CONSULTATION

PHARMAC
Pharmaceutical Management Agency

4 November 2013

Proposal relating to eltrombopag, zanamivir and various respiratory products

PHARMAC is seeking feedback on a proposal relating to a provisional agreement with GlaxoSmithKline for a number of products. In summary, from 1 January 2014 the proposal would result in:

- The listing of eltrombopag (Revolade) in the community and hospital for the treatment of idiopathic thrombocytopenic purpura (ITP), under Special Authority criteria and hospital restrictions;
- The listing of zanamivir (Relenza Rotadisk) in the hospital for treatment and prophylaxis of influenza in hospitalised patients, subject to hospital restrictions;
- The removal of the Special Authority and hospital restrictions from fluticasone with salmeterol combination inhalers (Seretide and Seretide Accuhaler).

The proposal would also result in changes to the commercial arrangement for fluticasone (Flixotide and Flixotide Accuhaler), salmeterol (Serevent and Serevent Accuhaler) and fluticasone with salmeterol (Seretide and Seretide Accuhaler) although the listings of these products in the Pharmaceutical Schedule would not be affected and they would remain fully funded in the community.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 15 November 2013** to:

Christine Chapman
Therapeutic Group Manager
PHARMAC

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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

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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

Eltrombopag

- Eltrombopag (Revolade) would be listed in Section B and Part II of Section H (the Hospital Medicines List) of the Pharmaceutical Schedule from 1 January 2014 at the following prices and subsidies (expressed ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Eltrombopag	Tab 25 mg	Revolade	28	$1771.00
Eltrombopag	Tab 50 mg	Revolade	28	$3,542.00

- Eltrombopag would be funded subject to the following Special Authority criteria in Section B of the Pharmaceutical Schedule:

  Initial application - (idiopathic thrombocytopenic purpura – post-splenectomy) only from a haematologist. Approvals valid for 6 weeks for applications meeting the following criteria:
  All of the following:
  1. Patient has had a splenectomy; and
  2. Patient has failed 2 immunosuppressive therapies after therapy of 3 months each (or 1 month for rituximab); and
  3. Either:
     3.1. Patient has a platelet count of ≤20,000 platelets per μL and has evidence of active bleeding; or
     3.2. Patient has a platelet count of ≤10,000 platelets per μL.

  Initial application - (idiopathic thrombocytopenic purpura – preparation for splenectomy) only from a haematologist. Approvals valid for 6 weeks where the patient requires eltrombopag treatment as preparation for splenectomy.

  Renewal– (idiopathic thrombocytopenic purpura – post-splenectomy) from a haematologist. Approvals valid for 12 months where the patient has obtained a response (see Note) from treatment during the initial approval or subsequent renewal periods and further treatment is required.

  Note: Response to treatment is defined as a platelet count of >30,000 platelets per μL.

- Eltrombopag would be listed subject to the following restrictions in Part II of Section H of the Pharmaceutical Schedule:

  Restricted
  Haematologist
  Initiation (idiopathic thrombocytopenic purpura – post-splenectomy)
  Re-assessment required after 6 weeks.
  All of the following:
  1. Patient has had a splenectomy; and
  2. Patient has failed 2 immunosuppressive therapies after therapy of 3 months each (or 1 month for rituximab); and
  3. Either:

3.1. Patient has a platelet count of ≤20,000 platelets per μL and has evidence of active bleeding; or
3.2. Patient has a platelet count of ≤10,000 platelets per μL.

Initiation - (idiopathic thrombocytopenic purpura – preparation for splenectomy)
Approvals valid for 6 weeks for patients requiring eltrombopag treatment as preparation for splenectomy.

Continuation – (idiopathic thrombocytopenic purpura – post-splenectomy)
Re-assessment required after 12 months where the patient has obtained a response (see note) from treatment during the initial approval or subsequent renewal periods and further treatment is required.
Note: Response to treatment is defined as a platelet count of >30,000 platelets per μL.

- A confidential rebate would apply to Revolade.

Zanamivir

- Zanamivir (Relenza Rotadisk) would be listed in Part II of Section H of the Pharmaceutical Schedule from 1 January 2014 at the following price (expressed ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Price
Zanamivir	Powder for inhalation 5 mg	Relenza Rotadisk	20 doses	$37.38

- Zanamivir would be listed subject to the following restrictions in Part II of Section H of the Pharmaceutical Schedule:

Restricted
Either:
1. Only for hospitalised patient with known or suspected influenza; or
2. For prophylaxis of influenza in hospitalised patients as part of a DHB hospital approved infections control plan.

Asthma Products

- The prices and subsidies of fluticasone (Flixotide, Flixotide Accuhaler), salmeterol (Serevent, Serevent Accuhaler) and fluticasone with salmeterol (Seretide, Seretide Accuhaler) would be unchanged, and these products would be protected from delisting and subsidy reduction until 1 January 2019.

- Confidential rebates would apply to Flixotide, Flixotide Accuhaler, Serevent, Serevent Accuhaler, Seretide and Seretide Accuhaler.

- The Special Authority and hospital restriction that applies to the Inhaled Corticosteroids with Long-acting Beta-Adrenoceptor Agonists would be removed from Seretide and Seretide Accuhaler from 1 January 2014.

Background

Eltrombopag

Eltrombopag is used to treat idiopathic thrombocytopenic purpura (ITP), a chronic condition that results in an increased risk of bleeding due to an abnormally low number of platelets (cells that help blood clot) in the blood. The aim of treatment with eltrombopag is to increase the number of platelets in the blood in order to reduce the risk of bleeding in patients with ITP.

Eltrombopag has been reviewed by PTAC and the Haematology Subcommittee of PTAC. PTAC recommended that it be funded with medium priority subject to Special Authority criteria for patients who have failed other treatments including a splenectomy. PTAC also considered that it would be appropriate to limit eltrombopag to patients with the most severe disease which are: (1) patients who have a platelet count of ≤20,000 platelets per µL and who have evidence of active bleeding or (2) patients who have a platelet count of ≤10,000 platelets per µL. Details of PHARMAC's assessment of eltrombopag to date, along with minutes from PTAC and Haematology Subcommittee meetings, can be found in PHARMAC's Application Tracker at:
http://www.pharmac.govt.nz/patients/ApplicationTracker?ProposalId=548.

Zanamivir

Zanamivir is a neuramidase inhibitor indicated for the treatment of both influenza A and B in adults and children (> 5 years of age) who present with symptoms typical of influenza when influenza is circulating in the community. PTAC reviewed neuramidase inhibitors in May 2013 for use in DHB hospitals only as part of the Hospital Medicine list and recommended they be listed for the following indications:

> *Inpatient use only where patient has confirmed or suspected influenza; or*
> *For inpatient treatment as part of infection control strategy according to a DHB approved infection control plan*

The full minute can be found at the following link:
http://www.pharmac.health.nz/ckeditor_assets/attachments/443/ptac-minutes-2013-05.pdf .

For the avoidance of doubt, zanamivir would only be able to be supplied to patients while they are an inpatient of a DHB hospital, i.e. not dispensed to a patient at discharge.

Asthma Products

Removal of the Special Authority and hospital restriction from the listing of Seretide and Seretide Accuhaler as outlined in this proposal would improve patient access to these products and is considered commercially acceptable in the context of this proposal.