CONSULTATION

PHARMAC
Pharmaceutical Management Agency

1 May 2014

Proposals to fund melatonin and to add the stat dispensing rule to buspirone

PHARMAC is seeking feedback on a proposal to fund melatonin 2 mg modified-release tablets (Circadin) from 1 July 2014 for secondary insomnia in children and adolescents with neurodevelopmental disorders, through a provisional agreement with Aspen. In summary:

- melatonin 2 mg modified-release tablets (Circadin) would be funded in the community from 1 July 2014 subject to Special Authority restrictions for the treatment of secondary insomnia in children and adolescents up to the age of 18 years with neurodevelopmental disorders (an off-label indication);
- the Circadin brand of melatonin 2 mg modified-release tablets would be listed on the Hospital Medicines List (HML) from 1 July 2014;
- the HML restrictions for melatonin would be widened to include the treatment of secondary insomnia in children and adolescents up to the age of 18 years with neurodevelopmental disorders; and
- all the unregistered presentations of melatonin currently listed on the HML (tab 1 mg, 2 mg and 3 mg and cap 2 mg and 3 mg) would be delisted from the HML on 1 October 2014.

PHARMAC is also seeking feedback on a proposal to apply the stat exemption (section F: Part I of the Pharmaceutical Schedule) to buspirone, which would mean that prescriptions would only be subsidised if they are dispensed all at once (up to three months' treatment).

Details of the proposals and background information can be found on the following pages.

Feedback sought

PHARMAC welcomes feedback on these proposals. To provide feedback, please submit it in writing by **5 pm on Thursday, 15 May 2014** to:

Geraldine MacGibbon
Therapeutic Group Manager
PHARMAC

Email: geraldine.macgibbon@pharmac.govt.nz
Fax: 04 460 4995
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.

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

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 proposals

Melatonin

- Melatonin 2 mg modified-release tablets (Circadin) would be listed in Section B and in Part II of Section H (the HML) of the Pharmaceutical Schedule from 1 July 2014 at a price and subsidy of $26.80 per pack of 30 (ex-manufacturer, excluding GST).

- Melatonin 2 mg modified-release tablets would be subject to the following Special Authority restrictions in Section B of the Pharmaceutical Schedule from 1 July 2014:

  Special Authority for Subsidy
  Initial application only from a psychiatrist or paediatrician or medical practitioner on the recommendation of a psychiatrist or paediatrician. Approvals valid for 12 months for applications meeting the following criteria:
  All of the following:
  1 Patient has been diagnosed with persistent and distressing insomnia secondary to a neurodevelopmental disorder (such as autism spectrum disorder or attention deficit hyperactivity disorder [ADHD])*; and
  2 Behavioural and environmental approaches have been tried or are inappropriate; and
  3 Patient is aged ≤18 years*.

  Note: Indications marked with * are Unapproved Indications.

  Renewal application only from a psychiatrist or paediatrician or medical practitioner on the recommendation of a psychiatrist or paediatrician. Approvals valid for 12 months for applications meeting the following criteria:
  Both:
  1 Patient is aged ≤18 years*; and
  2 Patient is continuing to benefit from treatment.

  Note: Indications marked with * are Unapproved Indications.

- From 1 July 2014 the restrictions applying to melatonin in the HML would be amended to add the secondary insomnia indication as follows:

  Restricted
  Initiation – insomnia secondary to neurodevelopmental disorder
  Psychiatrist or paediatrician
  Re-assessment required after 12 months
  All of the following:
  1 Patient has been diagnosed with persistent and distressing insomnia secondary to a neurodevelopmental disorder (such as autism spectrum disorder or attention deficit hyperactivity disorder [ADHD])*; and
  2 Behavioural and environmental approaches have been tried or are inappropriate; and
  3 Patient is aged ≤18 years*.

  Note: Indications marked with * are Unapproved Indications.

Continuation – insomnia secondary to neurodevelopmental disorder
Psychiatrist or paediatrician
Re-assessment required after 12 months
Both:
1 Patient is aged ≤18 years*; and
2 Patient is continuing to benefit from treatment.

Initiation – insomnia where benzodiazepines and zopiclone are contraindicated
Both:
1 Patient has insomnia and benzodiazepines and zopiclone are contraindicated; and
2 For in-hospital use only.

Note: Indications marked with * are Unapproved Indications

- All unregistered presentations of melatonin, i.e. tab 1 mg, 2 mg and 3 mg and cap 2 mg and 3 mg, would be delisted from the HML from 1 October 2014.

Buspirone

From 1 July 2014, buspirone hydrochloride tab 5 mg and 10 mg (Pacific Buspirone) would be subject to the Stat exemption (section F: Part I of the Pharmaceutical Schedule), which would mean that prescriptions for up to three months' treatment would only be subsidised if they are dispensed all at once.

Background

Melatonin

Melatonin is a naturally occurring hormone produced by the pineal gland. It is associated with the control of circadian rhythms and entrainment to the light-dark cycle. It is also associated with a hypnotic effect and increased propensity for sleep.

The Circadin brand of melatonin 2 mg modified-release tablets is registered in New Zealand for use as monotherapy for the short term treatment of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over. Circadin is the only registered brand of melatonin in New Zealand.

In November 2012 PHARMAC's Pharmacology and Therapeutics Advisory Committee (PTAC) reviewed an application from the supplier to fund melatonin 2 mg modified-release tablets for primary insomnia in patients aged ≥55 years, as well as clinician-initiated applications for melatonin in two off-label indications: insomnia secondary to dementia and insomnia secondary to neurodevelopmental or psychiatric disorders in children and adolescents.

PTAC recommended that the applications for primary insomnia in patients aged ≥55 years and for insomnia secondary to dementia be declined. The Committee recommended that melatonin be funded for insomnia secondary to neurodevelopmental disorders in children and adolescents with a low priority. Details of the applications for the different indications and PTAC's reviews can be found on PHARMAC's website at:
http://www.pharmac.govt.nz/patients/ApplicationTracker?SearchTerm_melatonin

More recently, PTAC reviewed feedback from the Paediatric Society and the Royal Australian and New Zealand College of Psychiatrists (RANZCP) in relation to funding of melatonin for insomnia secondary to neurodevelopmental disorders in children and

adolescents. The criteria proposed for melatonin in this consultation are essentially as recommend by PTAC in February 2014. The minutes of the February 2014 PTAC meeting are not published yet, but the Application Tracker for melatonin will be updated as soon as the minutes are available.

We note that the majority of the evidence for the use of melatonin in patients with neurodevelopmental disorders is in the paediatric/adolescent population, and that there is a limited range of suitable funded alternatives for this age group compared with the adult population.

The proposal also includes delisting the unregistered presentations of melatonin that are currently listed on the HML, given that this proposal would result in a registered presentation of melatonin being listed.

Buspirone

In June 2012 the Mental Health Subcommittee of PTAC advised that there is no clinical or safety reason to retain the monthly dispensing rule for buspirone and recommended that it be subject to a stat dispensing rule for funding purposes with high priority. This proposal is in line with the Subcommittee's recommendation. The relevant minutes can be found on PHARMAC's website at:
www.pharmac.health.nz/assets/ptac-mental-health-subcommittee-minutes-2012-06-08.pdf