

PUBLIC SUMMARY DOCUMENT

Product: Methylphenidate Hydrochloride, extended release tablets, 18 mg, 36 mg and 54 mg, Concerta[®]

Sponsor: Janssen-Cilag Pty Ltd

Date of PBAC Consideration: November 2006

1. Purpose of Application

The submission sought a Section 85 listing of methylphenidate hydrochloride extended release tablets as an authority required benefit for the treatment of attention deficit hyperactivity disorder in children and adolescents.

2. Background

The Concerta formulation of methylphenidate hydrochloride extended release tablet (MPH-CR) was considered by the PBAC for the first time at its March 2006 meeting. The PBAC rejected the submission because of uncertain extent of clinical benefit over the comparator, methylphenidate immediate release (MPH-IR), and uncertain and unacceptable cost-effectiveness at the price proposed.

The PBAC considered a minor re-submission at its July 2006 meeting. The uncertain extent of clinical benefit shown in the pragmatic trial still remained, while the randomised controlled trials showed no difference between MPH-IR and MPH-CR tablets. The PBAC again rejected the submission because of uncertain clinical benefit and uncertain and unacceptable cost-effectiveness at the price proposed.

3. Registration Status

Methylphenidate hydrochloride extended release tablets were registered by the TGA on 1 September 2003 for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents aged 6-18 years.

4. Listing Requested and PBAC's View

Authority required

For the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents aged 6-18 years who have demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who required continuous coverage over 12 hours.

See Recommendation and Reasons for the PBAC's view.

5. Clinical Place for the Proposed Therapy

An extended release formulation of methylphenidate hydrochloride will allow for single daily morning dosing and assist compliance with therapy for ADHD.

6. Comparator

The March 2006 submission nominated methylphenidate hydrochloride immediate release tablet (MPH IR) as the main comparator. The PBAC accepted this as appropriate. This has been previously reported in the March 2006 Public Summary Document (PSD).

7. Clinical Trials

The submission presented no new clinical trials. The clinical trials have been previously reported in the March 2006 Public Summary Document (PSD).

This minor re-submission proposed arrangements that improved the incremental cost-effectiveness ratio and addressed the issue of PBS budget impact uncertainty when comparing MPH-CR with MPH-IR for the treatment of attention deficit hyperactivity disorder in children and adolescents.

8. Results of Trials

No new clinical trials were presented. The results of previous trials have been reported in the March 2006 Public Summary Document (PSD).

9. Clinical Claim

The re-submission reasserted the previous submission's claim that Concerta is significantly more effective than immediate release methylphenidate and had similar or less toxicity.

The PBAC considered the extent of any clinical benefit over immediate release methylphenidate remained uncertain, but agreed that the likely improvements in compliance and in ease of administration, particularly in relation to the removal of the need for a dose of medication at school, were sufficient to justify listing. *See Recommendations and Reasons.*

10. Economic Analysis

The submission stated that the proposed arrangements addressed some of the uncertainty associated with the overall incremental cost-effectiveness estimates for MPH-CR versus MPH-IR. The submission claimed that the proposed arrangements improved the incremental cost per quality adjusted life year (QALY) to <\$15,000 in the base case scenario.

11. Estimated PBS Usage and Financial Implications

The financial cost to the PBS was recalculated to take into account the revised lower unit price of MPH-CR and a higher level of market substitution.

The revised net cost to the PBS was estimated to be in the range \$10 – 30 million in year 4.

12. Recommendation and Reasons

The PBAC recommended listing as an authority required benefit on a cost effectiveness basis over immediate release methylphenidate at the new price proposed.

Although the extent of any clinical benefit over immediate release methylphenidate remains uncertain, the Committee agreed that the likely improvements in compliance and in ease of administration, particularly in relation to the removal of the need for a dose of medication at school, were sufficient to justify listing.

The PBAC recommended the 20 day safety net rule should not apply.

Recommendation

Restriction: Authority required

Treatment of attention deficit hyperactivity disorder (ADHD) in a child or adolescent aged between 6-18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 12 hours.

NOTE:

Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.

Maximum quantity: 30

Repeats: 5

13. Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

14. Sponsor's Comment

The sponsor welcomes this decision by the PBAC to provide access to a treatment option that offers children and adolescents with ADHD a single daily dosing medication, leading to improved compliance and associated improved health outcomes.