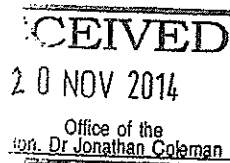


Health report

20 NOV 2014



Hon Dr Jonathan Coleman (Minister of Health)

Fluoride in drinking water: Urgent amendment to Medicines Regulations 1984 proposed

Background and rationale for an urgent amendment

1. The Crown has recently been involved in two court proceedings involving attempts by the same litigant to prevent fluoridation of public water supplies:
 - a. *New Health Inc v South Taranaki District Council* (Attorney-General was an intervening party in the High Court). New Health has now appealed the High Court decision upholding the legal basis for fluoridation, including the finding that provision of fluoride in drinking water was not mass medication. **That appeal has been set down for 12 March 2015**
 - b. *New Health Inc v Attorney-General* (High Court, Wellington). New Health sought declarations that the Ministry take steps to ensure that fluoride compounds are approved as medicines before they can be supplied for use in fluoridating water. The Court dismissed New Health's application, finding that the fluoride compounds are not medicines at the concentrations used in drinking water. **The judge went on to recommend that to provide more legal clarity, the Ministry pursue an amendment to the Medicines Regulations to exempt these fluoride compounds from the definition of *medicine* when they are used to fluoridate water.**
2. The Court of Appeal has given the Crown leave to vacate the fixture set down for 12 March 2015 if, by 6 February the Crown is in a position to satisfy the Court that the recommended regulation change **will be** implemented. This would have the effect of rendering the appeal moot, an outcome that would save considerable legal costs for the Crown and free up valuable Court time for other fixtures. Officials consider that such an amendment could be sufficiently progressed by 6 February if the streamlined process described in paragraphs 3 to 5 is adopted.

Proposed action and timing

3. Section 105(1)(i) of the Medicines Act 1981 (the Act) allows for the making of regulations to specify that a substance or class of substance is not a medicine. Following receipt of the judgement in *New Health Inc v Attorney-General*, Crown Law has recommended that an urgent amendment be made to the Medicines Regulations 1984 to provide legal clarity that fluoride when added to public drinking water is not a medicine.
4. This is a technically simple amendment that does not involve a change in policy in view of the recent High Court decisions. For this reason, and to move with urgency, officials are seeking your approval to consult on the proposed regulation change (see paragraph 5 below) and to issue drafting instructions to Parliamentary Counsel for the new regulation to be drafted without first taking the issue to Cabinet.


5. If you agree to this approach officials would issue a consultation document in early December and, at the same time issue drafting instructions to the Office of Parliamentary Counsel so that consultation and drafting can occur in parallel. This would enable the analysis of submissions to be completed by the end of January 2015 and a paper seeking Legislation Committee approval for the regulation change to be considered around 6 February. At that time officials recommend seeking a waiver of the 28 day rule on the grounds that it would be beneficial to provide early legal certainty. It should then be possible to have the new regulation come into force by the end of February 2015.

Consultation

6. Before making or amending a regulation, the Act requires that there be consultation with organisations or bodies that appear to be representative of persons likely to be substantially affected by the regulation. For this regulation change, the Ministry would consult with local bodies and with the lawyers representing the parties to the recent litigation and place the consultation document on its website. Given the narrow scope of the proposed amendment, Crown Law has advised that a five week consultation period would be appropriate.

The Ministry recommends that you:

- a) **Accept** the Crown Law recommendation to progress an urgent amendment to the Medicines Regulations 1984 to provide legal clarity that fluoride when added to public drinking water is not a medicine. Yes / No
- b) **Agree** that given the limited and technical nature of the proposed amendment it will not be necessary to seek an initial Cabinet decision to progress the proposed amendment. Yes / No
- c) **Agree** that officials may consult on the proposed amendment and issue drafting instructions to the Office of Parliamentary Counsel. Yes / No
- d) **Note** that officials will provide you with a Cabinet Legislation Committee paper in late January 2015 and a report on the outcome of consultation. Yes / No


Chris James
Acting Group Manager, Medsafe
Clinical Leadership, Protection & Regulation



Minister's signature

Date 24/11/14

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Minister's feedback on quality of report

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