1200 FAS to Signature 23/9/13

Australian Government

Department of Health and Ageing

Recent after election for making but

> cc: MINISTER PLIBERSEK
> Ms Jane Halton PSM
> Mr David Butt
> Mr David Learmonth
> Ms Mary McDonald

MINUTE TO THE PARLIAMENTARY SECRETARY

PARLIAMENTARY SECRETARY NEUMANN

NOTIFICATION OF A NEW ACTIVE INGREDIENT FOR USE IN LISTED MEDICINES

PURPOSE: To ADVISE you of the making and registration of the *Therapeutic Goods (Listing) Notice 2013 (No. 3)* (the Notice) a copy of which is at **Attachment A** and related Explanatory Statement at **Attachment B.**

ISSUE:

2. Under an instrument of delegation signed by the then Parliamentary Secretary, ~~the Honourable Catherine King MP~~, on 2 June 2011, the National Manager of the Therapeutic Goods Administration (TGA), and certain other position holders, have 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.
3. ~~I, John Skerritt, as National Manager of the TGA, have the relevant delegation under the legislation to exercise this power.~~
4. 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.
5. 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:

6. Part 1 of Schedule 4 to the Therapeutic Goods Regulations 1990 (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

☐ Health Reform ☐ Election Commitment ☐ COAG Reform ☐ Budget ☐ Other significant policy
☐ Minority Government ☒ Legislation ☐ Appointment ☐ Program or grant administration ☐ Other

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 (FRLI). 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.

7. 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/GOVERNMENT POLICY/COAG REFORM AGENDA:

8. There is no relevance to election commitments or government policy.

COMMENT:

9. Under an instrument of delegation signed by the then Parliamentary Secretary, I, as National Manager, have specified by notice made under subsection 9A(5) that therapeutic goods that contain 'sodium fluoride' as a therapeutically active ingredient are required to be included in the part of the Register for listed goods, subject to the conditions set out in the Listing Notice. The notice has now been registered on FRLI.

10. 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).

11. 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.

12. 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.

13. Advice was not sought from the Advisory Committee on Complementary Medicines (ACCM) in relation to whether 'sodium fluoride' is suitable for use as an ingredient in listed medicines. Such advice was not considered necessary, given its previous availability and relevant scheduling.

14. 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*.

15. 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:
16. Nil

Financial Implications:
17. Nil

Compliance with Commonwealth Grant Guidelines:
18. Nil

Legislation/Timing of Proposed Legislative Changes:
19. Nil

Timing/Handling:
20. Nil

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

22. The Secretary/Deputy Secretary:
- ☐ was consulted on the approach of this Minute
- ☐ has sighted this Minute
- ☒ none of the above

COMMUNICATION ACTIVITIES
23. There are no community awareness opportunities relating to this item.

RECOMMENDATION

R1. That you NOTE that a notice has now been made under subsection 9A(5) and registered on FRLI, 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 Register for listed goods.

[redacted]

Dr John Skerritt
National Manager
Therapeutic Goods Administraion
~~August 2013~~
Outcome: 1: Population Health

SHAYNE NEUMANN

R1. NOTED

Contact Officer:
Trisha Garrett x 8439
Office of Complementary Medicines

MINISTER'S COMMENTS:

I will 5.57 after 23/9/13

Advice Rating	1	2	3	4	5	Comments
Timeliness						
Presentation						
Quality of Advice						
		Poor		Satisfactory		Excellent

ATTACHMENTS:

A: *Therapeutic Goods (Listing) Notice 2013 (No. 3)*
B: Explanatory Statement for the *Therapeutic Goods (Listing) Notice 2013 (No. 3)*