CONSULTATION

PHARMAC
Pharmaceutical Management Agency

21 July 2015

Proposal to list icatibant solution for injection

PHARMAC is seeking feedback on a proposal to list icatibant resulting from a provisional agreement formed between Shire Australia Pty Limited and PHARMAC.

The provisional agreement is the first that PHARMAC has reached with a bidder from a Request for Proposals we ran in 2014, related to the supply of medicines for rare disorders.

In summary, this proposal would result in icatibant solution for injection 30 mg in 3 ml being funded in the community under Special Authority criteria and in DHB hospitals subject to restrictions. Listing in the Pharmaceutical Schedule would occur subject to Medsafe approval of the pharmaceutical.

Detail of the proposal and some background information is set out on the following pages.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Tuesday 4 August 2015** to:

Christine Chapman
Senior Therapeutic Group Manager
PHARMAC
PO Box 10 254
Wellington 6143

Email: Christine.chapman@pharmac.govt.nz

Fax: 04 460 4995

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

Level 9, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

Details of the proposal

Following Medsafe approval, icatibant (Firazyr) would be listed in Section B (the Community) and Part II of Section H (the Hospital Medicines List) of the Pharmaceutical Schedule as follows:

Chemical	Presentation	Brand	Strength	Pack size	Price and subsidy
Icatibant	inj prefilled syringe	Firazyr	10 mg per ml, 3 ml	1	$2,668.00

- Confidential rebates would apply to Firazyr which would reduce the net price of the treatment.

- It would be listed as soon as practicable following Shire's notification of PHARMAC that Medsafe has granted registration.

- Firazyr would be listed subject to the following Special Authority criteria in the community and restrictions in the Hospital Medicines List.

  Initial application from a clinical immunologist or relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:
  Both:
  1. Supply for anticipated emergency treatment of laryngeal/oro-pharyngeal or severe abdominal attacks of acute hereditary angioedema (HAE) for patients with confirmed diagnosis of C1-esterase inhibitor deficiency; and
  2. The patient has undergone product training and has agreed upon an action plan for self-administration.

  Renewal from any relevant practitioner. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.

- Firazyr would have subsidy and delisting protection until 1 July 2018.

- Prior to a listing on the Pharmaceutical Schedule (i.e. until Medsafe approval is granted) net pricing would apply to any individual patient funding applications approved via the Named Patient Pharmaceutical Assessment (NPPA) Policy.

Background

Icatibant is a selective bradykinin B_2 receptor antagonist used for the treatment of hereditary angioedema (HAE). HAE can present as attacks of swelling that can occur anywhere in the face, larynx (throat), gut or limbs. The swelling can be painful and if the larynx is affected may lead to fatal airway obstruction. Attacks are usually periodic and symptoms can persist for up to five days.

Hereditary angioedema is a rare disease. PHARMAC estimates that there may be up to 90 patients with HAE in New Zealand of whom up to 25 patients may meet the proposed criteria for treatment with icatibant. The proposed criteria are similar to those that apply to funding for icatibant in Australia.

Currently patients with life threatening attacks would require infusions with fresh frozen plasma or plasma-derived replacement purified C1-esterase inhibitor at the nearest hospital. Funded treatments to prevent symptoms are danazol and tranexamic acid.

Icatibant may be used in the event of a severe attack and could avoid the need for hospital infusion treatment. It is a subcutaneous injection in a pre-filled syringe which can be stored at or below 25°C and which could be administered by the patient at home -– an advantage particularly for those people who may live a long way from a hospital.

Icatibant is registered in Australia and it was submitted to Medsafe on 15 June 2015 for approval in New Zealand, see the Medsafe website for more information: http://www.medsafe.govt.nz/regulatory/ProductDetail.asp?ID=17717.

PHARMAC has previously considered NPPA funding applications for icatibant for individual patients and several applications have been approved. This funding pathway would remain a possibility until such time that icatibant is listed on the Pharmaceutical Schedule.

The evaluation of icatibant followed the process described in Schedule 2 of the RFP for the supply of medicines for rare disorders. The RFP can be found on the PHARMAC website at: https://www.pharmac.health.nz/news/rfp-2014-08-15-rare-disorders/.