May 2003 Meeting of the Pharmacology and Therapeutics Advisory Committee

Please note that these minutes are published in accordance with the following definitions from the PTAC Guidelines 2002:

""Minute" means that part of the record of a PTAC or Sub-committee meeting (including meetings by teleconference and recommendations made by other means of communication) that contains a recommendation to accept or decline an application for a new investment or a clinical proposal to widen access and related discussion."

"Once the record of a PTAC meeting is finalised, a Minute will be made publicly available by PHARMAC by publishing it on PHARMAC's website, provided that PHARMAC reserves the right to withhold any element(s) of a Minute that it considers appropriate on grounds of commercial confidentiality. In doing so PHARMAC will be guided by the principles and withholding grounds of the Official Information Act 1982." (PTAC Guidelines 2002)

Valsartan & valsartan with hydrochlorothiazide (Diovan/Co-Diovan)

The Committee noted the submission supplied by the manufacturer (Novartis). The Committee noted that valsartan, an angiotensin II receptor antagonist, has indications for both hypertension and congestive heart failure.

The Committee noted that the submission proposed listing according to criteria similar to those currently in place for losartan and candesartan.

The Committee considered there to be no additional benefit of the combination treatment of valsartan with hydrochlorothiazide over currently listed alternatives and noted the increased mortality in combination with beta blockers and ACE inhibitors in the Val HeFT trial.

The Committee considered that no additional health benefit would be gained by the listing of this combination treatment. It noted that there was no unmet health need as losartan and candesartan are already listed for the above indications on the Pharmaceutical Schedule.

The Committee noted that this product was more expensive than the currently available alternatives including ACE inhibitors and angiotensin II receptor antagonists.

The Committee recommended that this submission be treated as a "me-too" application (i.e. similar to other agents already listed on the Schedule). It did not recommend listing on the Pharmaceutical Schedule unless an appropriate commercial arrangement could be reached with the manufacturer.

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Record of the 18 November 2002 meeting of the Osteoporosis Sub-committee

The Committee reviewed the record of the 18 November 2002 Osteoporosis Sub-committee meeting as follows:

Raloxifene

The Committee agreed with the recommendations of the Osteoporosis Sub-committee in respect of raloxifene (Evista).

> "**Raloxifene (Evista)**
>
> The osteoporosis subcommittee considered an application from Eli Lilly for the listing of raloxifene (Evista) 60mg tablets for the treatment and prevention of osteoporosis in postmenopausal women, including those at risk of developing breast cancer, cardiovascular disease or uterine hyperplasia.
>
> The subcommittee noted that raloxifene had previously been considered by PTAC at its November 2000 meeting and noted PTAC's minute relating to raloxifene at this meeting asking for more information from the supplier.
>
> The subcommittee noted that raloxifene had a similar efficacy to etidronate for increasing bone density. However, the subcommittee noted that raloxifene had the same risk for deep vein thrombosis as oral contraceptives.
>
> The subcommittee considered that there was a limited need for an alternative osteoporosis treatment with HRT leaving, and that raloxifene may be useful to meet this need. However, the subcommittee considered that raloxifene should not be used instead of other, more effective agents such as alendronate.
>
> The subcommittee recommended that raloxifene be listed on the Pharmaceutical Schedule in the Hormones therapeutic group under the alendronate special authority criteria for patients who are intolerant of, or have clear contraindications to, oral bisphosphonates. The subcommittee considered this should be a high priority only for those patients intolerant of other oral bisphosphonates (when appropriately administered according to best practice) or when use of other bisphosphonates is contraindicated. The subcommittee recommended specialists only to prescribe raloxifene."

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Alendronate

The Committee agreed with the recommendations of the Osteoporosis Sub-committee to amend parts (a) and (b) of the existing Special Authority criteria as follows:

Special Authority - Retail pharmacy

a) Treatment of severe osteoporosis for patients meeting the following criteria:

   1) History of one previous significant osteoporotic fracture demonstrated radiologically, and **documented bone mineral density (BMD) ³ 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score £2.5); or**
   2) **History of two or more previous significant osteoporotic fractures demonstrated radiologically; or**
   3) documented bone mineral density (BMD) ~~>=~~ ³ 3.0 standard deviations below the mean normal value in young adults (i.e. T-Score <= -3.0).

b) Application **for Special Authority** to be made by e~~ndocrinologist, rheumatologist, geriatrician, general physician or gynaecologist.~~ **general practitioners or an appropriate specialist.**

c) Approvals are valid indefinitely.

d) Special Authority numbers for alendronate 10 mg and 70 mg can be interchangeable.

Note: In line with the Australian guidelines for funding alendronate, a vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

The Committee noted that the Osteoporosis Sub-committee had also considered widening access to alendronate for those patients with either established osteoporosis, or very high risk of established osteoporosis, who are using corticosteroids. It was noted that the 18 November meeting of the Sub-committee had considered etidronate to be an acceptable alternative for these patients.

PTAC also noted that PHARMAC was taking a proposal to widen access to etidronate to the PHARMAC Board in May 2003.

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Record of the 18 November 2002 Osteoporosis/HRT review meeting

The Committee reviewed the record of the 18 November 2002 Osteoporosis/ HRT Review meeting as follows:

It agreed with the recommendations of the Sub-committee in respect of widening access to etidronate. The Committee noted that PHARMAC was in the process of implementing this recommendation.