CONSULTATION

PHARMAC
Pharmaceutical Management Agency

18 April 2013

Proposal involving hospital use of sugammadex (Bridion)

PHARMAC is seeking feedback on a proposal to list sugammadex (Bridion) in Part II of Section H of the Pharmaceutical Schedule through a provisional agreement with Merck Sharp & Dohme as follows:

- Sugammadex (Bridion) would be listed in Part II of Section H of the Pharmaceutical Schedule from 1 June 2013 as follows:

Chemical	Presentation	Brand	Pack size	Price (ex-man, ex GST)
Sugammadex	Inj 100 mg per ml, 2 ml vial	Bridion	10	$1,200.00
Sugammadex	Inj 100 mg per ml, 5 ml vial	Bridion	10	$3,000.00

- From 1 July 2013 a rebate would apply to all sales of Bridion, reducing its net price to DHBs and the Funder.

- From 1 July 2013 sugammadex would be listed in Part II of Section H of the Pharmaceutical Schedule (the Hospital Medicines List) subject to the following restrictions:

  Any of:
  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. Patient has an unexpectedly difficult airway that can be ventilated but not intubated and requires a rapid reversal of anaesthesia and neuromuscular blockade; or
  3. The duration of the patient's surgery is unexpectedly short; or
  4. Neostigmine or a neostigmine/anticholinergic combination is contraindicated (for example the patient has ischaemic heart disease, morbid obesity or COPD); or
  5. Patient has a partial residual block after conventional reversal.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **5:00 pm Friday 3 May 2013** to:

Geraldine MacGibbon
Senior 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 Chief Executive acting under delegated authority) prior to making a decision on this proposal.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do. If you would like us to withhold any commercially sensitive, confidential

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

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.

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

Background

We previously consulted (via a letter dated 30 January 2013) on a proposal to list sugammadex from 1 July 2013, restricted to use only for patients with an unexpectedly difficult airway that can be ventilated but not intubated and in whom the anaesthetist plans a rapid reversal of anaesthesia and neuromuscular blockade. The consultation letter can be found on PHARMAC's website at www.pharmac.health.nz/news/item/proposal-to-list-sugammadex-bridion-for-reversal-of-neuromuscular-blockade.

We noted in the earlier consultation letter that PHARMAC would be willing to consider widening access subject to a commercially acceptable agreement being reached with the supplier and sufficient funding being available. After considering the feedback received on that proposal, we have now negotiated terms for a new provisional agreement with the supplier that include wider access and the payment of rebates for usage of sugammadex (Bridion).

That new provisional agreement forms the basis of this current consultation letter.

Analgesic Subcommittee advice

Sugammadex is a selective relaxant binding agent used in hospitals to reverse neuromuscular block induced by rocuronium or vecuronium. An application from the supplier for sugammadex to be listed on the Hospital Medicines List (HML) was reviewed by the Analgesic Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) at its April 2012 meeting. In summary, the Subcommittee recommended that sugammadex be listed with a high priority for five indications as follows:

- patients who require reversal of profound neuromuscular blockade following a rapid sequence induction that has been undertaken using rocuronium (i.e. suxamethonium contraindicated or undesirable);
- patients with an unexpectedly difficult airway that can be ventilated but not intubated and in whom the anaesthetist plans a rapid reversal of anaesthesia and neuromuscular blockade;
- unexpected short surgical duration;
- patients in whom neostigmine or the neostigmine/anticholinergic combination is contraindicated, such as those with ischaemic heart disease, morbid obesity or COPD; and
- patients with a partial residual block after conventional reversal.

Hospital Pharmaceuticals Subcommittee advice

The minutes of the Analgesic Subcommittee meeting were reviewed by the Hospital Pharmaceuticals Subcommittee of PTAC at its September 2012 meeting. The Subcommittee considered that the access restrictions that had been proposed by the Analgesic Subcommittee were very broad, given its current use in DHB hospitals, and that the criteria would position the agent as one for routine use, rather than as an emergency option. The Subcommittee considered that, while sugammadex should be included on the HML, the overall expenditure on sugammadex under the Analgesic Subcommittee's proposed access criteria would be large, and recommended that PTAC give consideration to refining these criteria further.

PTAC advice

The application for funding, along with the views of the Analgesic Subcommittee and of the Hospital Pharmaceuticals Subcommittee, was also reviewed by PTAC at its November 2012 meeting. The Committee considered that the clinical benefits from sugammadex are unclear, but that the benefit in terms of theatre time could be significant, depending on the extent to which sugammadex is used. The Committee agreed with the recommendation to list sugammadex on the HML, and gave a medium priority to this recommendation for all indications listed above. Members noted that there may be a potential to use sugammadex in other situations, such as patients with myasthenia gravis or muscular dystrophy.

Relevant minutes of the abovementioned PTAC and Subcommittees meetings are available on PHARMAC's website at:

www.pharmac.govt.nz/2012/11/19/Nervous%20System%20Group%20Web%20Minutes.pdf