

5.17 MORPHINE as morphine hydrochloride
10 mg/mL injection, 5 x 1 mL ampoules
20 mg/mL injection, 5 x 1 mL ampoules
50 mg/5 mL injection, 5 x 5 mL ampoules
100 mg/5 mL injection, 5 x 5 mL ampoules
Morphine Juno, Juno pharmaceuticals Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission requested listing of four strengths of morphine (as morphine hydrochloride) for the management of pain.

2 Requested listing

- 2.1 The submission sought to list 10 mg/mL, 20 mg/mL, 50 mg/5 mL, and 100 mg/5 mL strengths on the PBS as per the current listings for morphine (as morphine sulfate and morphine tartrate) (i.e. unrestricted with a CAUTION saying “The risk of drug dependence is high.”).

For more detail on PBAC’s view, see section 5 “PBAC outcome”

3 Background

- 3.1 The TGA approved the registration of morphine hydrochloride (Morphine Juno) on 28 April 2015. Morphine is TGA registered for:
- the relief of moderate to severe pain not responsive to non-opioid analgesics
 - symptomatic relief of severe and intractable pains of various categories, in terminal cancer patients
 - as a pre-operative medication and as an analgesic adjunct in general anaesthesia.

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item as it was a minor submission.

Consumer comments

- 4.2 The PBAC noted that no consumer comments were received for this item.

Economic analysis

- 4.3 As a minor submission, there was no economic comparison presented.

- 4.4 The submission assumed the listing of morphine (as morphine hydrochloride) to be cost neutral as it was calculated on a “pricing per mg” basis as the currently listed forms of morphine (as morphine sulfate) as per the following:
 10 mg/mL - same price as the morphine sulfate 10 mg/mL
 20 mg/mL - same price as the morphine sulfate 15 mg/mL
 50 mg/mL - same price as the morphine sulfate 30 mg/mL
 100 mg/mL - same price as the morphine sulfate 30 mg/mL
- 4.5 The price of the 10 mg/mL vial is appropriate; however the price calculations for the larger vials do not take into account the price per mg of the currently listed 120 mg/1.5 mL vial containing morphine tartrate, which is lower than the price per mg of morphine sulfate 30 mg/mL (see table below). To be cost neutral, the prices of the new forms would need to be adjusted to ensure they have the same relationship on a price per mg as the currently listed forms.

Table 1: Price per mg of currently listed forms of morphine injection

Form	Price per mg
morphine sulfate 10 mg/mL	\$0.14
morphine sulfate 15 mg/mL	\$0.11
morphine sulfate 30 mg/mL	\$0.07
morphine tartrate 120mg/1.5 mL	\$0.05

For more detail on PBAC’s view, see section 5 “PBAC outcome”

5 PBAC outcome

- 5.1 The PBAC recommended listing the 10 mg/mL, 20 mg/mL, 50 mg/5 mL, and 100 mg/5 mL strengths of morphine (as morphine hydrochloride) under the same circumstances as per the current listings for morphine (as morphine sulfate and morphine tartrate). The PBAC recommended that the price of morphine be determined on a price per mg basis in line with the currently listed injections containing morphine sulfate and morphine tartrate, including taking into account the currently listed 120 mg/1.5 mL vial containing morphine tartrate.
- 5.2 The PBAC noted that the TGA considered the new forms of morphine injection (as morphine hydrochloride) as bioequivalent to the currently listed forms of morphine injection (as morphine sulfate and morphine tartrate), and noted that the new listing would trigger a 16% statutory price reduction to the drug morphine with manner of administration injection.
- 5.3 The PBAC noted that morphine should be exempt from the Early Supply Rule in line with the current listings for morphine (as morphine sulfate and morphine tartrate).
- 5.4 The PBAC advised that morphine is suitable for prescribing by nurse practitioners, in line with the current listings for morphine (as morphine sulfate and morphine tartrate).

Outcome:

Recommended

6 Recommended listing

Public Summary Document – March 2016 PBAC Meeting

6.1 Add new items:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
MORPHINE HYDROCHLORIDE 10mg/1mL injection, 5 x 1 mL ampoules	1	0	MORPHINE (JUNO)	Juno pharmaceuticals

Category / Program	General Schedule
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input checked="" type="checkbox"/> Midwives
Cautions	The risk of drug dependence is high.

Category / Program	General Schedule
Prescriber type:	<input checked="" type="checkbox"/> Dental <input type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Cautions	The risk of drug dependence is high.
Administrative advice	Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Category / Program	Prescriber bag*
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
Cautions	The risk of drug dependence is high.

*to be made available as options in the same Prescriber Bag Group as current Prescriber Bag listings for morphine sulfate (items 3479D and 3480E) and morphine hydrochloride 20 mg/1 mL injection.

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
MORPHINE HYDROCHLORIDE 20mg/1mL injection, 5 x 1 mL ampoules	1	0	MORPHINE (JUNO)	Juno pharmaceuticals

Category / Program	General Schedule
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
Cautions	The risk of drug dependence is high.

Category / Program	General Schedule
Prescriber type:	<input checked="" type="checkbox"/> Dental <input type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Cautions	The risk of drug dependence is high.
Administrative advice	Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Category / Program	Prescriber bag^
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Public Summary Document – March 2016 PBAC Meeting

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
Cautions	The risk of drug dependence is high.

^to be made available as options in the same Prescriber Bag Group as current Prescriber Bag listings for morphine sulfate (items 3479D and 3480E) and morphine hydrochloride 10 mg/1 mL injection.

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
50mg/5mL injection, 5 x 5 mL ampoules	1	0	MORPHINE	Juno
100mg/5mL injection, 5 x 5 mL ampoules			(JUNO)	pharmaceuticals

Category / Program	General Schedule
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
Cautions	The risk of drug dependence is high.

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

8 Sponsor's Comment

The sponsor had no comment.

ADDENDUM

Following the PBAC Meeting, the PBAC acknowledged that the sponsor requested “a” flagging of morphine (as morphine hydrochloride) with morphine (as morphine tartrate and morphine sulfate) on the PBS on the basis that the TGA considered that these products are bioequivalent. The PBAC noted that the only forms of morphine with a common strength were morphine hydrochloride and morphine sulfate 10 mg/1 mL injection. The PBAC therefore recommended that morphine hydrochloride 10 mg/1 mL injection is suitable for “a” flagging with morphine sulfate 10 mg/1 mL injection.