24. However, noting the high clinical need for a small and targeted palliative care patient population and that manufacture of Panadol 24 would cease in December 2020, the PBAC pragmatically advised that a premium above the current unit price across both pack sizes was appropriate. The PBAC advised that it would be appropriate

that the Department negotiate the price of Panadol 24 to align with the new proposed proportional price for this pharmaceutical item, consistent with the requirements of section 85D of the Act. The PBAC noted that this was acceptable in the context of a premium that would be no more than 15% over the current per unit price, and treated a very small and high need patient group.

- 6.7 The PBAC advised that Panadol 10 should be listed with a maximum quantity of 10, allowing a maximum of 100 suppositories to be dispensed at once, and a maximum of 3 repeats.
- 6.8 The PBAC advised that, consistent with the listing for Panadol 24, Panadol 10 is suitable for prescribing by nurse practitioners.
- 6.9 The PBAC advised that, consistent with the listing for Panadol 24, the Early Supply Rule should not apply to the listing of Panadol 10.
- 6.10 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Panadol 10 is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over Panadol 24, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.

Outcome:

Recommended

7 Recommended listing

Add new item:

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
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[13954]	Indication: Analgesia or fever
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This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

GSK is pleased with the outcome. The continued availability of paracetamol suppositories via the PBS is very important for this patient population.