NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

22 May 2013

Notification of decisions on hospital use of sugammadex, methoxyflurane, COX-2 inhibitors and gabapentin

PHARMAC is pleased to announce the approval of proposals relating to the hospital use of sugammadex, methoxyflurane, COX-2 inhibitors and gabapentin. These proposals were the subject of two consultation letters dated 18 April 2013, which can be found on PHARMAC's website at www.pharmac.health.nz/news#consultation.

Details of the decisions

Sugammadex

- Sugammadex (Bridion) will 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 will apply to all sales of Bridion, reducing its net price.

- From 1 July 2013 sugammadex will be listed in Part II of Section H of the Pharmaceutical Schedule subject to the following restrictions:

  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. Patient has an unexpectedly difficult airway that cannot be 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.

Methoxyflurane

- Methoxyflurane will be listed in Part II of Section H of the Pharmaceutical Schedule from 1 July 2013 as follows:

Chemical	Presentation
Methoxyflurane	Soln for inhalation 99.9%, 3 ml bottle

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

- Methoxyflurane will be listed subject to the following restrictions:

  Both:
  1 Patient is undergoing a painful procedure with an expected duration of less than one hour; and
  2 Only to be used under supervision by a medical practitioner or nurse who is trained in the use of methoxyflurane.

- PHARMAC staff intend to work with DHB hospitals to collect data on the use of methoxyflurane to assist with a future review of the funding restrictions, including obtaining additional clinical advice from PTAC.

COX-2 inhibitors

- Etoricoxib and celecoxib will be listed in Part II of Section H of the Pharmaceutical Schedule from 1 July 2013 as follows:

Chemical	Presentations
Etoricoxib	Tab 30 mg, 60 mg, 90 mg and 120 mg
Celecoxib	Cap 100 mg, 200 mg and 400 mg

- Etoricoxib and celecoxib will be listed subject to the following restrictions:

  For preoperative and/or postoperative use for a total of up to eight days' use.

- The restrictions applying to meloxicam in Part II of Section H of the Pharmaceutical Schedule from 1 July 2013 will be widened as follows (new indication shown in **bold**):

  Any of the following:
  1 Haemophilic arthropathy, with both of the following:
    1.1 The patient has moderate to severe haemophilia with less than or equal to 5% of normal circulating functional clotting factor; and
    1.2 Pain and inflammation associated with haemophilic arthropathy is inadequately controlled by alternative funded treatment options, or alternative funded treatment options are contraindicated; or
  2 **For preoperative and/or postoperative use for a total of up to eight days' use.**

Gabapentin

- The restrictions applying to gabapentin in Part II of Section H of the Pharmaceutical Schedule from 1 July 2013 would be widened to include the following indication:

  For preoperative and/or postoperative use for a total of up to eight days' use.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses were considered in their entirety in making a decision on the proposals. Most responses were supportive of the proposals, and the following issues were raised in relation to specific aspects of the proposals:

Theme	Comment
Sugammadex	
A number of responders requested that access be wider than initially proposed, to include patients who cannot be intubated ***and*** cannot be ventilated.	We note that we have previously received specialist advice to the effect that this situation (i.e the patient cannot be intubated or ventilated) comprises a medical emergency requiring an urgent infraglottic airway, and it is not treated by sugammadex. However, given the nature of the feedback in the consultation responses we have amended the wording of the relevant criterion (criterion 2) to remove the requirement that the patient is able to be ventilated, which will allow sugammadex to be used in this situation at the prescriber's discretion.
One responder requested that sugammadex be available for use in patients with severe neuromuscular degenerative disease where the use of neuromuscular blockade is required.	We intend to seek further advice from the Analgesic Subcommittee on the use of sugammadex in this indication.
Methoxyflurane	
Two responders raised concerns about the safety of methoxyflurane. The first suggested that methoxyflurance should be available only " under supervision by a medical practitioner or nurse who is trained *and endorsed as competent by the organisation* in the use of methoxyflurane". The other responder noted that methoxyflurane can trigger a malignant hyperthermia reaction and the risk of this would be increased with suxamethonium use. Therefore, a history of malignant hyperthermia should be elicited from the patient if there is a possibility of subsequent suxamethonium use.	We consider that there is no need to make the change proposed by the first responder because each hospital will have the ability to determine which of its staff are competent to deliver a particular medication. With regards to the second point, as with any pharmaceutical, we consider that it is the responsibility of the prescriber to ensure that the pharmaceutical is prescribed appropriately and safely, which in the case of methoxyflurane would include a thorough patient history and assessment of the possibility of subsequent suxamethonium use.
COX-2 inhibitors and gabapentin	
Responders noted that COX-2 inhibitors are indicated for up to eight days' perioperative use, and considered that gabapentin should be available for both preoperative and postoperative use.	The wording of the restrictions for both COX-2 inhibitors and gabapentin has been changed to allow their use both preoperatively and postoperatively for up to eight days.

More information

If you have any questions about these decisions, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.