

27 FEB 2015

No.1 The Terrace  
PO Box 5013  
Wellington 6145  
New Zealand  
T+64 4 496 2000Lisa Hansen  
Barrister  
Po Box 8045  
Wellington 6143

Ref: H201500224

Dear Lisa Hansen

**Response to your request for official information**

Thank you for your request of under the Official Information Act 1982 (the Act) referred to the Ministry of Health by the Crown Law Office.

You have requested:

*1. Information about the costs of the consultation process. The costs should be the actual costs as at the date of the response.*

The Ministry of Health has not carried any costing in relation to the consultation process as the consultation process was managed in-house by Ministry staff.

It has been estimated that Ministry staff have spent 126 hours on the consultation process to date.

*2. All documents prepared for the purposes of or supporting the consultation process, including the RIS, any briefing papers, correspondence etc.*

The information (including the information withheld) is set out in the table below. Copies of documents (with redactions where the information is withheld) are attached. Where information is already publicly available we have provided a website link for your information.

Title	Author	Date	Reason for withholding /Deleting
Health Report 20141527 Fluoride in drinking water: Urgent amendment to Medicines Regulations 1984 proposed	Ministry of Health	20 November 2014	Information regarding a mobile phone number has been withheld under section 9(2)(a) to protect the privacy of natural persons.
Consultation on Proposed	Ministry of	25 November 2014	Refused under Section

Amendment to Regulations under the Medicines Act 1981	Health		18(d) of the Act as the information requested is publicly available on: <a href="http://www.medsafe.govt.nz/consultations/medicine-regulations-fluoride-in-drinking-water.asp">http://www.medsafe.govt.nz/consultations/medicine-regulations-fluoride-in-drinking-water.asp</a>
Preliminary Impact and Risk Assessment	Ministry of Health	25 November 2014	Some information has been withheld under Section 9(2)(a) to protect the privacy of natural persons.
Email From Treasury confirming a Regulatory Impact Assessment not required	Treasury	28 November 2014	Some information has been withheld under Section 9(2)(a) to protect the privacy of natural persons.
Health report H20141620 Proposed amendment to the Medicines Regulations	Ministry of Health	15 January 2015	No information withheld
Appendices: <ul style="list-style-type: none"> <li>Cabinet Paper: Medicines Amendment Regulations</li> <li>Draft Analysis of Submissions</li> <li>Health effects of water fluoridation: A review of the scientific evidence</li> </ul>	Ministry of Health  Ministry of Health  Royal Society of New Zealand and the Office of the Prime Minister's Chief Advisor		No information withheld   Refused under Section 18(d) of the Act as the information requested will soon be publicly available.  Refused under Section 18(d) of the Act as the information requested is publicly available on: <a href="http://www.royalsociety.org.nz/2014/08/22/review-finds-community-water-fluoridation-safe-and-effective/">http://www.royalsociety.org.nz/2014/08/22/review-finds-community-water-fluoridation-safe-and-effective/</a>
Email to The New Zealand Medical Association advising of consultation process	Ministry of Health	25 November 2014	Some information has been withheld under Section 9(2)(a) to protect the privacy of

			natural persons.
Email to Water New Zealand advising of consultation process	Ministry of Health	5 December 2014	Some information has been withheld under Section 9(2)(a) to protect the privacy of natural persons.
Email to Public Health Units advising of consultation process	Ministry of Health	5 December 2014	Some information has been withheld under Section 9(2)(a) to protect the privacy of natural persons.

Regulatory Impact Statement (RIS). A RIS was not required because the regulatory change did not change any current policy or practice settings. Your request is therefore refused under section 18(e) of the Act as the information requested does not exist.

I trust this information fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review my decision to withhold information under this request.

Yours sincerely



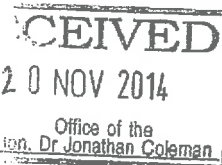
**Sarah Reader**  
**Acting Group Manager**  
**Medsafe**

Page 3 of 3



# 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

### Ministry of Health contacts

Dr Susan Martindale		Dennis Shum	
Principal Advisor Regulation, Medsafe		Senior Solicitor, Corporate Services, Health Legal	
Phone	04 819 6892	Phone	04 816 2139
Cellphone		Cellphone	

### Minister's feedback on quality of report

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



# Preliminary impact and risk assessment

**Purpose of the PIRA:** A preliminary impact and risk assessment (PIRA) is intended to:

- Help agencies determine whether Cabinet's Regulatory Impact Analysis (RIA) requirements apply to a policy initiative for which they are responsible.
- Help agencies identify the potential range of impacts and risks that might be presented by the policy options for a policy initiative or review, in order that these can be appropriately addressed in the regulatory impact analysis undertaken.
- Provide an initial plan for RIA processes and identify milestones, timeframes, and who to consult.
- Help Treasury policy teams determine the level and sort of policy engagement they wish to have with the lead agency on this policy initiative.
- Help Treasury confirm whether the nature and size of the potential impacts and risks warrant early RIAT engagement on RIA elements and involvement in providing independent quality assurance (QA) on the quality of the regulatory impact statement (RIS) that informs the policy proposals.

**When to complete a PIRA:** It should be started as early as possible in the policy development process (as soon as policy work commences). This includes processes such as reviews of policy or legislation where it is not known at the outset whether a regulatory option will ultimately be selected or preferred, but is one of the available policy options being considered.

**How to complete it:** Provide as much information as possible given the stage of policy development. **This may not require definitive answers to all questions**, and you may need to apply your judgement. Relevant supporting information may be attached. If there is insufficient information to enable Treasury to confirm "significance" at the initial stages of the policy process, the final confirmation of this may be deferred until later in the process.

**Who to send it to:** The PIRA should be provided to your Treasury policy team and copied to RIAT (email [ria@treasury.govt.nz](mailto:ria@treasury.govt.nz)). Please also liaise with your agency's RIA team or panel (if you have one).

**Who to contact if you have any questions:** Your Treasury policy team is your first point of contact for enquiries about completing the PIRA.

## Section 1: General information

Name of the responsible (or lead) government agency:

**Ministry of Health**

Title of policy work programme or proposal:

**Therapeutic Products Regulation**

If known, the title(s) of the main Act and/or Regulations that could be amended or created:

**Amendment to Medicines Regulations 1984**

Agency contact name and phone number:

**Susan Martindale** until 5 December (ph. (04) 819 6892; email: [susan\\_martindale@moh.govt.nz](mailto:susan_martindale@moh.govt.nz))

email:

Date completed: 25 November 2014

## Section 2: Do the RIA requirements apply?

Do the RIA requirements apply?	Yes/No/Not sure
Is this policy initiative expected to lead to a Cabinet paper?	<b>Yes</b> (a LEG paper in Jan / February 2015)
Will this policy initiative consider options that involve creating, amending or repealing legislation (either primary legislation or disallowable instruments for the purposes of the Legislation Act 2012)?	<b>Yes</b> (amending the Medicines Regulations 1984)

If you can answer “no” to **either** of these two questions, the RIA requirements do not apply. There is no need to complete a PIRA (though the questions might still provide useful prompts).

Additional exemptions from the RIA requirements	Yes/No/Not sure
If this initiative includes legislative options, are they covered by one or more of the following exemptions?	
<ul style="list-style-type: none"> <li>• Technical “revisions” or consolidations that substantially re-enact the current law in order to improve legislative clarity or navigability (including the fixing of errors, the clarification of the existing legislative intent, and the reconciliation of inconsistencies)</li> </ul>	<b>Yes</b>
<ul style="list-style-type: none"> <li>• Suitable for inclusion in a Statutes Amendment Bill (if not already covered by the point above).</li> </ul>	<b>No</b>
<ul style="list-style-type: none"> <li>• Would repeal or remove redundant legislative provisions.</li> </ul>	<b>No</b>
<ul style="list-style-type: none"> <li>• Provides solely for the commencement of existing legislation or legislative provisions (this does not include changing the existing commencement date).</li> </ul>	<b>No</b>
<ul style="list-style-type: none"> <li>• Needs to be authorised in an Appropriation Bill, an Imprest Supply Bill.</li> </ul>	<b>No</b>
<ul style="list-style-type: none"> <li>• Is for a Subordinate Legislation (Confirmation and Validation) Bill relating to regulations that have already been made</li> </ul>	<b>No</b>
<ul style="list-style-type: none"> <li>• Implements Deeds of Settlement for Treaty of Waitangi claims, other than those that would amend or affect existing regulatory arrangements.</li> </ul>	<b>No</b>
<ul style="list-style-type: none"> <li>• Brings into effect recognition agreements under the Marine and Coastal Area (Takutai Moana) Act 2011</li> </ul>	<b>No</b>
<ul style="list-style-type: none"> <li>• Essential (the minimum necessary) in order to comply with <u>existing</u> international obligations that are binding on New Zealand.</li> </ul>	<b>No</b>
<ul style="list-style-type: none"> <li>• Has no or only minor impacts on businesses, individuals or not-for-profit entities (such as might be the case for certain changes to the internal administrative or governance arrangements of the New Zealand government, like the transfer of responsibilities, staff or assets between government agencies).</li> </ul>	<b>Yes – the planned amendment does not change current policy or practice settings, but is intended to provide legal clarity as recommended by Crown Law</b>

If all the legislative options associated with this policy initiative qualify for one of these exemptions, then the RIA requirements do not apply.

If claiming a full exemption, please confirm this assessment with your Treasury policy team. You do not need to submit a PIRA for this purpose, but you will need to provide information in support of this claim.



If some aspects of the legislative options for this initiative can stand independently from the rest, and qualify for one of these exemptions, then the RIA requirements do not apply to those aspects. Since a PIRA will still need to be completed and submitted to your Treasury policy team, it should note any important aspects of the initiative for which an exemption is claimed.

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## Section 3: Description and context

### The policy issue

What is the intended scope of the policy initiative?

*No policy change is proposed. The amendment is being progressed on the recommendation of the High Court and Crown Law in order to provide legal certainty.*

What are the main underlying policy issues/problems to which this policy initiative is responding (ie, the root cause of the problem)?

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.**

What is known about the magnitude of these policy issues/problems?

See above

What is the type or nature of the evidence supporting the problem definition?

See above

### The policy process

Who has commissioned this work (ie, a portfolio Minister, an agency at the request of industry or the public, etc)? Is this initiative in your current regulatory plan? Who is responsible for its delivery?

*Recommended by the High Court and Crown Law. The Minister of Health has accepted Crown Law's recommendation to pursue an amendment to the regulations*

## The policy process

What is the expected policy process, and expected timing of key milestones?

Are there any process or timing commitments, existing obligations, constraints, or previous Cabinet decisions that are relevant?

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 below is adopted.

### Proposed action and timing

This is a technically simple amendment that does not involve a change in policy or practice settings in view of the recent High Court decisions. For this reason, and to move with urgency, the Minister has agreed that officials can consult on the proposed regulation change and issue drafting instructions to Parliamentary Counsel for the new regulation to be drafted without first taking the issue to Cabinet.

Officials released a consultation document on 25 November and will shortly issue drafting instructions to the Office of Parliamentary Counsel so that consultation and drafting can occur in parallel. This will enable the analysis of submissions to be completed around mid to late January 2015 and a paper seeking Legislation Committee approval for the regulation change to be considered around 6 February. At that time officials would recommend that the Minister seek 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.

What consultation process is planned, and who will be consulted?

2. 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 is consulting with local bodies and with the lawyers representing the parties to the recent litigation, and oral health groups and has placed the consultation document on its Medsafe website. Given the narrow scope of the proposed amendment, Crown Law has advised that a five week consultation period would be appropriate.

### The policy process

If any established methodology or form of analysis is to be followed or incorporated, please identify

N/A

### The policy options

Are there feasible non-regulatory options to consider? Is it possible that legislation is not required?

*Absolutely not (see above).*

If the range of policy options to be considered is already constrained by existing government commitments, Ministerial directions, or previous Cabinet decisions, what are those constraints?

N/A

If this involves only delegated legislation, what is the legislative authority under which it must be made?

*Section 105(1)(i) of the Medicines Act 1981*

Which groups are might be noticeably affected (either positively or negatively) by the policy options being considered?

N/A

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## Section 4: Are the significance criteria met?

A regulatory initiative is considered to trigger the significance criteria if any of the options being considered are likely to have:

- Significant direct impacts or flow-on effects on New Zealand society, the economy, or the environment, or
- Significant policy risks, implementation risks or uncertainty.

### Are there significant impacts?

Yes/No/Not sure

Will any policy options that may be considered, potentially:

- Take or impair existing private property rights? **No**

- Affect the structure or openness of a particular market or industry? **No**

*For example, assist or hinder businesses to provide a good or service; establish or remove a licence, permit or authorisation process; create or remove barriers for businesses to enter or exit an industry?*

- Impact on the environment, such as regulations that affect the use and management of natural resources? **No**

- Have any significant distributional or equity effects? **No**

*For example, where significant costs are imposed or significant benefits conferred on different sectors of the population?*

- Alter the human rights or freedoms of choice and action of individuals? **No**

- Have any other significant costs or benefits on businesses, local or central government, individuals or not-for-profit organisations etc?

*For example impose additional compliance costs; introduce or alter government cost recovery arrangements; impact on New Zealand's international capital flows or trade including the flows of goods, services, investment and ideas to and from New Zealand; impact on the incentives to work or the mobility of labour, or to invest in education or skills; impact on resource allocation, saving or investment, fiscal costs to government?*

**Potential cost savings to the Crown and possibly local government from reduced risk of litigation initiated by anti-fluoride groups**

For the major types of impacts you have identified, please provide brief information about the nature and likely magnitude of the impacts (in whatever dimensions seem most useful and available).

Savings on legal costs (quantum unknown) and court time if the appeal set down for March is rendered moot. The risk of further litigation involving local bodies may be reduced.



Are there significant policy, design or implementation risks?	Yes/No/Not sure
Are any of the legislative options likely to be novel, or unprecedented?	No
Is the evidence-base for the size of the problem or the effectiveness of different policy options weak or absent?	No
Are the benefits or costs of the policy options likely to be highly uncertain? Are there obvious risks that need to be managed?	No
Is the success of any of the options likely to be dependent on other policy initiatives or legislative changes?	N/A
Are any of the legislative options likely to have flow-on implications for the future form or effectiveness of related legislation?	No
Are there other issues with the clarity or navigability of, or costs of compliance with, the current legislation that it might be good to address at the same time?	No- a major and separate review is planned over a longer timeframe
Do any of the legislative options have the potential to be inconsistent with or have implications for New Zealand's international obligations?	No
Are there any issues arising in relation to New Zealand's commitment toward a single economic market with Australia?	No
Please check with the Ministry of Business Innovation and Employment. There may be, for instance, issues relevant to the Trans-Tasman Mutual Recognition Agreement (TTMRA).	
Are any of the legislative options likely create or extend a power to make delegated legislation, or grant a broad discretionary power to a public body?	No
Are any of the legislative options likely to include provisions that depart from existing legislative norms for like issues or situations?	No
<i>These may include Bill of Rights Act and Privacy Act issues, fundamental common law principles, retrospective rule-making, creation of strict liability offences or burden of proof reversals, and matters affecting civil or criminal immunity. Please see the <u>Legislative Advisory Committee Guidelines on Process and Content of Legislation</u>.</i>	
Are any of the options likely to create, amend, or remove offences or penalties (including pecuniary penalties), the jurisdiction of a court or tribunal, or impact on court-based procedures and workloads?	No
Has implementation testing and operational expertise been integrated into the plan for evaluating options?	N/A
Is there a possibility that local government will be expected to implement, administer, or enforce any options?	No
Are implementation timeframes likely to be challenging?	No
Are the actual costs or benefits highly dependent on the capability or discretionary action of the regulator?	No

## Section 5: Agency assessment and Treasury confirmation

### Agency's preliminary assessment

### Treasury's Assessment

Do the RIA requirements apply to this policy process or proposal?

No

Would any resulting regulatory proposal be likely to have a significant impact or risk and therefore require RIAT involvement?

No

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Sent by:

To: "S"

ck@treasury.govt.nz>

cc:

ck@treasury.govt.nz>

bcc:

ck@treasury.govt.nz>

28/11/2014 03:31 p.m.

Subject: RE: Proposed amendment to the Medicines Regulations 1984 to provide legal clarity- PIRA

Hi

Thanks for your email. I appreciate it.

Cheers, s

S

Regulatory Analysis and Delivery

Medsafe

Clinical Leadership, Protection & Regulation

Ministry of Health

DDI:

http://www.moh.govt.nz

mailto:Martin@treasury.govt.nz

mailto:Martin@treasury.govt.nz

[IN-CONFIDENCE] H...

28/11/2014 03:22:57 p.m.

From:

"Susan Martin" <susan.martin@treasury.govt.nz>

ck@treasury.govt.nz>

To:

"Susan Martin" <susan.martin@treasury.govt.nz>

ck@treasury.govt.nz>

Cc:

"Susan Martin" <susan.martin@treasury.govt.nz>

ck@treasury.govt.nz>

ck@treasury.govt.nz>

Date:

28/11/2014 03:22 p.m.

Subject:

RE: Proposed amendment to the Medicines Regulations 1984 to provide legal clarity- PIRA

[IN-CONFIDENCE]

Hi

Sorry for the delayed reply. I've just read through the PIRA and agree with your conclusion that the RIA requirements do not apply.

Many thanks,

Analyst | The Treasury

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- any use, dissemination or copying of this email is strictly prohibited and may be unlawful.

From: "Susan Martin" <susan.martin@treasury.govt.nz>

Sent: Wednesday, 26 November 2014 10:26 a.m.

To:

"Susan Martin" <susan.martin@treasury.govt.nz>

ck@treasury.govt.nz>

Cc:

"Susan Martin" <susan.martin@treasury.govt.nz>

Subject: Proposed amendment to the Medicines Regulations 1984 to provide legal clarity- PIRA

Dear [redacted]

I have completed a PIRA for a proposed amendment to the Medicines Regulations which is being progressed on the advice of the High Court and Crown Law in order to provide legal certainty about the status of fluoride compounds used to treat community water supplies.

The Ministry's assessment is that the nature of the proposed change (it will not change current practice or policy settings) is such that the RIA requirements do not apply. The Ministry is therefore claiming a full exemption from the RIA requirements and seeking confirmation that Treasury supports this claim.

The PIRA, describing the proposal is attached .

Please note that I will be leaving the Ministry on 5 December and that James Caldwell will be the contact person from that date. Happy to discuss before then if necessary.

Kind regards,

[redacted]  
Regulatory Analysis and Delivery  
Medsafe  
Clinical Leadership, Protection & Regulation  
Ministry of Health  
[redacted]

<http://www.moh.govt.nz>

[redacted] \*@windle@moh.govt.nz

\*\*\*\*\*

\*

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RECEIVED

16 JAN 2015

Office of the  
BY: Hon. Dr Jonathan Coleman

Health Report number: 20141620

File number: AD55-01

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

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

# 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 ☒ 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 ☒ Yes ☐ No
- d) **Sign** the enclosed Cabinet paper that is intended for consideration by Cabinet when it meets on 27 January. Yes/No ☒ 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 ☒ 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.



## **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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Sent by:

25/11/2014 12:21 p.m.

To: [info@nzma.org.nz](mailto:info@nzma.org.nz),  
cc:  
bcc:

Subject: Consultation document: Proposed amendment to the Medicines Regulations 1984 re fluoride in drinking water

Dear

I would like to draw the attention of the NZMA to a consultation doc published today on the Medsafe website at :

<http://www.medsafe.govt.nz/consultations/medicine-regulations-fluoride-in-drinking-water.asp>

The closing date for submissions is 9 January 2015.

Kind regards,

Principal Advisor Regulation  
Regulatory Analysis and Delivery  
Medsafe  
Clinical Leadership, Protection & Regulation  
Ministry of Health  
021-04 819 6892

<http://www.moh.govt.nz>

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Sent by:  
comms@watarnz.org.nz

05/12/2014 09:39 a.m.

To: <technical@watarnz.org.nz>  
cc: Susan Martin  
bcc:

Subject: Re: Consultation on proposed amendment to Medicines Regulations re fluoride in drinking water - submissions close 9 January 2015

Hi

We can put this in our e-newsletter which goes out on December 18. We will also publicise it through our social media.

Kind regards

L

**From:** [Susan Martin](#)  
**Sent:** Friday, 5 December 2014 9:32 a.m.  
**To:** L  
**Cc:** Susan Martin  
**Subject:** Consultation on proposed amendment to Medicines Regulations re fluoride in drinking water - submissions close 9 January 2015

Hi L

We wondered if the following may be able to be sent to your members in case any are interested in making a submission.

Kind regards -

Manager  
Environmental & Border Health  
Public Health  
Clinical Leadership, Protection & Regulation  
Ministry of Health  
DDI: C  
Mobile:

The Ministry of Health is seeking submissions, **by 9 January 2015**, on a proposed amendment to the regulations (Medicines Regulations 1894) made under the Medicines Act 1981. The proposed amendment would have the effect of providing legal clarity that the fluoride substances used to treat drinking water are not medicines.

The proposal is in response to a recent court case which found: *In the recent judgement the High Court dismissed the plaintiff's claim that HFA and SSF properly come within the definition of "medicine" and recommended use of regulation-making powers under the Act to exempt HFA and SSF from being medicines for the purposes of the Act. This would serve to provide greater clarity about the issue by removing any possible ambiguity and would also regularise the status quo as*

*regards the use of HFA and SSF in water fluoridation.*

The consultation link is on the Medsafe website and is also being provided to local government, DHB public health units, the New Zealand Dental Association and the New Zealand Medical Association:  
<http://www.medsafe.govt.nz/consultations/medicine-regulations-fluoride-in-drinking-water.asp>

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Sent by: f OH  
05/12/2014 07:54 a.m.

To: PHU managers, Medical Officers of Health,  
cc: Susan M. [redacted] William Reinger/MOH@MOH Stewart  
[redacted]  
[redacted]  
[redacted]  
bcc:

Subject: Consultation paper on proposed amendment to Medicines Regulations re  
fluoride in drinking water - submissions due 9 January 2015

Dear colleagues

**Please forward to any colleagues who may be interested. Please encourage submissions from relevant staff (following appropriate DHB and public health unit protocols).**

The Ministry of Health is seeking submissions, **by 9 January 2015**, on a proposed amendment to the regulations (Medicines Regulations 1894) made under the Medicines Act 1981. The proposed amendment would have the effect of providing legal clarity that the fluoride substances used to treat drinking water are not medicines.

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<http://www.medsafe.govt.nz/consultations/medicine-regulations-fluoride-in-drinking-water.asp>

Kind regards - Sally

Manager  
Environmental & Border Health  
Public Health  
Clinical Leadership, Protection & Regulation  
Ministry of Health  
061 331 3333  
[redacted]





Sent by:  
comms@watarnz.org.nz  
05/12/2014 09:39 a.m.

To: <technical@watarnz.org.nz>, <...@moh.govt.nz>  
Cc: Susan Martindale, <...@moh.govt.nz>  
bcc: ...

Subject: Re: Consultation on proposed amendment to Medicines Regulations re fluoride in drinking water - submissions close 9 January 2015

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Kind regards

L

From: ...  
Sent: Friday, 5 December 2014 9:32 a.m.  
To: L  
Cc: Susan Martindale, <...@moh.govt.nz>  
Jc  
Subject: Consultation on proposed amendment to Medicines Regulations re fluoride in drinking water - submissions close 9 January 2015

Hi L

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Kind regards -

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Manager  
Environmental & Border Health  
Public Health  
Clinical Leadership, Protection & Regulation  
Ministry of Health  
DDI: ...  
Mobile: ...

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*regards the use of HFA and SSF in water fluoridation.*

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<http://www.medsafe.govt.nz/consultations/medicine-regulations-fluoride-in-drinking-water.asp>

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