(ex 18530

INSTRUMENT CHECKLIST
(LEGAL INSTRUMENT/ORDER)

Therapeutic Goods (Listing) Notice 2013 (No. ~~3~~) No.6 JB
Sodium fluoride

DATE: 2 August 2013
ACTION OFFICER: Gerry Dendrinos 6232 8838

1. Prepare draft Instrument, Minute to National Manager, MTM, and Explanatory Statement.

2. Prepare RIS if needed.
   ☐ Needed ☑ Not needed

3. Sign off by Section Head, verification of Format and content.
   Clooley Clooy — 2 Aug 2013
   for Jennifer Burnett, Director, PREMAS — Date

4. Final check by OCM Medical Officer.
   [signature] — 07/08/2013.
   Dr Tony Hobbs — Date

5. Sent to Legal area: RECEIVED 08 AUG 2013 TGA - Legal Unit (2)

6. Sign off by Legal area.
   ☐ Technically correct
   ☐ Format correct
   Legal advice provided in relation to the proposed instrument and accompanying explanatory statement.
   [signature] — 13/8/13
   Date

7. Date returned to OCM: 13/8/13 cur

8. Submit to OCM Head for sign off on package
   Trisha Garrett — 14/8/13 — Date
   [signature] LISA STUDDERT 15/8/13

6. Package to National Manager for signature.
7. Package to Legal Area for gazettal and/or tabling.

NOTES:
Please note amendment to numbering of original listing notice - all documents have been amended accordingly.

Australian Government
Department of Health
Therapeutic Goods Administration

Minute

TRIM Reference: R13/492522

Professor John Skerritt
National Manager
TGA

APPROVAL OF A CHANGE TO AN ACTIVE INGREDIENT'S AVAILABILITY FOR USE IN LISTED MEDICINES

Purpose

To seek your agreement to change the availability of 'sodium fluoride' as an active ingredient in listed medicines.

Background

'Sodium fluoride' is currently an ingredient permitted for use in certain listed medicines, as set out in the Therapeutic Goods (Listing) Notice 2008 (No. 1). The conditions on its use include a concentration limit of not more than 1,000 mg fluoride ion/kg.

The supply of goods containing fluoride is controlled under Schedules 2, 3 and 4 of the *Standard for the Uniform Scheduling of Medicines and Poisons* (the Poisons Standard). Amongst other requirements, to be eligible for listing, medicines must not be subject to a schedule in the Poisons Standard. In 2008, therapeutic goods containing not more than 1,000 mg fluoride ion /kg were not subject to scheduling, hence this limit was incorporated into the Therapeutic Goods (Listing) Notice 2008 (No. 1).

However, in June 2012, amendments to the Poisons Standard came into effect and topical preparations containing not more than 1,500 mg fluoride ion /kg for both therapeutic and non-therapeutic use became exempt from scheduling requirements, subject to label warning requirements for amounts greater than 1,000 mg/kg.

To date, Therapeutic Goods (Listing) Notice 2008 (No. 1) has not been updated in line with the aforementioned change to the relevant schedule of the Poisons Standard.

On 25 February 2013, Catherine Oh, Regulatory & Technical Manager of ACCORD Australasia, wrote to the TGA in relation to discrepancies between the Poisons Standard and Therapeutic Goods (Listing) Notice 2008 (No. 1), noting that this issue had also been discussed at a recent TGA/ ACCORD bilateral meeting. ACCORD sought changes to the availability of sodium fluoride in listed medicines in line with current scheduling requirements.

In response to this request, a review of the availability of 'sodium fluoride' as an active ingredient in listed medicines was undertaken. This review concluded that it was appropriate to amend the conditions currently related to its use and these should be consistent with the scheduling requirements of the Poisons Standard.

It was also noted that while Therapeutic Goods (Listing) Notice 2008 (No. 1) nominates *oral* use of sodium fluoride, its intent is that sodium fluoride be used for dental application only. This intent is clarified in a condition in the listing notice and confirmed by existing business rules in TGA eBusiness Services (eBS). It is recommended that this ambiguity be removed when amending the conditions associated with the ingredient.

The appropriate mechanism to allow the changes to the conditions of use is the registration of a new listing notice on the Federal Register of Legislative Instruments (FRLI) and the revocation of the existing Therapeutic Goods (Listing) Notice 2008 (No. 1).

Regulatory basis for this request

Subsection 9A(5) of the *Therapeutic Goods Act 1989* (the Act) authorises the Minister for Health to publish a notice in the *Commonwealth of Australia Gazette* requiring specified goods to be included in the part of the Register for listed goods. Such notices generally require that goods containing particular ingredients or meeting a particular description be included in the part of the Register for listed goods. This mechanism permits the timely approval of new listable therapeutic goods containing particular ingredients or meeting particular descriptions prior to the inclusion of those therapeutic goods in Schedule 4 to the Therapeutic Goods Regulations 1990 (the Regulations).

Following commencement of the *Legislative Instruments Act 2003* on 1 January 2005, effect is given to these notices through registration on FRLI, rather than gazettal.

A person can apply for a new ingredient to be specified in a notice under subsection 9A(5) of the Act. After evaluation by the TGA to determine that the ingredient is of sufficiently low risk and of appropriate quality to allow its inclusion in listed medicines, any sponsor may use the ingredient in this manner.

On 23 October 2013, the Assistant Minister for Health, Fiona Nash, delegated by written instrument the Minister's power specified under subsection 9A(5) of the Act to the National Manager of the TGA.

New listing notice

Your agreement is sought on the publication of a new listing notice, under subsection 9A(5), to require therapeutic goods containing sodium fluoride as a therapeutically active ingredient, to be included in the part of the Register for listed goods, subject to the following conditions:

- the preparations are for dental use only; and
- 'sodium fluoride' is for use only in pastes, powders or gels for dental hygiene; and
- 'sodium fluoride' is in combination with at least one of the other therapeutically active ingredients referred to in item 3, Part 1 of Schedule 4 to the Regulations; and
- the concentration of fluoride ion is not more than 1,500 mg/kg; and
- when the concentration of fluoride ion is more than 1,000 mg/kg, the label for the preparation complies with the requirements of the Required Advisory Statements for Medicine Labels; and
- any claims made regarding the preparation in relation to fluoride content are restricted to those relating to improvements in dental hygiene or the use of fluoride for the prevention of tooth decay.

RECOMMENDATION

R1 That you SIGN the attached Listing Notice.

R2 That you APPROVE the attached Explanatory Statement.

Yes ☑
No ☐

R3 That you SIGN the attached Ministerial Submission to the Assistant Minister for Health.

Dr Lisa Studdert
Head, MAG
28/10 2013

R1: Noted

Comments

Professor John Skerritt
National Manager
1/11 2013

R1: Signed/Not signed

Comments

Contact Officer: Trisha Garrett
6232 8439
Office of Complementary Medicines

Attached for signature:

1) Listing Notice for registration of 'sodium fluoride' on FRLI.
2) Ministerial Submission to the Assistant Minister for Health, Senator the Hon Fiona Nash.

Attached for approval:

1) Explanatory Statement in relation to the Listing Notice.

Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989

Therapeutic Goods (Listing) Notice 2013 (No. 6)

I, JOHN SKERRITT, National Manager of the Therapeutic Goods Administration, delegate of the Minister for Health for the purposes of subsection 9A(5) of the *Therapeutic Goods Act 1989* (the Act) and acting under that provision, HEREBY:

1. REVOKE Therapeutic Goods Listing Notice 2008 (No.1); and

2. Require the following therapeutic goods to be included in the part of the Australian Register of Therapeutic Goods (the Register) for listed goods:

   - preparations, for the purpose of Item 3 of Part 1 of Schedule 4 to the Therapeutic Goods Regulations 1990 (the Regulations), that contain 'sodium fluoride' as a therapeutically active ingredient, subject to the following conditions:

     - the preparations are for dental use only; and
     - 'sodium fluoride' is for use only in pastes, powders or gels for dental hygiene; and
     - 'sodium fluoride' is in combination with at least one of the therapeutically active ingredients referred to in item 3, Part 1 of Schedule 4 to the Regulations; and
     - the concentration of fluoride ion is not more than 1,500 mg/kg; and
     - when the concentration of fluoride ion is more than 1,000 mg/kg, the label for the preparation complies with the requirements of the *Required Advisory Statements for Medicine Labels*; and
     - any claims made regarding the preparation in relation to fluoride content are restricted to those relating to improvements in dental hygiene or the use of fluoride for the prevention of tooth decay.

This Notice commences from the day after it is registered on the Federal Register of Legislative Instruments.

Pursuant to subsection 9A(6) of the Act, this Notice ceases to have effect on the day that amendments to the Regulations come into effect to require inclusion of the therapeutic goods listed in this Notice in the part of the Register for listed goods.

Dated this 1st day of Nov 2013

John Skerritt
Delegate of the Minister for Health

EXPLANATORY STATEMENT

THERAPEUTIC GOODS (LISTING) NOTICE 2013 (NO. 6)

Subsection 9A(5), Therapeutic Goods Act 1989

OUTLINE

Therapeutic Goods (Listing) Notice 2013 (No. 6) (the Listing Notice) is a notice made by the delegate of the Minister for Health under subsection 9A(5) of the *Therapeutic Goods Act 1989* (the Act).

The Listing Notice has the effect of revoking *Therapeutic Goods (Listing) Notice 2008 (No.1)*, and requiring that therapeutic goods that contain 'sodium fluoride' as a therapeutically active ingredient, subject to certain conditions, be included in the part of the Australian Register of Therapeutic Goods (the Register) for listed goods.

The Listing Notice commenced on the day after it was registered on the Federal Register of Legislative Instruments (FRLI).

BACKGROUND

The Act provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Therapeutic Goods Administration (the TGA) is responsible for administering the Act.

Unless specifically exempted or authorised under the Act, therapeutic goods are required to be included on the Register before being supplied in, imported into, manufactured in or exported from Australia (sections 19B and 19D of the Act refer). Medicines are either registered or listed on the Register, depending on the ingredients they contain and the therapeutic claims that are being made.

In general, products that contain low risk ingredients are referred to as listed medicines in Australia. Most listed medicines are considered to be of relatively low risk compared to other types of medicines, such as prescription and over-the-counter medicines, as they may only contain ingredients that have been approved by the TGA as being of low risk and may only make limited therapeutic claims.

Part 1 of Schedule 4 to the Therapeutic Goods Regulations 1990 (the Regulations) sets out those therapeutic goods that are required to be included in the part of the Register for listed goods. Part 1 of Schedule 4 does not currently include goods that are oral presentations containing 'sodium fluoride' as a therapeutically active ingredient.

Subsection 9A(5) of the Act authorises the Minister for Health to publish a notice in the *Commonwealth of Australia Gazette* requiring that specified goods be included in the part of the Register for listed goods. Such notices generally require that goods containing particular ingredients be included in that part of the Register. Once the notice is in effect, persons may apply for the listing on the Register of new therapeutic goods that contain ingredients or substances of the kind set out in the notice.

If Part 1 of Schedule 4 to the Regulations is amended to require goods that are the subject of a subsection 9A(5) notice to be included in the part of the Register for listed goods, the notice ceases to have effect (subsection 9A(6) of the Act refers).

A person can apply for a new ingredient or substance to be specified in a notice under subsection 9A(5). The TGA evaluates such applications, and the supporting data provided by the applicant, on the basis of safety and quality. The safety-focussed element determines whether the ingredient or substance is of sufficiently low risk to allow its inclusion in listed medicines, and the quality-focussed element characterises the precise and correct nature of the ingredient or substance.

Sodium fluoride

Sodium fluoride is a source of fluoride that is widely used in toothpaste products (such as pastes, powders and gels). Its quality is subject to monographs in the *British Pharmacopoeia* and the *United States Pharmacopeia-National Formulary* and its safety profile is well established.

In Australia, Therapeutic Goods (Listing) Notice 2008 (No. 1) permitted the use of sodium fluoride as an active ingredient in listed medicines for oral use in toothpaste products subject to certain conditions, including that the concentration of fluoride ion does not exceed 1,000 mg/kg.

In June 2012, amendments to the Poisons Standard came into effect such that topical preparations containing not more than 1,500 mg fluoride ion /kg for both therapeutic and non-therapeutic use became exempt from scheduling requirements subject to label warning requirements for amounts greater than 1,000 mg/kg.

A 2013 TGA review has now determined that the availability of sodium fluoride in listed medicines should be updated to provide consistency with the current scheduling of the substance in the Poisons Standard. The current Listing Notice therefore replaces and revokes Therapeutic Goods (Listing) Notice 2008 (No. 1).

The delegate of the Minister has determined that therapeutic goods containing 'sodium fluoride' as a therapeutically active ingredient be included in the part of the Register for listed goods where:

- the preparations are for dental use only; and
- 'sodium fluoride' is for use only in pastes, powders or gels for dental hygiene; and
- 'sodium fluoride' is in combination with at least one of the therapeutically active ingredients referred to in Item 3, Part 1 of Schedule 4 to the Regulations; and
- the concentration of fluoride ion is not more than 1,500 mg/kg; and
- when the concentration of fluoride ion is more than 1,000 mg/kg, the label for the preparation complies with the requirements of the Required Advisory Statements for Medicine Labels; and
- any claims made regarding the preparation in relation to fluoride content are restricted to those relating to improvements in dental hygiene or the use of fluoride for the prevention of tooth decay.

CONSULTATION

Consultation was not undertaken in relation to the making of the Listing Notice, as the notice is considered to be minor and machinery in nature, with low compliance costs for affected industry.

The effect of this Listing Notice is that sponsors wishing to use sodium fluoride in the formulation of a medicine can list the medicine on the Register rather than registering that medicine. Applications for new registered medicines are fully evaluated by the TGA for quality, safety and efficacy prior to inclusion on the Register, a process that is considerably more expensive and lengthy than the listing process.

The making of the Notice does not involve any new regulatory steps for industry, but rather provides a basis for products containing this ingredient to access the listing process rather than registration, a significant benefit for sponsors.

The Office of Best Practice Regulation (OBPR) has advised that a regulatory impact statement is not required in relation to Listing Notices (OBPR Ref. 14416).

In relation to compatibility with human rights, it is considered that the Listing Notice is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*, and a Statement of Compatibility setting that out in further detail is set out below.

SUPPLEMENTARY MATERIAL - STATEMENT OF COMPATIBILITY FOR A LEGISLATIVE INSTRUMENT THAT DOES NOT RAISE ANY HUMAN RIGHTS ISSUES

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Therapeutic Goods (Listing) Notice 2013 (No. 6) – 'Sodium fluoride'

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011.*

Overview of the Bill/Legislative Instrument

Therapeutic Goods (Listing) Notice 2013 (No. 6) (the Notice) is a notice made by the delegate of the Minister for Health under subsection 9A(5) of the *Therapeutic Goods Act 1989* (the Act). The effect of the Notice is to allow sponsors of orally ingested therapeutic goods containing 'sodium fluoride' as a therapeutically active ingredient to list, rather than register, those goods in the Australian Register of Therapeutic Goods (the Register) (registration being a considerably more expensive and lengthy process

than listing). Once the Notice has commenced, persons can apply to list goods containing this ingredient in the Register.

Human rights implications

This legislative instrument does not engage any of the applicable rights or freedoms.

Conclusion

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

Professor John Skerritt, delegate of the Minister for Health

MINISTERIAL SUBMISSION – STANDARD

Australian Government
Department of Health
Therapeutic Goods Administration

cc: MINISTER DUTTON
Ms Jane Halton PSM

ASSISTANT MINISTER NASH **Critical Date: N/A**

NOTIFICATION OF A NEW INGREDIENT FOR USE IN LISTED MEDICINES

RECOMMENDATION:

R1. That you NOTE that a listing notice has now been made under subsection 9A(5) of the *Therapeutic Goods Act 1989* and registered on the Federal Register of Legislative Instruments, the effect of which is that therapeutic goods that contain 'sodium fluoride' as the therapeutically active ingredient, subject to the conditions set out in the notice, are to be included in the part of the Australian Register of Therapeutic Goods for listed goods.

Noted

ASSISTANT MINISTER NASH

_____ / _____ / _____

MINISTER'S COMMENTS:

ISSUE:

Under an instrument of delegation signed by you, on 23 October 2013, the National Manager of the Therapeutic Goods Administration (TGA) has been given the power under subsection 9A(5) of the *Therapeutic Goods Act 1989* (the Act) to require specified goods to be included in the part of the Australian Register of Therapeutic Goods (the Register) for listed goods and to specify conditions to which such inclusion is subject.

I have now made a Notice under subsection 9A(5). Its effect is that therapeutic goods that contain 'sodium fluoride' as a therapeutically active ingredient, being a substance that is to be mentioned in Part 3 of Schedule 4 to the Therapeutic Goods Regulations 1990 (the Regulations), is subject to the following conditions:

- the preparations are for dental use only; and

- 'sodium fluoride' is for use only in pastes, powders or gels for dental hygiene; and
- 'sodium fluoride' is in combination with at least one of the therapeutically active ingredients referred to in item 3, Part 1 of Schedule 4 to the Regulations; and
- the concentration of fluoride ion is not more than 1,500 mg/kg; and
- when the concentration of fluoride ion is more than 1,000 mg/kg, the label for the preparation complies with the requirements of the Required Advisory Statements for Medicine Labels; and
- that any claims made regarding the preparation in relation to fluoride content are restricted to those relating to improvements in dental hygiene or the use of fluoride for the prevention of tooth decay.

As 'sodium fluoride' has been found to be of sufficiently low risk when these conditions are met, the effect of this Notice is that any sponsor may include this ingredient in a listed medicine.

BACKGROUND:

Part 1 of Schedule 4 to the Regulations sets out the kinds of therapeutic goods that are required to be included in the part of the Register for listed goods. Subsection 9A(5) of the Act authorises the Minister for Health, by notice in the *Commonwealth of Australia Gazette*, to require that specified therapeutic goods be included in the part of the Register for listed goods and to specify conditions to which that inclusion may be subject. Such a notice is a legislative instrument for the purposes of the *Legislative Instruments Act 2003* and must be registered on the Federal Register of Legislative Instruments. It takes effect from the day after it is registered. When Part 1 of Schedule 4 to the Regulations is amended to include goods covered by a subsection 9A(5) notice, the notice ceases to have effect.

A person can apply for a new ingredient or substance to be specified in a notice under subsection 9A(5). Applications and supporting data provided by the applicant are evaluated by the TGA for safety and quality. The safety-focussed element determines whether the ingredient or substance is of sufficiently low risk to allow its inclusion in listed medicines and the quality-focussed element characterises the precise and correct nature of the ingredient or substance. Once in effect, applications can be made for the listing on the Register of new therapeutic goods that contain ingredients/substances of the kind set out in the notice.

RELEVANCE TO ELECTION COMMITMENTS:

There is no relevance to election commitments or government policy.

COMMENT:

Until now, 'sodium fluoride' was subject to Therapeutic Goods (Listing) Notice 2008 (No. 1), which permitted the use of 'sodium fluoride' as an active ingredient in listed medicines for oral use subject to certain conditions, including that the concentration of fluoride ion did not exceed 1,000 mg/kg. This condition was consistent with the scheduling requirements for fluoride specified in the *Standard for the Uniform Scheduling of Drugs and Poisons* (the Poisons Standard) at the time of publication of Therapeutic Goods (Listing) Notice 2008 (No. 1).

In June 2012, amendments to Schedule 3 of the Poisons Standard came into effect exempting topical preparations containing not more than 1,500 mg/kg fluoride ion for both therapeutic and non-therapeutic use from scheduling requirements, subject to label warning requirements for amounts greater than 1,000 mg/kg. However, Therapeutic Goods (Listing) Notice 2008 (No. 1) was not updated in line with the aforementioned change to the relevant schedules of the Poisons Standard.

In response to a request by ACCORD Australasia to bring the availability of sodium fluoride in listed medicines in line with current scheduling requirements in the Poisons Standard, the TGA reviewed the availability of sodium fluoride as an active ingredient in listed medicines. This review concluded that it was appropriate to amend the conditions currently related to its use and these should be consistent with current scheduling requirements of the Poisons Standard.

In some instances, a Compositional Guideline is prepared by the Office of Complementary Medicines (OCM) in relation to a newly approved substance. However, this is not necessary for 'sodium fluoride' as the quality of the ingredient is assured by mandatory compliance with the monograph in either the *British Pharmacopoeia* or the *United States Pharmacopeia-National Formulary*.

To that end, the delegate of the Minister has determined that therapeutic goods containing 'sodium fluoride' as a therapeutically active ingredient be included in the part of the Register for listed goods, when such goods are dental preparations; when the concentration of fluoride ion in the preparation is not more than 1,500 mg/kg; when containing more than 1,000 mg/kg fluoride ion, is compliant with the requirements of the *Required Advisory Statements for Medicine Labels*; is for use only in pastes, powders or gels for dental hygiene; and claims in relation to fluoride content are restricted to those relating to improvements in dental hygiene or the use of fluoride for the prevention of tooth decay.

Sensitivity:
N/A

Financial Implications:
N/A

Timing/Handling (including legislative changes):
N/A

Consultations:
No divisions or agencies were consulted in the preparation of this Submission.

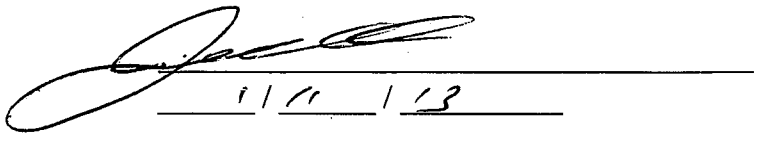
The Secretary was not consulted on the approach of this Submission.

COMMUNICATION ACTIVITIES:

There are no community awareness opportunities relating to this item .

Contact Officer details:
Professor John Skerritt
National Manager
Therapeutic Goods Administration
02 6232 8200

Clearance Officer details:
Professor John Skerritt
National Manager



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ATTACHMENTS:

A: *Therapeutic Goods (Listing) Notice 2013 (No. 6)*
B: Explanatory Statement for the *Therapeutic Goods (Listing) Notice 2013 (No. 6)*