

RELEASED UNDER THE
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In Confidence

Office of the Minister of Health

Cabinet

Medicines Amendment Regulations 2015

Proposal

- 1 This paper seeks authorisation to submit the Medicines Amendment Regulations 2015 to the Executive Council.

Policy

- 2 The purpose of the Medicines Amendment Regulations 2015 is to provide legal clarity that fluoride when added to community water supplies is not a medicine. In recent litigation (*New Health New Zealand v Attorney-General* [2014] NZHC 24870) the High Court, while dismissing the plaintiff's claim that the fluoride substances used in community water fluoridation are medicines, recommended the making of such a regulation. Crown Law has also recommended, as a matter of good public administration and to remove the basis for any further litigation on the matter, fast-tracking the making of the regulation to put the issue beyond doubt.
- 3 The Medicines Amendment Regulations 2015 will specify that fluoride-containing substances, including the substances hydrofluorosilicic acid and sodium silicofluoride, are not medicines for the purposes of the Medicines Act 1981 when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies.
- 4 The supply of community drinking water is undertaken by Local Authorities who are required to undertake consultation with their community prior to commencing fluoridation of a community water supply. The proposed amendment to the Medicines Act will not consequentially amend, or remove, the need for Local Authority consultation.
- 5 Fluoridation of community water supplies by Local Authorities has been occurring in New Zealand since 1955 and is regulated by Part 2A of the Health Act 1956. This Act refers to water quality standards required for all community drinking water supplies including controls over the maximum concentration of a number of substances, including fluoride and other naturally occurring minerals and chemicals, permitted to be present in drinking water. The chemicals used to fluoridate drinking water supplies are regulated by the Hazardous Substances and New Organisms Act 1996.

Timing and 28-day rule

- 6 The Regulations will come into force the day after notice in the Gazette. A waiver of the 28-day rule is sought to enable legal certainty to be provided as soon as possible.

Compliance

7 The Regulations comply with:

- the principles of the Treaty of Waitangi
- the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993
- the principles and guidelines set out in the Privacy Act 1993
- relevant international standards and obligations
- LAC Guidelines: *Guidelines on Process and Content of Legislation*, a publication by the Legislation Advisory Committee.

8 There is a statutory pre-requisite set out in section 105(1) of the Medicines Act 1981 for consultation with organisations or bodies representative of persons likely to be substantially affected by the regulation. Consultation with relevant organisations and bodies has been undertaken and the statutory prerequisite has been met.

Regulations Review Committee

9 There are no grounds for the Regulations Review Committee to draw the Regulations to the attention of the House under Standing Order 319.

Certification by Parliamentary Counsel

10 The draft Regulations were certified by Parliamentary Counsel as being in order for submission to Cabinet.

Regulatory impact analysis

11 A Regulatory Impact Statement is not required because the regulatory change has no impact on businesses, individuals or not for profit entities and does not change current policy or practice settings.

Publicity

12 The Ministry of Health will inform Local Government New Zealand and Crown Law directly about the amendment, and publish a statement on the website of its business unit Medsafe to inform other interested parties about the regulation change.

Consultation

13 The Department of Internal Affairs has been consulted. The Department of Prime Minister and Cabinet and Crown Law Office have been informed of the proposal.

14 The following interested groups were also consulted: Local Government New Zealand, Medical Officers of Health, New Zealand Medical Association and New Zealand Dental Association. The Ministry of Health received 1411 submissions on its November 2014 consultation document, *Consultation on Proposed Amendment to Regulations under the Medicines Act 1981*. Feedback was received from a cross-section of interested stakeholders. Feedback from health authorities, public health units and health professional organisations has been positive in recognising the benefits of fluoridation, acknowledging that the present controls on fluoridation of water set out in Part 2A of the Health Act 1956 are appropriate to protect the public health, noting that the legal

status of fluoride when used for water fluoridation is not changing, and agreeing that clarification of this legal position has value.

- 15 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.
- 16 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. As this report represents the latest expert opinion on the safety of fluoride available and refutes the claims made by the submitters, no change to the proposed amendment is necessary.
- 17 Several submissions advised that in addition to hydrofluorosilicic acid and sodium silicofluoride, the two chemicals specifically named in the proposed regulation, sodium fluoride may also be used in fluoridation of community water supplies. It is therefore recommended that the proposed regulation include a reference to sodium fluoride as well as a generic statement designed to include other products that have been used to fluoridate community water supplies in other jurisdictions.

Recommendations

- 18 I recommend that Cabinet:
 1. **note** that on the recommendation of the High Court and Crown Law I have determined 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
 2. **note** that the Medicines Amendment Regulations 2015 give effect to the exclusion referred to in recommendation 1 above
 3. **note** that section 105(1) of the Medicines Act 1981 requires that consultation be undertaken with organisations or bodies representative of persons likely to be substantially affected by the regulation
 4. **note** the advice of the Minister of Health that this requirement has been met
 5. **note** that a waiver of the 28-day rule is sought:
 - 5.1 on the grounds that the regulation change does not change current policy or practice settings
 - 5.2 because it would be beneficial to provide legal certainty about the status of fluoride in community water supplies as quickly as possible.
 6. **agree** to waive the 28-day rule so that the regulations can come into force and provide legal certainty as soon as possible.

- 7 **authorise** the submission to the Executive Council of the Medicines Amendment Regulations 2015 for consideration at its first meeting of 2015 to remove the basis for further litigation.

Hon Dr Jonathan Coleman
Minister of Health

Date:

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