CONSULTATION

PHARMAC
Pharmaceutical Management Agency

11 April 2014

Proposal to list Diazoxide 50 mg per ml, 30 ml Oral Liquid

PHARMAC is seeking feedback on a provisional agreement with Link Pharmaceuticals to fund diazoxide oral liquid 50 mg per ml, 30 ml (Proglycem Liquid) from 1 July 2014 subject to the Special Authority and hospital access restrictions.

Diazoxide oral liquid is an unapproved pharmaceutical (i.e. it does not have Medsafe consent/registration) therefore supply, sale and prescribing of the product would be subject to the requirements of section 25 or section 29 of the Medicines Act 1981, as applicable.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Wednesday, 30 April 2014** to:

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Wellington 6143

Email: greg.williams@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

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Details of the proposal

- Diazoxide oral liquid 50 mg per ml, 30 ml (Proglycem) would be listed in Section B, and in the Hospital Medicines List (HML, Part II of Section H), of the Pharmaceutical Schedule from 1 July 2014 at a price and subsidy of $620.00 per 30 ml bottle (ex-manufacturer, excluding GST). For the avoidance of doubt, the wastage rule in the Schedule would apply.

- Diazoxide oral liquid 50 mg per ml, 30 ml (Proglycem) would be listed in Section B of the Pharmaceutical Schedule subject to the same Special Authority criteria as diazoxide capsules:

  Special Authority for Subsidy
  Initial application from any relevant practitioner. Approvals valid for 12 months where used for the treatment of confirmed hypoglycaemia caused by hyperinsulinism

  Renewal from any relevant practitioner. Approvals valid without further renewal unless notified where the treatment remains appropriate and the patient is benefiting from treatment

- Diazoxide oral liquid 50 mg per ml, 30 ml (Proglycem) would be listed in the HML subject to the following restrictions:

  Restricted
  For patients with confirmed hypoglycaemia caused by hyperinsulinism

Background

Diazoxide capsules (25 mg and 100 mg), which are unapproved medicines (i.e. do not have Medsafe consent/registration), and the extemporaneous formula were listed in the Pharmaceutical Schedule in April 2013 as a result of a consultation dated 14 January 2013.

A formula for an extemporaneously compounded diazoxide oral liquid 10mg/ml is available on the emixt website[1]; however there is no New Zealand standardised batch sheet. The expiry date for the extemporaneously compounded product is seven days and it must be refrigerated.

In response to consultation on the proposal to fund diazoxide capsules, several responders requested funding of a proprietary oral liquid, particularly for paediatric patients. One responder considered that an extemporaneously compounded product made from the capsules would not be appropriate, mainly due to its short stability period and the refrigeration requirement.

Since the listing of diazoxide capsules in April 2013, there have been approximately 6 patients in community receiving prescriptions for the capsules, 1 of which receives the compounded product. The compounded product is also used in hospitals for a neonate population.

PHARMAC therefore estimates that there would be approximately 1-2 bottles of diazoxide oral liquid dispensed in the community per month and 1 bottle per month dispensed in the hospital setting.

[1] http://www.pharminfotech.co.nz/manual/Formulation/mixtures/diazoxide.html

PHARMAC is acutely aware of the issues regarding funding unregistered medicines, however it considers that the listing of this unregistered proprietary liquid should not cause any difficulties in addition to those experienced already with the unregistered extemporaneously compounded liquid. PHARMAC considers the benefits to patients, specifically a longer expiry date, would be significant in assisting with ease of access for patients. PHARMAC would appreciate feedback on these views.

PHARMAC prefers to fund registered pharmaceuticals wherever possible; however despite our best endeavours, we have been unable to source a registered version of a proprietary diazoxide oral liquid or diazoxide capsules, and we consider it unlikely that we would be able to do so in the foreseeable future. Should a registered version of the pharmaceutical become available in New Zealand, we would work to ensure that the registered version was listed in the Pharmaceutical Schedule.

Finally, we would like to highlight that PHARMAC's funding of an unapproved medicines is not an endorsement of the medicine's quality, safety or efficacy, nor does it impact upon a medical practitioner's obligations to comply with relevant legislation and regulations (including the Health and Disability Commissioner's Code of Consumer Rights). As with any pharmaceutical funded by PHARMAC, if this proposal is approved medical practitioners would not be obliged to prescribe these pharmaceuticals; however, funding would be provided if a prescriber chose to do so (providing any funding access criteria were met).