

THERAPEUTICS POLICY AND PLANNING COMMITTEE – Agenda Item 3.6

DATE: **TUESDAY 14 JUNE 2005**

SPONSOR: **MR PIO CESARIN**

SUBJECT: **PROPOSED AMENDMENT OF THE THERAPEUTIC GOODS (EXCLUDED GOODS) ORDER**

RECOMMENDATION: **THAT THE COMMITTEE ENDORSE THE PROPOSED *THERAPEUTIC GOODS (EXCLUDED GOODS) ORDER NO 1 2005***

BACKGROUND:

- At its 14 December 2004 meeting, the Therapeutic Policy and Planning Committee (TPPC) endorsed the gazettal of sodium monofluorophosphate (SMFP) as a substance that could be used in pastes, powders or gels for the cleaning of teeth (dentrifrices) when:
 - in combination with at least one other Listable active ingredient (eg. a herbal ingredient); and
 - the concentration of fluoride is not more than 1000 mg/kg; and
 - claims in relation to fluoride content are restricted to those relating to improvements in oral hygiene or the use of fluoride for the prevention of tooth decay.

ISSUES TO CONSIDER:

- Currently, all pastes, powders or gels for the cleaning of teeth (dentrifrices) containing 1000 mg/kg or less of fluoride ion are unscheduled in the Standard for the Uniform Scheduling of Drugs and Poisons. They are also “excluded goods” under Therapeutic Goods (Excluded Goods) Order No 1 2004, as long as they do not make claims other than those relating to improvements in oral hygiene or the use of fluoride for the prevention of tooth decay.
- During consultation with the TGA Legal Unit on the proposed gazettal notice, concerns were raised that the approval of SMFP as a Listable substance may inadvertently capture products that are currently excluded or which are required to be included in the Australian Register of Therapeutic Goods (ARTG) as Registered over-the-counter (OTC) medicines.
- To ensure that this does not occur, it is proposed that the Excluded Goods Order be amended, with the intention of ensuring that:
 - a) dentrifrices that are currently excluded remain so; and
 - b) Registered OTC dentrifrices (containing fluoride with or without another Registrable active) and Listable dentrifrices (containing not more than 1000 mg/kg SMFP in combination with another Listable active ingredient) are required to be included on the ARTG.

- Specifically, it is proposed that the reference to the goods referred to in Item 2 in the Table in Section 3 of the Excluded Goods Order be amended as follows:

a substance a vapour
"Oral hygiene preparations or devices (including dentifrices, mouth washes, breath fresheners, brushes and flosses) that are not other than those:

(a) included in a Schedule to the Poisons Standard; or
(b) required to be included in the part of the Australian Register of Therapeutic Goods for listed goods."

- The OTC Medicines Section and the TGA Legal Unit have been consulted on, and accept, the proposed amendment.

Attachments:

1. Draft Therapeutic Goods (Excluded Goods) Order No 1 2005

CONTACT:

Dr John Hall
Office of Complementary Medicines