November 2002 Meeting of the Pharmacology and Therapeutics Advisory Committee

Metronidazole Gel

The Committee first considered an application from St Ives Medical to list the Orion brand of metronidazole gel 0.5%, 10g on the Pharmaceutical Schedule at its 22 August 2002 meeting. PTAC had requested that the supplier provide further clinical evidence to support the use of a 0.5% metronidazole topical product and also requested that the supply of a larger pack size be investigated.

The Committee noted that the supplier was unable to provide any clinical trials to support the use of a 0.5% metronidazole gel.

The Committee commented on the supplier's response to the request to provide a larger pack size. It noted that the 10g tube (the only size available) was an expensive option for use in fungating tumours, which could be large. The Committee also noted that microbial contamination of a larger pack size may not be an issue given the proposed use to treat the odour arising from fungating tumours.

The Committee discussed the issue of extemporaneously compounding a metronidazole cream or gel from metronidazole tablets. It noted that PHARMAC has a policy of funding a proprietary product wherever possible rather than funding an extemporaneously compounded one. However the Committee considered that, due to the small pack size and the high cost of the proprietary product, in this case an extemporaneously compounded product would be suitable.

The Committee recommended that a Standard Formula for an extemporaneously compounded metronidazole 1% product be listed in Section C of the Pharmaceutical Schedule. It recommended that the listing of the extemporaneously compounded product be given a moderate priority.

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Terbinafine hydrochloride (Lamisil) tablets – amendment to SA criteria

The Committee considered an application from Novartis for the widening of access to terbinafine (Lamisil) 250mg tablets to remove the specialist restriction.

The Committee noted that the evidence provided by the supplier showed the effectiveness of terbinafine. The committee noted that terbinafine appeared to have a better side effect profile than ketoconazole, and did not require liver function monitoring as ketoconazole does. The Committee noted that there was a clinical need for an oral antifungal now that griseofulvin was no longer available.

The Committee recommended that the specialist restriction be removed from terbinafine 250mg tablets. The Committee agreed that the use of Terbinafine for the treatment of fungal infections should only occur after confirmation of the infection by appropriate skin or nail scrapings. This process could be indicated by the prescriber annotating the prescription with "Certified Condition". The Committee gave this recommendation a high priority. The Committee considered the relevant decision criteria in this case to be: *(i) the health needs of all eligible people within New Zealand; (ii) the particular health needs of Maori and Pacific peoples; (iv) the clinical benefits and risks of pharmaceutical; and vi) the budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget).*