Transplant Immunosuppressant Subcommittee of PTAC meeting held

16 March 2010

(minutes for web publishing)

Transplant Immunosuppressant 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 Transplant Immunosuppressant Subcommittee meeting; only the relevant portions of the minutes relating to Transplant Immunosuppressant Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are published.

The Transplant Immunosuppressant 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.

These Subcommittee minutes were reviewed by PTAC at its meeting on 5 & 6 August 2010, the record of which is available on the PHARMAC website.

Contents

1 Tender for Sole Supply of Transplant Pharmaceuticals

1.1 The Subcommittee noted several pharmaceuticals in the transplant therapeutic subgroup are either off patent or coming off patent in the near future and that some generic brands were available. The Subcommittee noted the registration process for generic medications in New Zealand.

1.2 The Subcommittee noted that azathioprine and tacrolimus were included in the 2009/10 Invitation to Tender (ITT). However, members noted that neither cyclosporin or mycophenolate mofetil were included in the 2009/10 ITT because PHARMAC had entered into Alternative Commercial Proposals for these pharmaceuticals, such that both the Cellcept brand of mycophenolate and the Neoral brand of cyclosporin have protection from subsidy reduction and delisting until June 2012. The Subcommittee noted that these arrangements did not prevent PHARMAC from listing generic brands of cyclosporin or mycophenolate in the Pharmaceutical Schedule.

1.3 The Subcommittee considered that there was no clinical reason not to list generic transplant medications. The Subcommittee reiterated its view there was no clinical reason not to award a sole supply tender for transplant medications, including those in the 2009/10 (ITT). The Subcommittee considered that there was no clinical issue with patients switching between different brands of transplant medications with the exception of cyclosporin. The Subcommittee reiterated its view that that any generic cyclosporin should be based on a microemulsion formulation, but also noted that different brands of microemulsion cyclosporin may have clinically significant pharmacokinetic variability which meant that switching between brands would have to be carefully managed, through increased therapeutic drug monitoring, which was not desirable.

1.4 The Subcommittee reviewed tender bids received for tacrolimus (0.5 mg capsule, 1 mg capsule, 5 mg capsule). The Subcommittee noted that no bids had been received for the 5 mg injection formulation of tacrolimus, however, members considered that this formulation was rarely used and therefore funding was not important. The Subcommittee also reviewed relevant letters received in October 2009 in response to consultation on the draft 2009/10 ITT.

1.5 The Subcommittee considered that there was no clinical reason not to award a sole supply tender for tacrolimus or azathioprine. However, because of pharmacokinetic variability, members considered that a brand switch for tacrolimus may require that patients undertake a clinic visit for therapeutic drug monitoring and potential dose adjustment. The Subcommittee **recommended** that PTAC review bioequivalence data for relevant generic brand(s) of tacrolimus before a sole supply tender is awarded. The Subcommittee also considered that, if available, information regarding international market experience and/or literature for relevant generic brand(s) of tacrolimus should also be reviewed by PTAC.