

2 August 2010

## Approval of proposal for meloxicam and mitomycin C

PHARMAC is pleased to announce the approval of a proposal involving the funding of meloxicam and mitomycin C through an agreement with Arrow Pharmaceuticals. This proposal was the subject of a consultation letter dated 12 July 2010. In summary:

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

Further details of the decision can be found below and on the following page.

### Details of the decision

#### *Meloxicam*

- Meloxicam 7.5 mg tablets will be listed in Section B of the Pharmaceutical Schedule from 1 September 2010 at a price and subsidy of \$11.50 per 30 tablets (ex-manufacturer, excluding GST); and
- The funding of meloxicam will 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 moderate to severe haemophilia with less than or equal to 5% 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.

#### *Mitomycin C*

- Mitomycin C 5 mg injection will be listed in Part II of Section H of the Pharmaceutical Schedule from 1 September 2010 at a price of \$72.50 per vial (ex-manufacturer, excluding GST);

- Mitomycin C will 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;
- Arrow Pharmaceuticals will use its best endeavors to obtain Medsafe approval for mitomycin C; and
- Mitomycin C will have protection from subsidy reduction and delisting until 1 July 2013.

### Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 26 July 2010 were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal. The following key issues were raised in relation to specific aspects of the proposal:

Theme	Comment
A responder asked if it would be possible to fund a 20 mg vial of mitomycin C	Currently only a 5 mg vial is available. However, if a 20 mg vial was available we would be pleased to consider it for funding.
Suppliers of other COX-2 inhibitors enquired as to whether additional products could be funded for the same indication as meloxicam.	We consider that the clinical need has been met by the decision for meloxicam. However, we would be willing to consider the funding of other COX-2 inhibitors (or alternative brands of meloxicam) for the same indication should a commercially acceptable agreement be reached.
Several responders considered that patients with moderate haemophilia and arthropathy should have access to meloxicam (ie, in addition to patients with severe haemophilia with <1% of normal circulating functional clotting factor as originally proposed) because there is a small group of patients with moderate haemophilia who have severe haemophilic arthropathy and could benefit from meloxicam.	This issue was considered and the relevant Special Authority criterion has been altered (versus the version consulted on) such that access to meloxicam will include patients with moderate to severe haemophilia with less than or equal to 5% of normal circulating functional clotting factor.

### More information

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