

28 May 2014

## Proposal involving flecainide acetate and beclometasone dipropionate

PHARMAC is seeking feedback on a proposal relating to a provisional agreement with Valeant Pharmaceuticals (NZ) Limited for the supply of Tambocor and Tambocor CR brand of flecainide acetate and for the supply of the Qvar brand of extra fine beclometasone dipropionate aerosol inhalers in Section B and in Part II of Section H of the Pharmaceutical Schedule. In summary, this proposal would result in:

- a reduction in price and subsidy of the following flecainide acetate products: 50 mg tablets (Tambocor), 100 mg long-acting capsules (Tambocor CR) and 200 mg long-acting capsules (Tambocor CR);
- the delisting of flecainide acetate 100 mg tablets from the Pharmaceutical Schedule;
- the Tambocor brand of flecainide injection, 10 mg per ml, 15 ml ampoule remaining listed at the current price and subsidy;
- subsidy and delisting protection for the Tambocor brand of flecainide acetate until 31 July 2017; and
- the listing of the Qvar brand of extra fine beclometasone dipropionate aerosol inhalers.

### Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Thursday, 12 June 2014** to:

Katie Appleby	Email: <a href="mailto:tambocorandqvarconsult@pharmac.govt.nz">tambocorandqvarconsult@pharmac.govt.nz</a>
Therapeutic Group Manager	Fax: 04 460 4995
PHARMAC	Post: PO Box 10 254, Wellington 6143

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request.

## Details of the proposal

### *Flecainide acetate*

- The price and subsidy for the following presentations of flecainide acetate would be amended in Section B (community listing) and in Part II of Section H (HML; Hospital Medicines List) of the Pharmaceutical Schedule from 1 August 2014 as follows (expressed ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Current price and subsidy	Proposed price and subsidy
Flecainide acetate	Tab 50 mg	Tambocor	60	\$45.82	\$38.95
Flecainide acetate	Cap long-acting 100 mg	Tambocor CR	30	\$45.82	\$38.95
Flecainide acetate	Cap long-acting 200 mg	Tambocor CR	30	\$80.92	\$68.78
Flecainide acetate	Inj 10mg per ml, 15 ml ampoule	Tambocor	5	\$52.45	\$52.45

- Flecainide acetate 100 mg tablets would be delisted from Section B and Part II of Section H of the Pharmaceutical Schedule at some point in the future. We would notify the market prior to this occurring.
- Tambocor 50 mg tablets, Tambocor injection and Tambocor CR capsules (both the 100 mg and 200 mg presentations) would have protection from subsidy reduction and delisting until 31 July 2017.

### *Extra fine beclometasone dipropionate*

- Extra fine beclometasone dipropionate aerosol inhalers (Qvar 50 and Qvar 100) would be listed in Section B (community listing) and in Part II of Section H (HML; Hospital Medicines List) of the Pharmaceutical Schedule from 1 September 2014 as follows (expressed ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Beclometasone dipropionate	Aerosol inhaler, 50 mcg per dose	Qvar 50	200 dose	\$9.30
Beclometasone dipropionate	Aerosol inhaler, 100 mcg per dose	Qvar 100	200 dose	\$15.50

## **Background**

### *Flecainide acetate*

Flecainide acetate is a pharmaceutical that is used to treat and prevent supraventricular and ventricular arrhythmias (a type of irregular heartbeat). Our most recent advice from our specialist clinical advisors, the Cardiovascular Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC), indicates that switching patients to a different brand of flecainide would require close clinical supervision. Tambocor and Tambocor CR is the brand of flecainide acetate that is currently funded in New Zealand. This proposal would ensure that Tambocor and Tambocor CR remain fully funded, reducing the likelihood that patients would need to switch brands onto an alternative brand of flecainide acetate and would ensure continuity of supply of Tambocor and Tambocor CR.

With regard to the delisting the 100 mg flecainide acetate tablets, advice from the Cardiovascular Subcommittee of PTAC has highlighted a concern regarding the potential for confusion between the immediate-release 100 mg tablet and the long-acting 100 mg capsule. It has recommended that the 100 mg tablet formulation be delisted and considered that patients requiring a 100 mg immediate-release flecainide acetate tablet formulation can be managed using the alternative flecainide acetate preparations that will remain available.

### *Extra fine beclometasone dipropionate*

Beclometasone dipropionate is an inhaled corticosteroid used in the treatment of asthma. The extra fine preparation is designed to deliver smaller particles of beclometasone dipropionate compared to other inhaled beclometasone dipropionate preparations.

A funding application for Qvar extra fine was reviewed by the Respiratory Subcommittee of PTAC at its meeting in May 2013 and the minutes were reviewed by (PTAC) in August 2013. In summary, the Respiratory Subcommittee considered that extra fine beclometasone can be considered equivalent to other corticosteroids used with spacers and recommended that it be listed with a medium priority. The Respiratory Subcommittee members noted that clinical evidence confirms that adult and elderly patients required approximately half the dose of Qvar to achieve the same degree of asthma control as with a CFC beclometasone dipropionate inhaler. In long-term assessments, patients taking a CFC beclometasone dipropionate inhaler could be switched to Qvar at half the daily dose without exacerbation of their asthma symptoms

Minutes relating to these discussions can be found on the PHARMAC website at:

<http://www.pharmac.govt.nz/patients/ApplicationTracker?ProposalId=793>