Neurological Subcommittee of PTAC meeting

held 2 April 2009

(minutes for web publishing)

Neurological 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 Neurological meeting; only the Minutes relating to Neurological discussions about an application that contain a recommendation in relation to an application are published.

The Neurological 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.

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1 Pramipexole

1.1 The Subcommittee noted that PHARMAC had received a request from a restless legs syndrome (RLS) support group to re-review the funding of pramipexole in the context of its niche role in RLS.

1.2 The Subcommittee noted that the prevalence of RLS is high, with approximately 10% of the general population affected.

1.3 The Subcommittee noted that there is a large range of funded pharmaceuticals that are effective in the treatment of RLS, including benzodiazepines, gabapentin and opioids; however, dopamine agonists such as ropinirole remained the treatment of choice for long-term or severe RLS. The Subcommittee considered that there was currently no significant unmet clinical need for an additional treatment for RLS, with the possible exception of patients who are unable to tolerate ropinirole and in whom ergot derivatives such as pergolide are not considered appropriate due to potential for serious side effects.

1.4 The Subcommittee noted that there were no head to head studies comparing pramipexole with ropinirole, but the results of a meta-analysis (Quilici et al. Sleep Med 2008;9:715-26) suggested that the two treatments provide similar efficacy in RLS, with pramipexole having a slight advantage over ropinirole. However, the Subcommittee noted that indirect comparison analyses such as this are associated with a number of limitations and, therefore, did not consider the advantages of pramipexole over ropinirole to be conclusive. The Subcommittee considered that there could be some benefits of pramipexole over ropinirole in terms of its side effect profile, with ropinirole associated with more nausea, vomiting, dizziness and somnolence than pramipexole. Again, the Subcommittee noted that these differences have not been substantiated by head-to-head comparisons and may be clinically insignificant. The Subcommittee noted that augmentation occurs with most dopamine agonist treatments for RLS, including in approximately 38% of patients taking pramipexole within two years.

1.5 The Subcommittee considered that if pramipexole was funded there would be no clinical reason to place any restriction on its use, and any such restriction would be for financial reasons.

1.6 The Subcommittee considered that the funding of pramipexole would be unlikely to be offset by reductions in non-pharmaceutical health-sector expenditure.

1.7 The Subcommittee **recommended** that pramipexole be listed in the Pharmaceutical Schedule only if it was cost-neutral versus ropinirole (assuming an open listing). The Decision Criteria particularly relevant to this recommendation are: *(i) The health needs of all eligible people within New*

Zealand; (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; and (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule.

1.8 The Subcommittee requested that PHARMAC staff conduct a literature search and cost-utility analysis pertaining to the use of pramipexole as a second-line treatment for Parkinson's disease and RLS and bring it back to the Subcommittee for review.