

12 July 2010

Proposal to fund meloxicam and mitomycin

PHARMAC is seeking feedback on a proposal involving the funding of Arrow Pharmaceuticals' brands of mitomycin C 5 mg injection and meloxicam 7.5 mg tablets. In summary:

- mitomycin C would continue to be funded as a pharmaceutical cancer treatment (PCT): and
- meloxicam would be funded from 1 September 2010, subject to Special Authority criteria, for patients with severe haemophilia and pain and inflammation associated with haemophilic arthropathy where alternative funded treatment options have failed or are contraindicated.

Further details of the proposal can be found below and on the following 2 pages.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **4 pm Monday, 26 July 2010** to:

Jackie Evans	Email: jackie.evans@pharmac.govt.nz
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 Chief Executive acting under delegated authority) prior to making a decision on this proposal.

Details of the proposal

PHARMAC has reached a provisional agreement with Arrow Pharmaceuticals (NZ) Limited for the supply of mitomycin C and meloxicam. Details of the proposal are as follows:

Mitomycin C

- Mitomycin C would be listed in Part II of Section H of the Pharmaceutical Schedule from 1 September 2010 at the following price (ex-manufacturer, excluding GST):

Pharmaceutical	Brand	Form and Strength	Pack Size	Proposed price
Mitomycin C	Mitomycin	Inj 5 mg	1	\$72.75

- Mitomycin C would continue to be listed in Section B of the Pharmaceutical Schedule for the purposes of claiming by DHB hospitals when used for the treatment of cancer at a price and subsidy of \$72.75 per vial;
- Arrow would use its best endeavors to obtain Medsafe approval for mitomycin C;

- Mitomycin C would have protection from subsidy reduction and delisting until 1 July 2013.

Meloxicam

- Meloxicam would be listed in Section B of the Pharmaceutical Schedule from 1 September 2010 at the following price and subsidy (ex-manufacturer, excluding GST):

Pharmaceutical	Brand	Form and Strength	Pack Size	Proposed price and subsidy
Meloxicam	Arrow-Meloxicam	Tab 7.5	30	\$11.50

- The funding of meloxicam would be subject to the following Special Authority criteria:

Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

- 1 The patient has severe haemophilia with <1% of normal circulating functional clotting factor; and
- 2 The patient has haemophilic arthropathy; and
- 3 Pain and inflammation associated with haemophilic arthropathy is inadequately controlled by alternative funded treatment options, or alternative funded treatment options are contraindicated.

Background

Mitomycin C

Bristol Myers Squibb recently discontinued supply of its brand of mitomycin C. Arrow Pharmaceuticals' brand of mitomycin C has been listed in Section B of the Pharmaceutical Schedule since 1 June 2010.

Mitomycin C is used as a salvage agent during palliative care in the treatment of a number of cancers. In these settings there are other funded alternative treatments. However, Mitomycin C is also used in a number of other situations for which there are no alternative funded treatments. For example, it is used intravesically in the treatment of superficial bladder cancer and compounded to be used topically for ocular surface squamous neoplasia.

Arrow's brand of mitomycin C is not approved by Medsafe; therefore, it would need to be prescribed and used in accordance with Section 29 of the Medicines Act. This proposal would see long term security of supply for mitomycin C and the supplier would be required to use its best endeavours to get the product approved by Medsafe.

Meloxicam

Meloxicam is a selective COX-2 inhibitor non-steroidal anti-inflammatory drug (NSAID) indicated for the systemic treatment of painful osteoarthritis and the treatment of rheumatoid arthritis.

In August 2009 the Pharmacology and Therapeutics Advisory Committee (PTAC) recommended funding a COX-2 inhibitor with a high priority for the treatment of haemophilic arthropathy associated with severe haemophilia, because of the reduced bleeding risk compared with alternative anti-inflammatory treatments. PTAC considered that funding any of the available COX-2 inhibitors would be appropriate. The full minute of this discussion can be viewed on PHARMAC's website at www.pharmac.govt.nz/2009/10/15?q=COX-2.

We note that PHARMAC has previously declined to fund COX-2 inhibitors for other patient populations, in part because of their relatively unfavourable risk/benefit profile in comparison to other funded options. However, we consider that, based on the advice from PTAC, meloxicam would have an acceptable risk/benefit profile under the proposed criteria.