CONSULTATION

PHARMAC
Pharmaceutical Management Agency

11 October 2013

Proposal relating to the listing of montelukast (Singulair) in the Pharmaceutical Schedule.

PHARMAC is seeking feedback on a proposal relating to a provisional agreement with Merck Sharp and Dohme (New Zealand Ltd) (MSD) for the supply of Singulair.

In summary, this proposal would result in:

- A reduction in the net price paid for Singulair from 1 December 2013;
- Subsidy and delisting protection until 31 December 2016; and
- A change in the Special Authority criteria relating to use for pre-school wheeze and exercise induced asthma.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 25 October 2013** to:

Christine Chapman
Therapeutic Group Manager
PHARMAC
PO Box 10 254
Wellington 6143

Email: christine.chapman@pharmac.govt.nz

Fax: 04 460 4995

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.

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

Details of the proposal

- The list price and subsidy of Singulair supplied by MSD would remain the same as currently listed in both Part B and Part II of Section H of the Pharmaceutical Schedule:

Chemical	Presentation	Brand	Pack size	Price and subsidy (ex-man., ex. GST)
Montelukast	Tab	Singulair	28 x 4 mg	$18.48
Montelukast	Tab	Singulair	28 x 5 mg	$18.48
Montelukast	Tab	Singulair	28 x 10 mg	$18.48

- Proposed changes to the Special Authority criteria and restrictions that apply to montelukast are as follows (additions in bold, deletions in strike through):

Initial application (Pre-school wheeze) from any relevant practitioner. Approvals valid for one year for applications meeting the following criteria:

~~All of the following~~ **Both:**

1 To be used for the treatment of intermittent severe wheezing (possibly viral) ~~in children under 5 years~~; and

2 ~~The patient has trialled inhaled corticosteroids at a dose of up to 400µg per day beclomethasone or budesonide, or 200 µg per day fluticasone for at least one month; and~~

~~3~~ The patient ~~continues to have~~ **has had** at least three episodes in the previous 12 months of acute wheeze severe enough to seek medical attention. ~~severe exacerbations at least one of which required hospitalisation defined as in-patient stay or prolonged Emergency Department treatment) in the past 12 months.~~

Renewal (pre-school wheeze) - only from a relevant practitioner. Approvals valid for two years where the treatment remains appropriate and the patient is benefitting from treatment.

Initial application (exercise-induced asthma) from any relevant practitioner. Approvals valid without further renewal, unless notified, for applications meeting the following criteria:

Both:

1 Patient ~~is being treated~~ **has been trialed** with maximal asthma therapy, including inhaled corticosteroids and long-acting beta-adrenoceptor agonists; and

2 Patient continues to receive optimal inhaled corticosteroid therapy; and

3 Patient continues to experience frequent episodes of exercise-induced bronchoconstriction.

Initial application (aspirin desensitisation) only from a clinical immunologist or allergist. Approvals valid for one year, for applications meeting the following criteria:

All of the following:

1. Patient is undergoing aspirin desensitisation therapy under the supervision of a clinical immunologist or allergist; and
2. Patient has moderate to severe aspirin-exacerbated respiratory disease or Samter's triad; and
3. Nasal polyposis, confirmed radiologically or surgically; and
4. Documented aspirin or NSAID allergy confirmed by aspirin challenge or a clinical history of severe reaction to aspirin or NSAID where challenge would be considered dangerous

- Singulair would have protection from subsidy reduction and delisting until 31 December 2016;

- A rebate, reducing the net price of the product from 1 December 2013, would apply to Singulair.

Background

In response to PHARMAC's consultation on the 2013/2014 Invitation to Tender product list, MSD submitted an alternative commercial proposal (ACP) involving the supply of the Singulair tablets currently supplied by MSD. This ACP forms the basis of PHARMAC's provisional agreement with MSD and would result in all three strengths of Singulair remaining fully funded, subject to the provisional agreement's terms, until at least 31 December 2016.

Funding criteria for the treatment of pre-school wheeze would be amended by removing the requirement for patients to have trialed inhaled corticosteroids for at least one month prior to treatment with Singulair and the requirement for patients to have been hospitalised (or received prolonged Emergency Department treatment) would be removed.

PHARMAC has received feedback that the requirement for patients to have required hospitalisation (or prolonged Emergency Department treatment) was too restrictive, particularly in rural settings where a patient may have a severe exacerbation requiring medical attention which is provided by medical clinics due to the distance from the nearest hospital.

The requirement for patients being treated with montelukast under the exercise-induced criteria to remain on maximal asthma therapy, including inhaled corticosteroids and long-acting beta-adrenoceptor agonists, would be amended to require that patients have been trialed with these drugs in the initial instance with an additional criteria that patients remain on optimal inhaled corticosteroid therapy while receiving montelukast.

In May 2013 the Respiratory Subcommittee of PTAC considered that unstable patients should not be required to be treated with maximal asthma therapy, including inhaled corticosteroids and long acting beta-adrenoreceptor agonists, and recommended that the Special Authority criteria be amended accordingly. The changes proposed are in accordance with this recommendation.