

23 April 2008

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

### *Proposal summary*

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.

We issued a request for proposals (RFP) in which pharmaceutical companies were invited to compete to be the 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 Pacific Pharmaceuticals for its brand of fentanyl transdermal patches (Fensic).

As a result of the agreement, Fensic patches, including a new lower strength (12.5 µg/hour), would be listed on the Pharmaceutical Schedule fully subsidised. The product is currently undergoing regulatory consideration by Medsafe and would be listed as soon as is practicable should regulatory approval be given.

Access to Fensic patches would be without a requirement for a Special Authority. The currently listed brand of fentanyl patches, Durogesic, would remain fully subsidised on Special Authority and would be delisted a minimum of six months after the listing of Fensic (but not prior to 1 July 2009). Fensic would then be the only subsidised brand of fentanyl transdermal patch until 30 June 2011.

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

### *Feedback sought*

We welcome your feedback on this proposal. To provide feedback please submit an email, fax or letter by **4 pm, Friday 9 May 2008** to:

Geraldine MacGibbon	Email: <a href="mailto:geraldine.macgibbon@pharmac.govt.nz">geraldine.macgibbon@pharmac.govt.nz</a>
Therapeutic Group Manager	Fax: (04) 460 4995
PHARMAC	
PO Box 10-254	
Wellington 6143	

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.

### ***The details of the proposal***

We have entered into a provisional agreement with Pacific Pharmaceuticals Limited to list fentanyl transdermal patches, reservoir formulation (Fensic), in the Opioid Analgesics section of Section B, and in Section H, of the Pharmaceutical Schedule as soon as is practicable following Medsafe registration, at the following prices and subsidies (ex-manufacturer, excluding GST):

<b>Strength</b>	<b>Pack Size</b>	<b>Current price and Subsidy (Durogesic matrix patch)</b>	<b>Proposed price and subsidy (Fensic reservoir patch)</b>
12.5 µg/hour	5	Not subsidised	\$13.53
25 µg/hour	5	\$55.23	\$19.33
50 µg/hour	5	\$100.52	\$35.18
75 µg/hour	5	\$139.18	\$48.71
100 µg/hour	5	\$171.22	\$59.93

- Fensic would be listed without the requirement for Special Authority for subsidy that currently applies to the Durogesic brand of fentanyl transdermal patches.
- Following the listing of Fensic there would be a minimum 6-month transition period during which both Fensic and Durogesic would be fully subsidised, after which Durogesic would be delisted from the Pharmaceutical Schedule (providing that delisting of Durogesic does not occur before 1 July 2009 due to Durogesic's contractual protection from subsidy reduction prior to this date).
- Durogesic would remain fully subsidised subject to the current Special Authority for subsidy that applies to fentanyl transdermal patches until it is delisted from the Pharmaceutical Schedule.
- Following delisting of Durogesic, Fensic would be the only subsidised brand of fentanyl transdermal patches in the community, and would have Hospital Supply Status from the date of delisting of Durogesic until no later than 30 June 2011.
- Additionally, Fensic would have protection from delisting and subsidy reduction from the date of listing until at least 30 July 2012.

### ***Background to the proposal***

PHARMAC received an application to widen access to fentanyl transdermal patches to include patients with severe pain of malignant origin in November 2005. This application was 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 the application proposed, and also considered that a 12.5 µg/hour strength should be funded.

We issued an RFP in which suppliers were asked to compete for the supply of fentanyl transdermal patches. Suppliers were able to submit proposals that included a period of sole subsidised supply and widening of access, and guidance was given on the amount of price reduction that would enable access widening to be considered.

The proposal from Pacific Pharmaceuticals has resulted in a provisional agreement for the supply of fentanyl transdermal patches, at prices that would also enable removal of the Special Authority.

The Fensic brand of fentanyl transdermal patches is a reservoir formulation, whereas the Durogesic brand recently changed from a reservoir to matrix formulation. We have taken clinical advice on the differences in formulation and have been advised that there is no clinical reason not to award sole supply for fentanyl transdermal patches, providing that if this would involve a change from a matrix to reservoir formulation there should be a 6-month transition period where both patch types were fully subsidised prior to sole supply commencing.

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