

PTAC meeting held 21 February 2003
(minutes for web publishing, prepared 10/2013)

PTAC minutes are published in accordance with the *PTAC Guidelines 2002*.

Note:

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

PTAC 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.

Some material has been withheld, in accordance with the Official Information Act 1982 (OIA) in order to:

- (i) protect information where the making available of the information would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information (section 9(2)(b)(ii))

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1. Etanercept (Enbrel) for Juvenile and Adult Rheumatoid Arthritis

PTAC considered the application from Wyeth for the listing of etanercept (Enbrel) on the Pharmaceutical Schedule.

The Committee noted that etanercept is now approved for the treatment of active polyarticular juvenile rheumatoid arthritis (JRA) in patients (4 to 17 years) who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).

PTAC considered that the application provided evidence that etanercept was effective in treating children with polyarticular JRA who had on-going active disease despite DMARD therapy (including methotrexate). It considered that there were about 20-40 children with polyarticular JRA in New Zealand and approximately 30-40% of them fail to respond to methotrexate. The Committee considered that there were fewer treatment options available for children. It considered that etanercept had the potential to provide greater benefits in children especially in relation to the prevention of growth retardation, deformities and fractures, and would therefore be likely to reduce the need for reconstructive surgery and would improve educational, social and employment opportunities.

The Committee noted that etanercept was extremely expensive and that the injection was only available in a 25 mg dose with no smaller vials for children (who are treated with lower dose of 0.4 mg/kg). It considered therefore that the treatment cost for children could be the same as for adults (unless more than one child was being treated at the same time or within 14 days after reconstitution). PTAC also noted that etanercept is indicated for the treatment of adults with active rheumatoid arthritis (RA), either as monotherapy or in combination with methotrexate, where classical antirheumatic therapy was insufficient or inappropriate and that this indication was considered at the August 2002 PTAC meeting.

The Committee considered that in the application for the adult indication, leflunomide should have been used as the comparator agent to etanercept and that the supplier should have addressed this in the application. It requested that PHARMAC do a Cost Utility Analysis (CUA) on etanercept with leflunomide as the comparator agent for adults.

PTAC noted that a report that had been requested to assist in developing appropriate targeting criteria and had been received from the New Zealand Rheumatology Association (NZRA). It requested that a letter be sent to thank the Association for its report but to also express concerns about the proposed targeting criteria. PTAC considered that the criteria proposed by the NZRA were too liberal and had the potential to expose the pharmaceutical budget to considerable expenditure. It noted that they were aware that the Australian Rheumatology Association had also produced some guidelines, which were thought to have tighter restrictions and asked if the NZRA could obtain a copy of the guidelines and forward a copy to PHARMAC along with their comments on the Australian guidelines.

The Committee noted that there was an error on page 20 of the NZRA report where the dose of methotrexate had been quoted as 20 mg/kg/week.

The Committee commented that using a high cost panel could have advantages for etanercept because it would provide a national registry to help monitor the safety and efficacy of this new

agent and would provide consistency on selecting the patients most likely to benefit from etanercept.

On the basis of efficacy, PTAC gave etanercept a high priority for JRA. Some concern was expressed about the lack of long-term safety data, in particular for use in children. It requested that etanercept be brought back to the Committee for further consideration once the Australian guidelines had been received and the CUA completed.

2. Topical Clindamycin phosphate USP 1%

PTAC considered the application to list topical clindamycin phosphate USP 1% (brand names Dalacin T, Clinac and Topicil) on the Pharmaceutical Schedule.

The Committee noted that in November 2002 Medsafe reclassified this product from 'OTC' to 'prescription only medicine' in an attempt to limit the increasing rates of clindamycin resistance and the development of cross-resistance to other antibiotics (e.g. erythromycin and other macrolides). It considered that the increasing rates of resistance and cross-resistance were due to inappropriate use of this product previously (i.e. in many cases too long duration of treatment and too large volumes used).

The Committee considered that while acne could be a severe and psychologically debilitating condition it was a minor medical problem in most patients. It noted that current dermatology guidelines for mild to moderate cases were moving away from prolonged use of oral antibiotics towards shorter treatments with agents such as benzoyl peroxide as a first-line choice, followed by the addition of topical clindamycin where response with benzoyl peroxide alone was unsatisfactory. The Committee considered that oral antibiotics and oral isotretinoin should be reserved for more severe and resistant cases.

PTAC noted that topical clindamycin was only approved for use in mild to moderate acne. It considered that at this stage there was no evidence that wider availability of topical clindamycin would reduce the cost of funding oral isotretinoin (given that the latter was used in more severe cases); or that it would reduce the number of referrals to dermatologists.

PTAC was uncertain whether the full funding of topical clindamycin was appropriate at this stage given that: (1) the first line treatments, i.e. benzoyl peroxide or the combined benzoyl peroxide/clindamycin product were not funded at present; and (2) the full funding of topical clindamycin would most likely increase its use which might potentially be counter-productive by increasing rates of resistance and cross-resistance.

PTAC noted that since the change to prescription medicine status had occurred only recently, it would like to see more data on how the market would react before making any further recommendation. In addition, PTAC requested that the supplier should provide more data on the use of topical clindamycin in combination with benzoyl peroxide, and whether a single combination product would become available in future. The Committee recommended that the Consumer Advisory Committee (CAC) be invited to make a comment regarding the funding of treatments for mild to moderate acne.

Clinical and Other Issues

3. Growth Hormone Therapy for Prader-Willi Syndrome

PTAC considered a report from the New Zealand Growth Hormone Committee (NZGHC) regarding the issues concerning making treatment with growth hormone (GH) available for children with Prader-Willi Syndrome (PWS).

The Committee noted that children with PWS have well defined features, which include short stature, morbid obesity, hypogonadism and cognitive deficit. The Committee noted that the estimated incidence of PWS in New Zealand is between 1 in 10,000 and 1 in 25,000 births per year.(TT). The Committee noted that short stature is present in approximately 90% of patients, however severe growth failure is not commonly present until puberty.

The Committee noted that the studies provided show children with PWS have varying degrees of growth hormone deficiency, with impaired GH release to standard and novel secretagogues and lower levels of IGF1 compared with short normal children.

The Committee noted the Wollman paper, which stated mean height for males with PWS > 18 years to be 161.6 ± 8.1 cm (SDS -2.4) and in females with PWS > 16 years 150.2 ± 5.5 cm (SDS -2.5). The Committee noted that currently in New Zealand access to GH therapy for short stature requires a height SDS < -3.0, and GH deficiency is defined by a reduced or absent GH peak.

The Committee noted that treatment of PWS with GH is practiced overseas, and has shown a short-term gain in height velocity. The Committee noted that studies have shown improvements in motor performance up to 2 years, with some reductions in fat mass and increases in muscle mass.

The Committee considered that GH therapy should remain restricted to children with GH deficiency and/or severely reduced growth velocity, including children with PWS where applicable under the current GH criteria. The Committee noted that widening of access only for children with PWS would be inequitable. The Committee recommended that the application be declined at this stage.

4. Wasp/Bee venom Albay Allergy Treatment Kits

The Committee considered information supplied to it from Ebos Group Ltd regarding Albay Allergy Treatment kits and noted that the company had requested a subsidy increase from PHARMAC. The Committee noted that the information supplied was not particularly relevant to allergy treatment, but was focused more towards allergic rhinitis and asthma.

The Committee noted that 0.5% to 8% of the population would have a clinical need for allergy treatment kits. The Committee noted that patients using these kits had severe allergies and could die if not treated. The Committee noted that beekeepers were the most prevalent patient group.

The Committee noted that the allergy treatment kits provided full protection for patients after three to five years of maintenance treatment. The Committee considered that bee venom and wasp venom allergy treatment kits should continue to be listed fully funded on the Pharmaceutical Schedule.

5. Pegylated Interferon: cost effectiveness

The Committee considered the cost-utility analysis for pegylated interferon alfa-2a for genotype 1 chronic hepatitis C.

The Committee considered that the level of detail in the analysis was significant, although noted the use of price estimates from Australia, the US and Auckland as possible weaknesses; the committee noted that the supplier had incorporated Australian ribavirin prices, which reduced the incremental cost of pegylated interferon.

The committee noted that the two major factors in the outcome of the analysis were the rates of sustained virological response (SVR) and the price of pegylated interferon, the latter being the limiting factor. In November 2002 PTAC recommended that Pegasys and Copegus be listed on the Pharmaceutical Schedule in the Immune Modulators therapeutic subgroup. At that time the Committee declined to give the recommendation to list a priority rating until it had reviewed a cost-utility analysis. [withheld under OIA section 9(2)(b)(ii)], the Committee recommended that pegylated interferon be given a low priority for listing in the Pharmaceutical Schedule.