



05OCE/1362

Health System Management
Executive

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Ms I Arnaud
Director
Adjudication Branch
Australian Competition & Consumer Commission
PO Box 1199
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Dear Ms Arnaud

I respond on behalf of the Chief Executive, Department of Health to your letter of 5 December 2005, regarding an application from Medicines Australia Inc for revocation and substitution of authorisations A90779-80.

I do not wish to make any specific comments in relation to questions raised in your correspondence however, there are some issues I believe should be addressed.

The Medicines Australia Code of Conduct includes a section on Product Familiarisation Programs (PFPs) which has been considered in light of views expressed by the South Australian Therapeutics Advisory Group (SATAG) on the operation of PFPs in public hospitals.

The SATAG expressed concerns relating to the implications of PFPs and the broader use of sample packs in public hospitals where there has not been consideration by the hospitals' Drugs and Therapeutics Committees. The SATAG is currently considering a state-wide policy relating to PFPs.

The information provided in the Medicines Australia Code parallels some of the matters covered by the proposed SATAG policy, however the following issues should also be considered:

- All PFPs must be considered and approved by the hospital Drug and Therapeutics Committee and stored, managed and dispensed through the hospital pharmacy.
- Ongoing patient management must not be compromised by access to or cessation of a PFP.
- Acceptance of the PFP does not commit the hospital to ongoing supply.



Continuity of supply was recognised as a major issue by the SATAG. While the Medicines Australia Code indicates that the length of time each patient may receive treatment would be determined by clinical rationale, this may not be sufficiently explicit to prevent patients from receiving benefits from the new medicine and then being faced with a situation where they cannot continue treatment due to ongoing cost.

I understand that this issue has been considered by Therapeutics Advisory Groups in other jurisdictions. Given the potential impact on the public hospital system, it is recommended that further consultation with jurisdictional Therapeutics Advisory Groups and the Society of Hospital Pharmacists of Australia be undertaken before the Medicines Australia Code is finalised.

If you wish to discuss this matter further please contact Bill Dollman in Pharmaceutical Services on (08) 8274 3432.

Yours sincerely

A handwritten signature in black ink, appearing to read 'T. Stubbs', is positioned above the printed name.

TOM STUBBS
EXECUTIVE DIRECTOR

24 / 1 / 2006