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16 JAN 2015

BY: Hon. Dr Jonathan Coleman
Office of the

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Action required by: 21 January 2015

Proposed Amendment to the Medicines Regulations

To: Hon Dr Jonathan Coleman (Minister of Health)

Ministry of Health

Copy to: Hon Peter Dunne (Associate Minister of Health)

15 JAN 2015

Purpose

DISPATCHED

This report provides you with a Cabinet paper recommending that Cabinet authorise the submission to the Executive Council of an amendment to the Medicines Regulations 1984 to specify that fluoride substances used to treat community water supplies are not medicines.

Key points

- This paper is intended for consideration by Cabinet when it meets on 27 January 2015.
- Enclosed with this report are a copy of the **CAB100 form to be completed by you** and the signature cover sheet that is needed when the regulation is submitted to the Executive Council. A final copy of the regulation will be supplied to your office as soon as it is available to the Ministry.
- The Parliamentary Counsel Office will deliver the certified copy of the new regulation directly to the Cabinet Office.
- The signed CAB paper, completed CAB100 form and signature cover sheet need to be **received by the Cabinet Office no later than 10am on Thursday 22 January.**

Contacts: Dr Don Mackie, Chief Medical Officer 021 656 000
Dr Stewart Jessamine, Acting Director of Public Health 021 650 278

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Proposed Amendment to the Medicines Regulations

Background

1. In late November you accepted a High Court and Crown Law recommendation to progress an urgent amendment to the Medicines Regulations 1984 to exempt fluoride compounds from the definition of *medicine* when they are used to fluoridate community water supplies and authorised officials to consult stakeholders on the proposal and issue drafting instructions to the Parliamentary Counsel Office (Health Report 20141527 refers).
2. The Ministry subsequently instructed Parliamentary Counsel and published a consultation document on the Medsafe website on 25 November 2014. Local Government New Zealand, Medical Officers of Health and oral health groups were contacted directly and invited to provide submissions on the document. The lawyer acting for the plaintiff in the recent *New Health Inc v Attorney General* case was also advised of the consultation.

Outcome of consultation

3. 1411 submissions were received by the closing date of 9 January 2015. 72 submissions supported the proposed regulation. Of these 19 were from health professionals, 17 from health organisations and the balance from members of the public.
4. 1339 submissions do not support the proposal. These include 15 from health professionals, 12 from interest groups and the balance from members of the public.
5. A large number of submissions received as standard letters do not support the proposed amendment. These submissions essentially restate many of the arguments made in *New Health New Zealand v Attorney-General [2014]* which were rejected by Justice Collins in his judgement.
6. The submissions also make a series of statements about the toxicity of fluoride and claim that the risk of harm associated with consumption of fluoridated water outweighs any possible benefits. These claims are not supported by the 2014 review of the scientific evidence of the safety and efficacy of fluoride undertaken by the Royal Society of New Zealand and the Office of the Prime Minister's Chief Science Advisor (Appendix 1).
7. The Ministry considers that the statutory requirement to consult stakeholder groups before amending regulations under the Medicines Act 1981 (section 105(1) refers) has been met.
8. A copy of the draft Report of the Analysis of Submissions is attached. A full list of submitters is being prepared and will be copied to you for your information once completed.

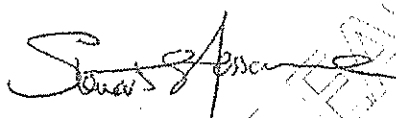
Next Steps

9. The drafting process for the new regulation has been completed and a Cabinet paper is enclosed for your consideration and signature. The paper includes a request for a waiver of the 28 day rule.
10. The Secretary for the LEG Committee has recommended taking the paper directly to Cabinet when it meets on **27 January 2015**. This would enable the new regulation to be signed by the Executive Council around the end of January - a timeframe that would allow Crown Law to advise the Court of Appeal, by 6 February, that the regulation has been implemented. The Court has advised this would render the pending appeal by *New Health* moot.
11. Also enclosed with this report are a CAB100 form which needs to be completed by you and a signature cover sheet that is required by the Executive Council. The mechanics and timing for submission of the necessary papers to Cabinet Office are set out in the cover sheet for this Health Report.

Recommendations

The Ministry recommends that you:

- a) **Note** that the statutory prerequisite to consult stakeholders on the proposal to amend the Medicines Regulations 1984 has been met.
- b) **Agree** that the Medicines Regulations 1984 that sit under the Medicines Act 1981 be amended to provide legal certainty that fluoride substances used to treat community water supplies are not medicines. Yes/No
- c) **Agree** to seek a waiver of the 28 day rule so that the amended regulation can come into effect as soon as it is signed by the Executive Council. Yes/No
- d) **Sign** the enclosed Cabinet paper that is intended for consideration by Cabinet when it meets on 27 January. Yes/No
- e) **Complete** the enclosed CAB100 form and forward it with the signed Cabinet paper and the enclosed signature cover sheet to the Cabinet Office by 10am Thursday 22 January 2015. Yes/No


 Dr Stewart Jessamine
 Acting Director of Public Health
 CLPR

Minister's signature

Date: 20.1.15

Minister's feedback on quality of report

Very poor (1)	Poor (2)	Neutral (3)	Good (4)	Very good (5)
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END.