



MINUTE TO THE MINISTER/PARLIAMENTARY SECRETARY

MR PYNE

AMENDMENT OF THERAPEUTIC GOODS (EXCLUDED GOODS) ORDER AND APPROVAL OF SODIUM MONOFLUOROPHOSPHATE AS A NEW LISTABLE SUBSTANCE

PURPOSE:

To advise you of the amendment of the Therapeutic Goods (Excluded Goods) Order and approval of sodium monofluorophosphate (SMFP) for use as an active ingredient in listable therapeutic goods, with particular restrictions.

ISSUE

2. The National Manager of the Therapeutic Goods Administration (TGA) has signed a Listing Notice which approved sodium monofluorophosphate (SMFP) has been approved for use in listable therapeutic goods, provided that:

- the preparation includes at least one other therapeutically active Listable ingredient;
- the concentration of the fluoride ion is not more than 1000 mg/kg;
- the substance is for use only in pastes, powders or gels for the cleaning of teeth; 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.

3. Currently, products for the cleaning of teeth (dentrifrices) containing 1000 mg/kg or less of fluoride ion are classified as "excluded goods" under Therapeutic Goods (Excluded Goods) Order No 1 2004, provided the goods do not make claims other than those relating to improvements in oral hygiene or the use of fluoride for the prevention of tooth decay.

4. The Excluded Goods Order has been amended to ensure that dentrifices that are currently excluded remain so, and Registrable over-the-counter dentrifices (containing fluoride with or without another Registrable active ingredient) and Listable dentrifices (containing not more than 1000 mg/kg SMFP in combination with another Listable active ingredient) are required to be included on the ARTG.

BACKGROUND

4. The Office of Complementary Medicines (OCM) received an application to include SMFP up to 1000 parts per million (ppm) for use as an active ingredient in Listed toothpaste products, in combination with herbal ingredients for which therapeutic claims are to be made.

5. SMFP is a source of fluoride which is widely used in unscheduled and excluded toothpaste products at up to 1000 mg/kg without evidence of safety concerns.

6. A safety review by the OCM did not reveal any safety concerns with this source of fluoride that would preclude its use in Listed medicines provided that:

- the concentration of the fluoride ion is not more than 1000 mg/kg;
- the substance is for use only in pastes, powders or gels for the cleaning of teeth; 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.

7. Currently, all pastes, powders or gels for the cleaning of teeth 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 the goods do not make claims other than those relating to improvements in oral hygiene or the use of fluoride for the prevention of tooth decay.

8. The Excluded Goods Order has been amended, to make it clear that:

- dentrifrices that are currently excluded remain so; and
- Registrable over-the-counter dentrifrices (containing fluoride with or without another Registrable active ingredient) 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.

COMMUNITY AWARENESS

9. There are no community awareness opportunities relating to this item.

RECOMMENDATION

R1. That you NOTE the gazettal of Therapeutic Goods (Excluded Goods) Order No 1 2005.

R2. That you NOTE that sodium monofluorophosphate has been listed as a substance approved for use as an active ingredient in listable therapeutic goods, with particular restrictions.



Dr David Graham
National Manager
Therapeutic Goods Administration
Outcome: 1: Population Health and Safety
28 October 2005

Contact Officer: Pio Cesarin
(02) 6232 8660
Office of Complementary Medicines

CHRISTOPHER PYNE
Noted

MINISTER'S COMMENTS:

Advice Rating	1	2	3	4	5	Comments
Timeliness						
Presentation						
Quality of advice						

Poor Satisfactory Excellent

ATTACHMENTS: N/A