

23 November 2015

Proposal for glycopyrronium bromide, dexamethasone phosphate and neostigmine metilsulfate with glycopyrronium bromide

PHARMAC is seeking feedback on a provisional agreement with Max Health Limited. This arose from an Alternative Commercial Proposal in response to consultation on the 2015/16 invitation to tender.

The proposal is to amend the terms of listing of the following products supplied by Max Health Limited listed on the Pharmaceutical Schedule (community and/or hospital) from 1 February 2016:

- glycopyrronium bromide inj 200 mcg per ml, 1 ml ampoule listed in the hospital and community
- dexamethasone phosphate inj 4 mg per ml, 1 ml and 2 ml ampoules listed in the hospital and community
- neostigmine metilsulfate inj 2.5 mg with glycopyrronium bromide 0.5 mg per ml, 1 ml ampoule listed in the hospital only

In summary:

- the prices and subsidies (where applicable) for all three products would be reduced
- all listings would be subject to protection from delisting and subsidy/price reduction until 30 June 2019
- the hospital listings would all be subject to Hospital Supply Status until 30 June 2019

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Monday, 7 December 2015** to:

An-Ruo Bian	Email: an-ruo.bian@pharmac.govt.nz
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 withheld. PHARMAC will give due consideration to any such request

Details of the proposal

- The prices and subsidies for dexamethasone phosphate injection and glycopyrronium bromide injection listed in Section B and in Part II of Section H of the Pharmaceutical Schedule would be reduced from 1 February 2016 as follows (prices and subsidies expressed ex-manufacturer; ex GST):

Chemical	Presentation	Brand	Pack size	Current price and subsidy	Proposed price and subsidy
Dexamethasone phosphate	Inj 4 mg per ml, 1 ml ampoule	Max Health	10	\$25.80	\$14.19
Dexamethasone phosphate	Inj 4 mg per ml, 2 ml ampoule	Max Health	5	\$17.98	\$12.59
Glycopyrronium bromide	Inj 200 mcg per ml, 1 ml ampoule	Max Health	10	\$28.56	\$17.14

- The price of neostigmine metilsulfate with glycopyrronium bromide injection listed in Part II of Section H of the Pharmaceutical Schedule would be reduced from 1 February 2016 as follows (prices expressed ex-manufacturer; ex GST):

Chemical	Presentation	Brand	Pack size	Current price	Proposed price
Neostigmine metilsulfate with glycopyrronium bromide	Inj 2.5 mg with glycopyrronium bromide 0.5 mg per ml, 1 ml ampoule	Max Health	10	\$27.86	\$20.90

- From 1 February 2016, glycopyrronium bromide, dexamethasone phosphate and neostigmine metilsulfate with glycopyrronium bromide injections detailed in the above tables would be listed subject to protection from delisting and subsidy and/or price reduction until 30 June 2019 (all listings) and Hospital Supply Status until 30 June 2019 with a 1% DV limit (Section H listings only).
- From 1 February 2016 the brand name for dexamethasone phosphate injections listed on the Pharmaceutical Schedule would change from 'Dexamethasone-hameln' to 'Max Health' to align with Medsafe sponsor registration. There would be no product change.

Background

In response to PHARMAC's consultation on the 2015/16 Invitation to Tender product list, Max Health Limited submitted an alternative commercial proposal (ACP) involving glycopyrronium bromide, dexamethasone phosphate, and neostigmine metilsulfate with glycopyrronium bromide injections.

Dexamethasone phosphate injection is listed under the Corticosteroids and Related Agents for Systemic Use subheading of the Hormones Preparations – Systemic Excluding Contraceptive Hormones therapeutic group. Dexamethasone is a synthetic corticosteroid (glucocorticoid). It is indicated for anti-inflammatory actions and to prevent the development of immunological responses.

Glycopyrronium bromide injection is listed under the Antispasmodics and Other Agents Altering Gut Motility subheading of the Alimentary Tract and Metabolism therapeutic group. Glycopyrronium bromide is indicated for use as a preoperative antimuscarinic to reduce salivary, tracheobronchial and pharyngeal secretions; to reduce the volume and free acidity of gastric secretions and to block cardiac vagal inhibitory reflexes during induction of anaesthesia and intubation when indicated.

Neostigmine metilsulfate with glycopyrronium bromide is listed under the Anticholinesterases subheading of the Musculoskeletal System therapeutic group. Neostigmine metilsulfate with glycopyrronium bromide is indicated for the reversal of residual non-depolarising (competitive) neuromuscular block.