CONSULTATION

PHARMAC
Pharmaceutical Management Agency

29 November 2013

Proposals to amend access to sugammadex and atomoxetine and to fund baclofen injection in the community

PHARMAC is seeking feedback on the following proposals, all with a proposed implementation date of 1 February 2014:

- Funding for sugammadex (Bridion) in hospitals would be widened to include severe neuromuscular degenerative disease where the use of neuromuscular blockade is required.

- Funding for atomoxetine (Strattera) in the community and in hospitals would be widened to include its first-line use for Attention Deficit and Hyperactivity Disorder (ADHD) in patients with existing or previous psychoses and/or who have a first-degree relative with schizophrenia.

- Baclofen injection (Lioresal Intrathecal) would be funded in the community, subject to a prescription endorsement, for use in a programmable pump in patients with severe chronic spasticity of cerebral origin or due to multiple sclerosis, spinal cord injury or spinal cord disease, where oral antispastic agents have failed or have caused unacceptable side effects.

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

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday 13 December 2013** to:

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Therapeutic Group Manager	Fax: 04 460 4995
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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 and background information for the proposals

Sugammadex

- Sugammadex is a pharmaceutical used in anaesthetic procedures to reverse neuromuscular blockade induced by rocuronium or vecuronium.

- The proposal is to amend the restrictions applying to sugammadex (Bridion) inj 100 mg per ml, 2 ml and 5 ml vials, in the Hospital Medicines List (HML; Part II of Section H of the Pharmaceutical Schedule) from 1 February 2014 as follows (additions in bold):

  Any of the following:
  1 Patient requires reversal of profound neuromuscular blockade following a rapid sequence induction that has been undertaken using rocuronium (i.e. suxamethonium is contraindicated or undesirable); or
  2 Severe neuromuscular degenerative disease where the use of neuromuscular blockade is required; or
  3 Patient has an unexpectedly difficult airway that cannot be intubated and requires a rapid reversal of anaesthesia and neuromuscular blockade; or
  4 The duration of the patient's surgery is unexpectedly short; or
  5 Neostigmine or a neostigmine/anticholinergic combination is contraindicated (for example the patient has ischaemic heart disease, morbid obesity or COPD); or
  6 Patient has a partial residual block after conventional reversal.

- The Analgesic Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) recommended adding the proposed indication to the restrictions. The Subcommittee noted that the alternative treatment, suxamethonium, was considered contraindicated or undesirable in patients with neuromuscular disease because of excessive potassium release which has the potential to cause fatal cardiac events.

- The Subcommittee estimated that up to 50 additional patients per year would be able to access funded sugammadex if the proposed amendment is made.

Atomoxetine

- Atomoxetine is a non-stimulant treatment for ADHD.

- The proposal is to amend the initial Special Authority criteria for atomoxetine (Strattera) cap 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg in Section B of the Pharmaceutical Schedule from 1 February 2014 as outline below (additions in bold). The HML restrictions would be similarly amended from 1 February 2014.

  SAXXXX Special Authority for Subsidy
  Initial application from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
  All of the following:
  1 Patient has ADHD (Attention Deficit and Hyperactivity Disorder) diagnosed according to DSM-IV or ICD 10 criteria; and
  2 Once-daily dosing; and
  3 Any of the following:
  3.1 Treatment with a subsidised formulation of a stimulant has resulted in the development or worsening of serious adverse reactions or where the combination of subsidised stimulant treatment with another agent would pose an unacceptable medical risk; or

3.2 Treatment with a subsidised formulation of a stimulant has resulted in worsening of co-morbid substance abuse or there is a significant risk of diversion with subsidised stimulant therapy; or

3.3 An effective dose of a subsidised formulation of a stimulant has been trialled and has been discontinued because of inadequate clinical response; **or**

3.4 The patient has existing or previous psychoses and/or has a first-degree relative with schizophrenia, and treatment with a subsidised stimulant is considered inappropriate; and

4 The patient will not be receiving treatment with atomoxetine in combination with a subsidised formulation of a stimulant, except for the purposes of transitioning from subsidised stimulant therapy to atomoxetine.

- The Mental Health Subcommittee of PTAC recommended that funded access to atomoxetine be widened as proposed, with a high priority. The Subcommittee considered that the available evidence, principally consensus expert opinion, indicates that stimulants are a known psychotomimetic for individuals with schizophrenia, such that stimulants should not be used in patients with an Axis I disorder of schizophrenia, psychosis not otherwise specified or manic episode with psychosis. The Subcommittee considered that it would be reasonable to assume that patients with ADHD who have a strong family history of psychosis may also be at increased risk of psychosis associated with stimulant use.

- The Subcommittee considered that the number of additional atomoxetine patients if funded access was widened as recommended would be approximately 100 patients per year.

Baclofen injection

- Baclofen is an antispastic agent. Baclofen intrathecal injection is indicated in patients with severe chronic spasticity of spinal origin (associated with injury, multiple sclerosis, or other spinal cord diseases) or of cerebral origin who are unresponsive to orally administered antispastics (including oral baclofen) and/or who experience unacceptable side effects at effective oral doses.

- Baclofen inj 0.05 mg per ml, 1 ml ampoule and inj 2 mg per ml, 5 ml ampoule (Lioresal Intrathecal) are currently listed on the HML without restriction. The proposal is to list these presentations in Section B of the Pharmaceutical Schedule from 1 February 2014, fully funded at a price and subsidy of 11.55 and 209.29 per injection, respectively, subject to the following prescription endorsement for subsidy:

  > Baclofen injection is subsidised for use in a programmable pump in patients with severe chronic spasticity of spinal or cerebral origin, where oral antispastic agents have been ineffective or have caused intolerable side effects, and the prescription is endorsed accordingly.

- Although the HML rules currently allow DHB hospitals to dispense baclofen injection into the community, we have received recent advice from the Rheumatology Subcommittee of PTAC that lack of community funding was proving a barrier to the appropriate clinical use of intrathecal baclofen. The Subcommittee recommended that PHARMAC list baclofen intrathecal injection in Section B of the Pharmaceutical Schedule, restricted to use in a programmable pump.

- We consider that this proposal would be unlikely to significantly increase the number of patients taking baclofen injection, but it would help improve access to treatment for those patients requiring baclofen injection for use in a programmable pump.