

4 March 2010

Proposal to widen access to fentanyl transdermal patches under a sole supply arrangement

PHARMAC is seeking feedback on a proposal to list a new brand of fentanyl transdermal patches, Duropatch, as soon as possible (following Medsafe registration) under a sole supply arrangement with Mylan New Zealand Limited. This proposal would provide savings to the Pharmaceutical Budget and would result in access to fentanyl patches being widened.

In summary, under the proposal:

- access to Duropatch, including a new lower strength (12.5 µg/hour), would not require a Special Authority;
- once Duropatch was listed, the currently funded brand of fentanyl patches, Durogesic, would remain fully subsidised (via Special Authority) for existing patients for at least 6 months, after which time Durogesic would be delisted;
- Durogesic would not be subsidised for new patients from the date of listing Duropatch; and
- following the delisting of Durogesic, Duropatch would be the only subsidised brand of fentanyl patches until 30 June 2013.

It is anticipated that, if approved by the PHARMAC Board, this proposal would be implemented in the second half of 2010.

Further details of the proposal can be found on the following pages.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Thursday, 18 March 2010** to:

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All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

Details of the proposal

Duropatch fentanyl transdermal patches would be listed in Section B, and in Part II of Section H, of the Pharmaceutical Schedule as soon as is practicable following Medsafe registration, at the following prices and subsidies (ex-manufacturer, excluding GST):

Strength	Pack Size	Current price and subsidy (Durogesic)	Proposed price and subsidy (Duropatch)
12.5 µg/hour	5	Not subsidised	\$8.90
25 µg/hour	5	\$55.23	\$9.15
50 µg/hour	5	\$100.52	\$11.50
75 µg/hour	5	\$139.18	\$13.60
100 µg/hour	5	\$171.22	\$14.50

- Duropatch would be listed without any requirement for Special Authority for funded access (as currently applies to the Durogesic brand of fentanyl patches).
- From the date of listing Duropatch there would be a minimum 6-month transition period, during which Durogesic would remain fully subsidised only for existing patients with a valid Special Authority approval given prior to the date of listing Duropatch, after which Durogesic would be delisted from the Pharmaceutical Schedule.
- Durogesic would not be subsidised for new patients from the date of listing of Duropatch.
- Following the delisting of Durogesic, Duropatch would be the sole subsidised brand of fentanyl patches in the community, and would have Hospital Supply Status, until 30 June 2013.

Additional information about Duropatch

The Duropatch brand of fentanyl patches is a matrix formulation and it is also supplied by Mylan in the United States (US) under the brand name 'Fentanyl Transdermal System (C-II)'. Fentanyl Transdermal System (C-II) received approval from the US Food and Drug Administration in January 2005.

Mylan submitted its application for registration of all strengths of Duropatch to Medsafe on 22 December 2008 and the Medsafe website (www.medsafe.govt.nz) currently records that the application is undergoing additional evaluation.

If this proposal is approved, Mylan has advised PHARMAC that it intends to provide educational materials to support clinicians prescribing, and patients using, Duropatch.

Background to this proposal

The opioid analgesic fentanyl, formulated as a transdermal patch, is currently subsidised (funded) only via Special Authority for patients who are terminally ill and opioid-responsive, and who are unable to take oral medication or unable to take morphine.

PHARMAC received an application to widen access to fentanyl patches to include patients with severe pain of malignant origin. This application has been considered by the Pharmacology and Therapeutics Advisory Committee (PTAC) and its specialist Analgesic Subcommittee.

PTAC and the Subcommittee considered that access should be widened further (under Special Authority) than proposed in the application, and also considered that a 12.5 µg/hour strength of fentanyl patch should be considered for funding.

We issued a request for proposals (RFP) in which pharmaceutical companies were invited to compete to be the sole subsidised supplier of fentanyl patches. The intent of the RFP was to achieve price reductions that would allow widening of access to fentanyl patches. The RFP has resulted in a provisional agreement with Mylan New Zealand Limited for its brand of fentanyl patches (Duropatch). Under this agreement Duropatch would be listed without any Special Authority, therefore it would be fully funded for any patient with a prescription.

If this proposal is approved by PHARMAC's Board, it would address all outstanding funding applications for fentanyl patches that have been received by PHARMAC.

Further background information

In 2008 the PHARMAC Board approved the listing of another brand of fentanyl patches (Fensic) without any Special Authority restrictions, subject to Medsafe registration of Fensic; however, this decision was not implemented because Fensic did not gain Medsafe registration.

During consultation in 2008 on the proposal to list Fensic, some responses raised concerns about the possibility of inappropriate/unsafe prescribing if fentanyl patches were listed without the requirement for Special Authority for subsidy. Responders were concerned about the increased potential for abuse/diversion of fentanyl patches if they were more widely available to prescribers. Responders highlighted the need for prescriber education.

PHARMAC considers that, in general, it is the role of the relevant registering bodies for each prescriber group, not PHARMAC, to determine competency to prescribe. We also note that all other funded opioid analgesics are funded without restrictions on who can prescribe them.

The September 2008 issue of Best Practice Journal (BPJ) contains information on the safe and appropriate use of fentanyl patches. This information was developed by BPAC NZ and is available online at www.bpac.co.nz.