Respiratory Subcommittee of PTAC meeting held 5 July 2010

(minutes for web publishing)

Respiratory Subcommittee minutes are published in accordance with the *Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees 2008*.

Note that this document is not necessarily a complete record of the Respiratory Subcommittee meeting; only the relevant portions of the minutes relating to Respiratory Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are published.

The Respiratory Subcommittee may:

(a) recommend that a pharmaceutical be listed by PHARMAC on the Pharmaceutical Schedule and the priority it gives to such a listing;
(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or
(c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

These Subcommittee minutes were reviewed by PTAC at its meeting on 4 & 5 November 2010, the record of which is available on the PHARMAC website.

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1 Montelukast

Aspirin-sensitive asthma

1.1 Further to its review of montelukast at its February 2010 meeting, the Subcommittee considered further information on the use of montelukast in treating aspirin-sensitive asthma and a proposed Special Authority for use in this therapeutic area.

1.2 The Subcommittee noted the paper by Barranco et al *(J Investig Allergol Clin Immunol.2009; Vol.19(6): 446-452)* which discussed the tests for the diagnosis of aspirin-sensitive asthma. The Subcommittee considered that an appropriate test to define aspirin-induced asthma that could easily be performed in all New Zealand centres may be difficult to identify.

1.3 The Subcommittee noted that a very small patient population would benefit from treatment with montelukast for aspirin-sensitive asthma. The Subcommittee noted that there are difficulties identifying this patient population and that the diagnosis would generally be made by Immunologists or allergy Physicians.

1.4 The Subcommittee considered that a Special Authority was necessary to list montelukast for the treatment of this patient population and that the Special Authority should include a bronchial test, demonstrating a decrease in FEV_1 upon challenge with salicylates. The Subcommittee noted that a suitable test was not available currently in New Zealand and that laboratories would have to set one up. The Subcommittee considered that more information was required with respect to the bronchial test and that a decision on the details of the Special Authority should be deferred until the information is available. John MacLachlan offered to investigate if such a test is available in New Zealand and PHARMAC will see if any pricing is available.

1.5 The Subcommittee **recommended** that montelukast be listed under a Special Authority for the treatment of aspirin-sensitive asthma with a low priority.

1.6 The Decision Criteria relevant to this recommendation are: *(i) The health needs of all eligible people within New Zealand; (ii) The particular health needs of Maori and Pacific peoples; (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services; (viii) The Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere.*

Exercise-induced asthma

1.7 Following a recommendation, from their February 2010 meeting, to fund montelukast for the treatment of exercise-induced asthma, subject to appropriate targeting criteria, the Subcommittee considered a proposed Special Authority for prescribing montelukast for the treatment of exercise-induced asthma.

1.8 The Subcommittee noted that there were very few patients with exercise-induced asthma who could not be well controlled with the medications that are currently funded, including nedocromil. However, the Subcommittee noted that there is a patient group who cannot be well controlled with the currently funded treatments. The Subcommittee noted that montelukast may be of benefit to this patient group.

1.9 The Subcommittee **recommended**, with a medium priority, that montelukast be listed in the Pharmaceutical Schedule for the treatment of exercise-induced asthma under the following Special Authority:

> **Initial application** (exercise-induced asthma) from any relevant practitioner. Approvals valid without further renewal, unless notified, for applications meeting the following criteria:
>
> All of the following:
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> 1 Patient is being treated with maximal asthma therapy, including inhaled corticosteroids and long-acting beta-adrenoceptor agonists; and
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> 2 Patient continues to experience frequent episodes of exercise-induced bronchoconstriction; and
>
> 3 An effective dose of nedocromil has been trialled and has been discontinued because of inadequate clinical response.

1.10 The Decision Criteria relevant to this recommendation are: *(i) The health needs of all eligible people within New Zealand; (ii) The particular health needs of Maori and Pacific peoples; (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services; (viii) The Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere.*

Preschool wheeze

1.11 The Subcommittee considered further information on montelukast and its use in treating preschool wheeze. Members noted that the information had been provided by PHARMAC, sourced from recommendations made by Dr Ian Shaw and by a literature search undertaken by PHARMAC staff.

1.12 The Subcommittee noted that there were up to five different phenotypes of wheezing in preschool children. Members noted that there is difficulty in diagnosis and identification

as to which patients may respond to inhaled corticosteroids, which may respond to montelukast and which will not respond to either treatment.

1.13 The Subcommittee noted that of the tens of thousands of children who get viral induced wheeze there are a number who become significantly unwell requiring repeated hospitalisations especially during the winter (June to October) season. The Subcommittee noted that there was an unmet need in these patients. Members noted that treatment options in this group are limited as neither salmeterol nor eformoterol are registered for use in under four year olds and clinicians will be unwilling to increase the inhaled corticosteroid dose higher due to the possibility a high dose may affect the growth rate of young children.

1.14 The Subcommittee noted that the papers by Bachier et al (*J Allergy Clin Immunol.2008 December; 126(6):1127-1135)*, Bisgaard et al (*Am J Respire Crit Care Med Vol 171 pp315-322,2005)* and Robertson et al (*Am J Respire Crit Care Med Vol 175 pp 323-329, 2007)* were all positive studies with respect to short term treatment with montelukast with the results from the Roberston study being used to help formulate the UK guidelines.

1.15 The Subcommittee considered that montelukast may have a role in the treatment of children one to four years of age who have failed on up to 100 to 200 µg fluticasone per day.

1.16 The Subcommittee **recommended** listing montelukast with a high priority for the treatment of viral-induced pre-school wheeze under the following Special authority:

> **Initial application only from a paediatrician.** Approvals valid for three months for applications meeting the following criteria:
>
> All of the following:
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> 1 To be used for the treatment of intermittent severe wheezing (possibly viral) in children under 4 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 at least three severe exacerbations at least one of which required hospitalisation.
>
> **Renewal only from a XXXX.** Approvals valid for two years where the treatment remains appropriate and the patient is benefitting from treatment.

1.17 The Subcommittee considered that multiple-trigger wheeze responds to treatment with corticosteroids and does not require treatment with Montelukast.

1.18 The Decision Criteria particularly relevant to this recommendation are: *(i) The health needs of all eligible people within New Zealand; (ii) The particular health needs of Maori and Pacific peoples; (iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (iv) The clinical benefits and risks of pharmaceuticals*; *(v) The cost-effectiveness of meeting health needs by funding*

pharmaceuticals rather than using other publicly funded health and disability support services; (viii) The Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere.