CONSULTATION

PHARMAC
Pharmaceutical Management Agency

8 August 2013

Proposal to list riluzole for the treatment of amyotrophic lateral sclerosis (motor neurone disease)

PHARMAC is seeking feedback on a provisional agreement with Sanofi-Aventis to fund riluzole (Rilutek) for the treatment of amyotrophic lateral sclerosis (ALS, also known as motor neurone disease) from 1 October 2013 subject to the Special Authority and hospital access restrictions outlined on the following page.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **5 pm on Thursday 22 August 2013** to:

Geraldine MacGibbon	Email: geraldine.macgibbon@pharmac.govt.nz
Senior 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

- Riluzole 50 mg tablets (Rilutek) would be listed in Section B, and in the Hospital Medicines List (HML, Part II of Section H), of the Pharmaceutical Schedule from 1 October 2013 at a price and subsidy of $400.00 per pack of 56 tablets (ex-manufacturer, excluding GST). A confidential rebate would apply to Rilutek, reducing its net price.

- Riluzole would be listed subject to the following Special Authority restrictions in Section B of the Pharmaceutical Schedule. Similar restrictions would apply in the HML.

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Special Authority for Subsidy
Initial application only from a neurologist or respiratory specialist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following
1 The patient has amyotrophic lateral sclerosis with disease duration of 5 years or less; and
2 The patient has at least 60 percent of predicted forced vital capacity within 2 months prior to the initial application; and
3 Either:
  3.1 All of the following:
    3.1.1 The patient is ambulatory; and
    3.1.2 The patient has not undergone a tracheostomy; and
    3.1.3 The patient has not experienced respiratory failure; or
  3.2 All of the following
    3.2.1 The patient is not ambulatory; and
    3.2.2 The patient has not undergone a tracheostomy; and
    3.2.3 The patient has not experienced respiratory failure; and
    3.2.4 The patient is either able to use upper limbs or is able to swallow.

Renewal only from a neurologist or respiratory specialist. Approvals valid for 18 months for applications meeting the following criteria:
Either:
1 All of the following:
  1.1 The patient is ambulatory, and
  1.2 The patient has not undergone a tracheostomy, and
  1.3 The patient has not experienced respiratory failure; or
2 All of the following:
  2.1 The patient is not ambulatory, and
  2.2 The patient has not undergone a tracheostomy, and
  2.3 The patient has not experienced respiratory failure, and
  2.4 The patient is either able to use upper limbs or is able to swallow.

- Rilutek would have protection from subsidy reduction and delisting until 1 July 2015.

Background

This proposal arose from a funding application from Sanofi-Aventis for riluzole for the treatment of ALS. The proposed restrictions are consistent with the recommendations from PHARMAC's main clinical advisory committee, the Pharmacology and Therapeutics Advisory Committee (PTAC), and the Neurological Subcommittee of PTAC. More information, including links to the relevant advisory committee reviews of riluzole, can be found on the Application Tracker on PHARMAC's website at:

www.pharmac.govt.nz/ApplicationTracker?ProposalId=292