



Submission to Consultation on Proposed Amendment to Regulations
under the Medicines Act 1981 - Fluoride (2014)

askmedsafe

08/01/2015 04:33 p.m.

History:

This message has been replied to.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act
1981 – Fluoride (2014)

Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
Wellington 6145

“It is proposed that a new regulation be made under section 105(1)(i) that:

Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies.” Medsafe

Name
Email
Address:

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to “first do no harm”
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines.

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are **not** used to ‘**treat**’ community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**.

I do not wish to speak to my submission.

Western Australia 6511

IS





Act 1981-Flouride (2014)

to: askmedsafe@moh.govt.nz

08/01/2015 04:41 p.m.

History:

This message has been replied to.

As someone, sensitive to all forms of fluorides, I beg you to please personally speak with some of those writing to you, to not do this. Because I recently underwent a very rapid, extensive biochemical detoxification of my neural pathways and completely lost all the severe ADD and ADHD and all kinds of other health issues, you cannot in all consciousness. Do not do this. Please!

It took me 41 years to research and discover fluoride was the cause. It was an answered prayer when I so miraculously recouped my abilities. I know for a fact, I have hypothyroidism because fluoride is so ionically active, iodine cannot compete with the other bromide. Hence the thyroid receptors sites get cemented over with fluoride.

Please call me. I am not a zealot...I am only one of the many who have had to learn the hard way about the extreme harmfulness of this toxin. It is a bioaccumulative building up in tissue. Everyone has their own toxic level. Once this point has been reached, one sip of fluoridated water, or a shower will take you over the limit of tolerance.

Please. Contact me at ; u can ask me about anything. I can tell you the other many medical conditions which were fluoride induced. My name in I know you are someone who recognized the gravity of your position. You have a huge responsibility for making decisions which will effect the lives and health of do many. Children's cells, particularly the brain are like sponges. They are harmed the very most...way, way past the threat of having caries.

Comment re. NZ Ministry of Health proposal to exempt fluoridation chemicals from the Medicines Act

January 7, 2014

Name: C

Email: c@... ..

Address:

USA

Question 1. Do you support the proposed amendment?

NO, I do not support the proposed amendment.

If not why not?

I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine
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Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds, when added to community water supplies, is to treat people, not to treat water.

I do not wish to speak to my submission.

Post to:

Regulations under the Medicines Act 1981 Consultation

Medsafe

Clinical Leadership Protection & Regulation

Ministry of Health

PO Box 5013

Wellington 6145

Email to: askmedsafe@moh.govt.nz





: askmedsafe

08/01/2015 04:49 p.m.

History:

This message has been replied to.

I do not support the proposed amendment because:

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3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people. Fluoride in drinking water has been banned in most EU countries due to evidence of health problems that it causes, this must be analysed in New Zealand environmental and health making policies.

Regards



**Submission to Consultation on Proposed Amendment to Regulations
under the Medicines Act 1981 - Fluoride (2014)**

to: askmedsafe

08/01/2015 04:50 p.m.

History: This message has been replied to.

SUBMISSION FORM

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

**Submission to Consultation on Proposed Amendment to Regulations under the
Medicines Act 1981 – Fluoride (2014)**

"It is proposed that a new regulation be made under section 105(1)(i) that:

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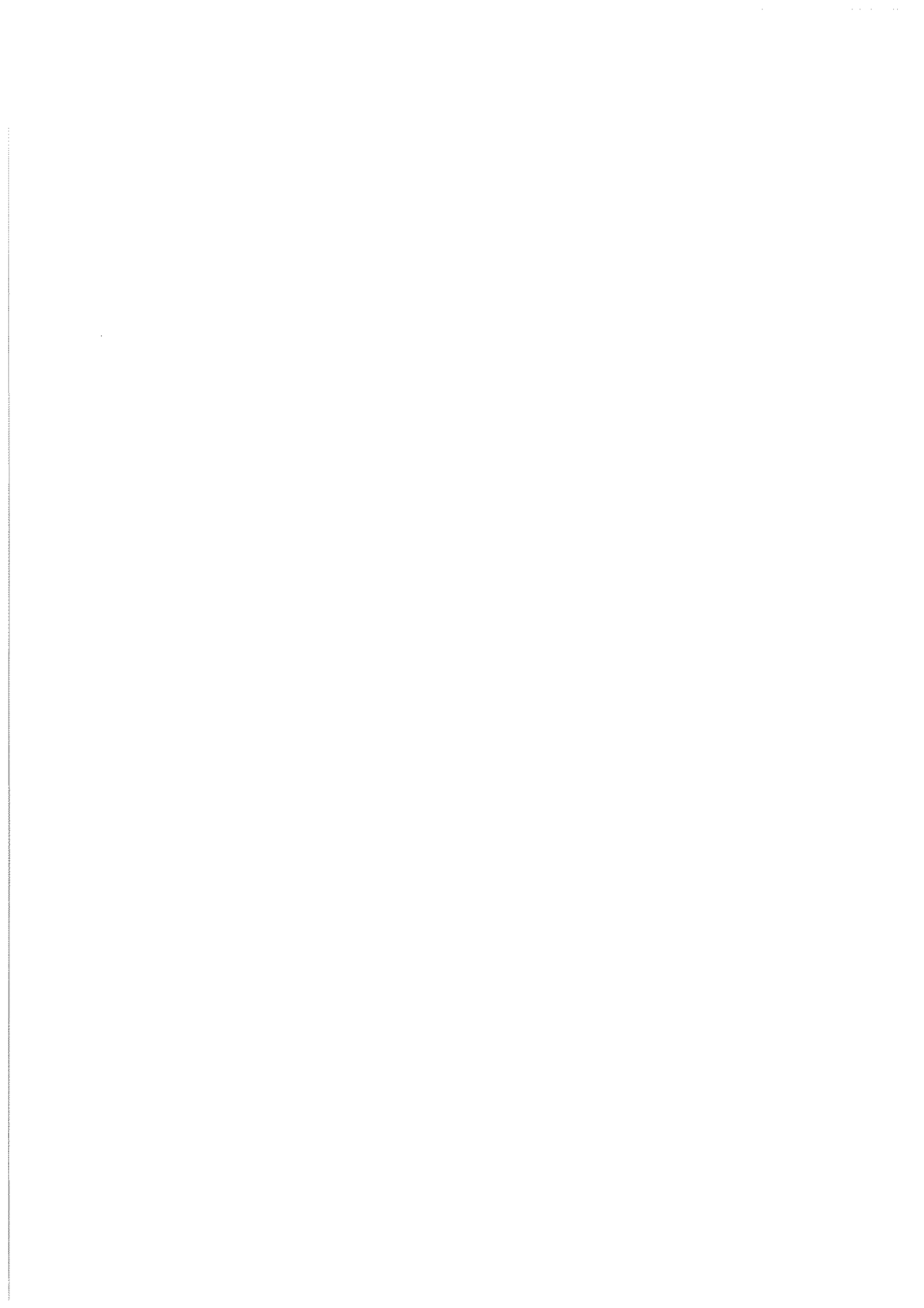
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General Information

I moved to Onehunga to get away from fluoridation of my water supply. I do not wish this right to be taken away from me.

I do not wish to speak to my submission.





Fluoridation Submission

askmedsafe

08/01/2015 05:06 p.m.

... response

History: This message has been replied to.

SUBMISSION FORM

I DO NOT (delete whichever does not apply) give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

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Name:

Email:

Address:

-

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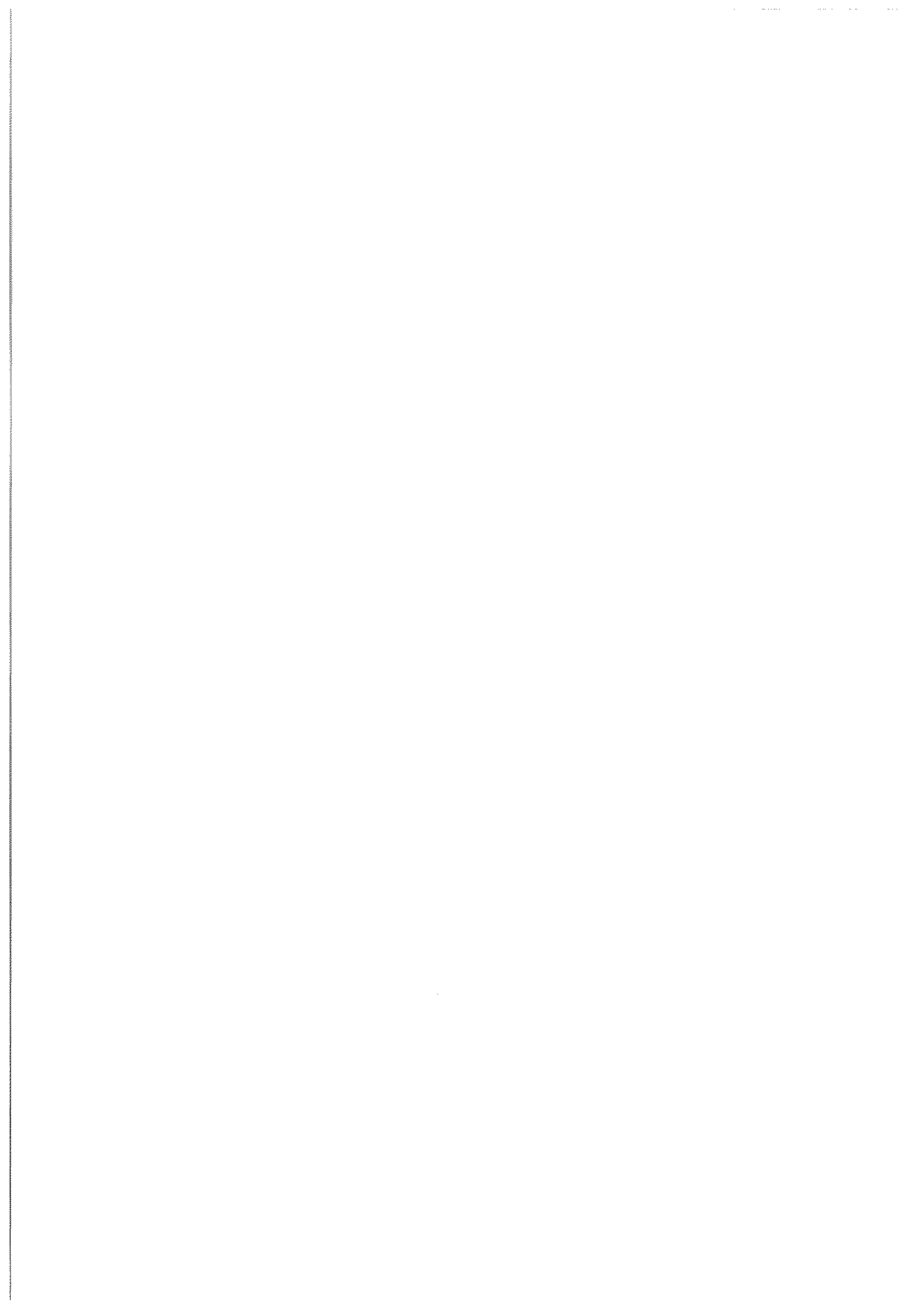
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Post to:

Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
Wellington 6145

Email to: askmedsafe@moh.govt.nz





Fluoride submission

askmedsafe@moh.govt.nz

08/01/2015 05:29 p.m.

Please respond

History: This message has been replied to.

SUBMISSION FORM

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Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

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Email: I

Address

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NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

The question we should be asking here is why is the MoH even considering this as a proposal?

I do wish to speak to my submission.

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fax: .

mob: .



**Submission to Consultation on Proposed Amendment to Regulations
under the Medicines Act 1981 - Fluoride (2014)**

taskmedsafe

08/01/2015 06:05 p.m.

History: This message has been replied to.

Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
Wellington 6145

SUBMISSION FORM

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**Submission to Consultation on Proposed Amendment to Regulations under the
Medicines Act 1981 – Fluoride (2014)**

“It is proposed that a new regulation be made under section 105(1)(i) that:
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supplies.” Medsafe

Name:

Email:

Address:

USA

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NO. I do not support the proposed amendment because:

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2. Fluoride is added to the water as treatment for the disease of dental caries; therefore, it is a medicine.
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to “first do no harm.”
4. The proposed amendment would effectively remove the safety precaution protecting people from harm, thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines.

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are **not** used to ‘**treat**’ community water supplies. In

community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people. What's more, fluoride is dangerous and has been shown to produce dental fluorosis, lower I.Q., and increase the risk of osteosarcoma, among other adverse effects. Medicating people without their consent is unethical.**

I do not wish to speak to my submission.



Fluoride Submission

: askmedsafe

08/01/2015 05:49 p.m.

History:

This message has been replied to.

SUBMISSION FORM

I / do not (delete whichever does not apply) give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

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NO. Fluoride and its compounds are **not** used to ‘**treat**’ community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I / do not (delete whichever does not apply) wish to speak to my submission.

I do not approve of this governments socialist/liberal engineering policies as they will only lead us into the fiascos being experienced by the European countries



**Fluoride**

3

08/01/2015 06:12 p.m.

History:

This message has been replied to.

Dear Sir,

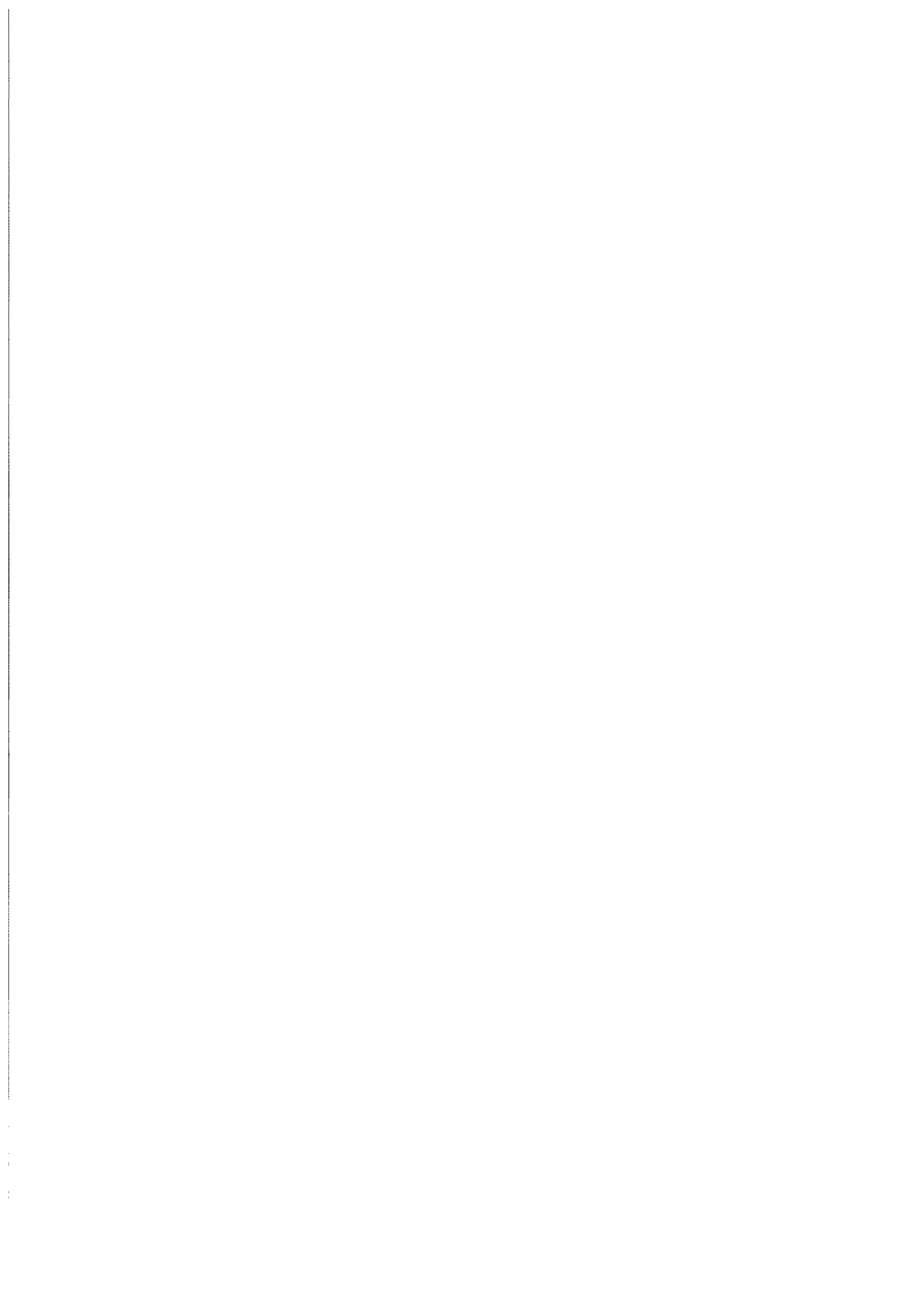
I would ask you to make a simple submission regarding the exemption of fluoride containing chemicals from the Medicines Act.

Fluoride as an addition to community water supplies has been consistently shown to significantly reduce the incidence of dental caries in the population and at the levels used is a safe and effective way of achieving this.

New Zealand has many water supplies that are suitable for this type of addition and it should be available to all water authorities to use it. Exemption from the medicines act will allow the authorities to add the appropriate chemicals if there is a general consensus of that area's population to request it. Guidance from the MOH should encourage the authorities to add the fluoride until such times as the Government makes a wider decision to take the process away from local authorities and add fluoride to all suitable water supplies nationally.

Thank You,

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Name: I

Email:

Address: 2

I, USA

Te

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NO. Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**
I do not wish to speak to my submission. Although I would be available for a tel call

Post to:

Regulations under the Medicines Act 1981 Consultation

Medsafe

Clinical Leadership Protection & Regulation

Ministry of Health

PO Box 5013

Wellington 6145

Email to: askmedsafe@moh.govt.nz

Just a short note in addition:

I was born and raised in the UK and in the 70's saw the introduction of mass Fluoridation to the water system, At the time I couldn't understand why a small minority of "cranks" as I thought of them then would oppose mass fluoridation, after all the doctors and medical officials were all for it and it all seemed to make sense. However 40 years later I now see the folly of my ways. I see the effects that fluoridation has had on my kids teeth, I have read the literature that proves it is non-sensical to force mass fluoridation on the public and I see how many advanced European and other countries banned fluoridation and have as good as rates of tooth decay, without the serious side effects of mass fluoridation.



Fluoride

to: askmedsafe

08/01/2015 06:25 p.m.

History:

This message has been replied to.

SUBMISSION FORM

I do not (delete whichever does not apply) give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

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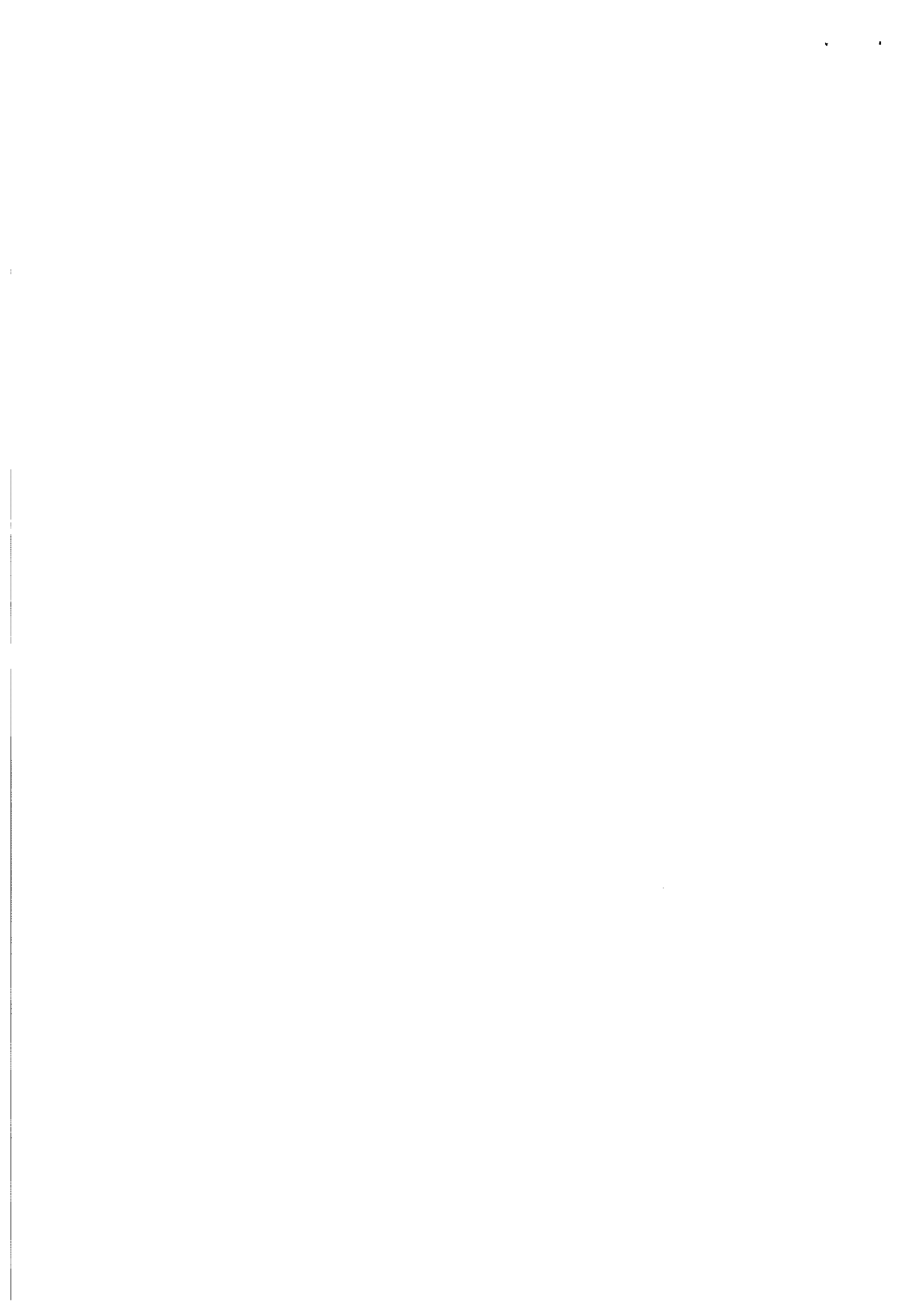
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I do (delete whichever does not apply) wish to speak to my submission.



H63

(duplicate of
1162)



Fluoride

1

.skmedsafe

08/01/2015 06:25 p.m.

History:

This message has been replied to.

SUBMISSION FORM

I do not (delete whichever does not apply) give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

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I do (delete whichever does not apply) wish to speak to my submission.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I / do not (delete whichever does not apply) give permission for my personal details to be released to persons under the Official Information Act 1982

I / do not (delete whichever does not apply) wish to speak to my submission

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Ministry of Health
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Wellington 6145

Email to: askmedsafe@moh.govt.nz

SUBMISSION FORM

Change proposal

It is proposed that a new regulation be made under section 105(1)(i) that:

Fluoride-containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purposes of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies.

Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

email (putting fluoride in the subject line): askmedsafe@moh.govt.nz

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Consumer
Question 1 <i>Do you support the proposed amendment? If not, why not?</i>	No. See attached submission below.
Question 2 <i>Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?</i>	N/A Do not support this regulation.

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you

consider should be properly withheld under this legislation, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

If information from your submission is requested under the Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box:

I do not give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

Submission against proposed amendment/regulation;

I submit that the proposal to exempt water fluoridation from the Medicines Act is a weak proposition. This could only be justified if all who presently promote the health benefits of water fluoridation were to cease doing so; however this seems unlikely. The Act is clear that any substance intended to treat a disease must be classified and regulated as a medication (more on this below).

Overview

My broad interpretation of the proposal is that it simply precludes one particular area of medical practice from future scrutiny and/or challenges. Such exemption from regulatory oversight is not promoted for any other class of medical treatment, for good reason! If this exemption were approved for fluoride, this would set a dangerous precedent for other low-dose chemicals to be approved as health treatments without regulatory oversight.

Medical practitioners are expected to uphold the highest standards of ethics and ongoing improvement of treatments and practices. This ongoing improvement requires open, frank discussion and debate regarding current practices.

An exemption of one class of substances from the relevant Act is therefore counter to the high standards to which the medical profession is expected to uphold.

The Medical Council of New Zealand states in its *Good medical practice: a guide for doctors*, a Doctor's "obligation to maintain and improve standards".

I expect that a modern profession, in a modern democratic society must welcome open debates about best practices. Therefore, if the medical profession were to be shielded from future criticism of fluoridation practices, the reputation of the medical profession will be devalued in my view.

Definitions of important terms

For reference, the Medicines Act provides definitions:

"medicine means any substance ... sold, or supplied wholly or principally - for administering to one or more human beings for a therapeutic purpose"

Therapeutic purpose includes - Treating or preventing disease.

Medsafe clarifies that “A product is regulated as a medical device or a medicine if the manufacturer or sponsor claims or implies a therapeutic purpose for it.”

Indeed a therapeutic purpose is claimed by the Ministry of Health for water fluoridation: “to prevent and reduce tooth decay”.

Definitions from the online Oxford English Dictionary are consistent with those above:

1. *Medication*: a drug or other form of medicine that is used to treat or prevent disease.
2. *Disease*: a disorder of structure or function in a human, animal, or plant, especially one that produces specific symptoms or that affects a specific location and is not simply a direct result of physical injury.
3. *Treatment*: Medical care given to a patient for an illness or injury.

Given these definitions, fluoridation of potable water is undoubtedly a medication; the sole purpose being to treat the disease of tooth decay. Therefore there is no reasonable justification for fluoride compounds to be exempted from regulatory oversight. The Act must apply and no exemption can be reasonably justified.

Low Concentration Claims

The low concentration of fluoride in potable water is irrelevant to the issue of regulation, given the declared intention of adding this substance to the water; to treat disease. The fluoride compounds serve no other purpose; they do not substantively kill microbes in water, enhance the flavour, the colour/clarity or the odour of the water. The sole purpose of these fluoride substances are to treat a disease in people who consume the water. If fluoride were for a non-medicinal purpose (eg water clarity), then it would be natural for the Medicines Act not to apply. But given the explicit medical treatment intention of fluoridated water supplies, the Medicines Act must apply.

It is interesting to note the use of the term ‘concentration’ by fluoride advocates, when all other medications are controlled by the ‘dose’ administered. These terms are not equivalent and the ‘low concentration’ claims are therefore misleading. The problem is that the dose received by people varies greatly with their personal diet and cannot be controlled by those administering the fluoride. I suggest that such uncontrolled dosage would not be accepted for any other medication substance; all the more reason for strong medical oversight of this practice.

It is reasonable to expect that suitably qualified public servants must oversee this disease treatment protocol and be accountable to the public which they serve. An essential aspect of this oversight is the Medicines Act 1981; fluoride compounds must therefore not be exempted.

Not an Essential Element

A recent review of fluoride by the European Commission’s Scientific Committee on Health and Environmental Risks (SCHER) stated that:

"Fluoride is not essential for human growth and development."

SOURCE: European Commission. (2011). Critical review of any new evidence on the hazard profile, health effects, and human exposure to fluoride and the fluoridating agents of drinking water. Scientific Committee on Health and Environmental Risks (SCHER).

I am aware of other publications showing benefits for fluoride intake; however this does not qualify fluoride as an essential element for the human body.

Fluoride is not an essential nutrient for the human body; no tissue or cellular process requires fluoride. Given this fact, it is reasonable to expect fluoride to be appropriately regulated as a medication, regardless of its concentration or dose. The deliberate act of administering fluoride to people qualifies it as essential to be regulated by trained medical professionals.

Patient Rights

Every person who drinks fluoridated water instantly becomes a patient receiving treatment; this includes New Zealand citizens and visitors alike. Given that a medical treatment [prevention/treatment of tooth decay] is being employed, these individuals automatically attain patient rights:

The New Zealand Health and Disability Commissioner lists the fundamental rights for patients in receiving health care. Right number seven states that "It is your decision whether to go ahead with treatments [eg. fluoridation] or not and you are able to change your mind at any time." This is commonly known as 'the right to choose'. All medical professionals are bound by this code of ethics. I expect that those reviewing this amendment also be bound by this code of ethics.

The Medical Council of New Zealand states in its *Good medical practice: a guide for doctors*, item #32: "With rare and specific exceptions you should not provide treatment unless ... the patient consents to treatment."

I insist that the rights of those receiving medical treatments be upheld. Viable alternative medication delivery methods exist, which allow consumers their right to choose.

Hypothetical Scenario

Consider a new substance being promoted by some medical professionals to treat a widespread disease. They claim that it is a substance that everyone in the country should receive and that the exact dose received by each person doesn't really matter. The mystery substance is naturally-occurring, so the promoters request dispensation from the health regulations. (For clarity: 'naturally-occurring' is not equivalent to either 'essential' or 'safe'.)

They also claim that this disease is so devastating that people cannot be relied on to voluntarily take this treatment, even if the treatment were free; treatment should be mandatory. To support their claims, the promoters produce some research showing that this treatment produces small improvements in other populations who receive it.

As a new treatment, this would naturally fall under the regulation of the Medicines Act 1981 and the Ministry of Health.

Is this so different to the practice of fluoridation of municipal water supplies to treat an 'epidemic' of tooth decay? Why should this new hypothetical treatment be regulated, but not fluoridation of potable water supplies?

Conclusion

The only circumstances in which fluoride could be legitimately exempted from the Medicines Act 1981 would be for all claims of therapeutic action to cease. This would preclude the promotion of water fluoridation by the Ministry of Health, District Health Boards, Local Councils and all medical professionals in any form. If this were to happen, then fluoride compounds would not be regulated by the Act, as the promoters of this regulation amendment appear to desire.

I trust that the logic described above is sufficient to refute the arguments in favour of this proposed exemption for fluoride compounds.

Thank you for your time and consideration.



Fluoride Regulations Amendment

From: askmedsafe

08/01/2015 06:44 p.m.

History:

This message has been replied to.

SUBMISSION FORM

I do give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:

Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name:

Email:

Address:

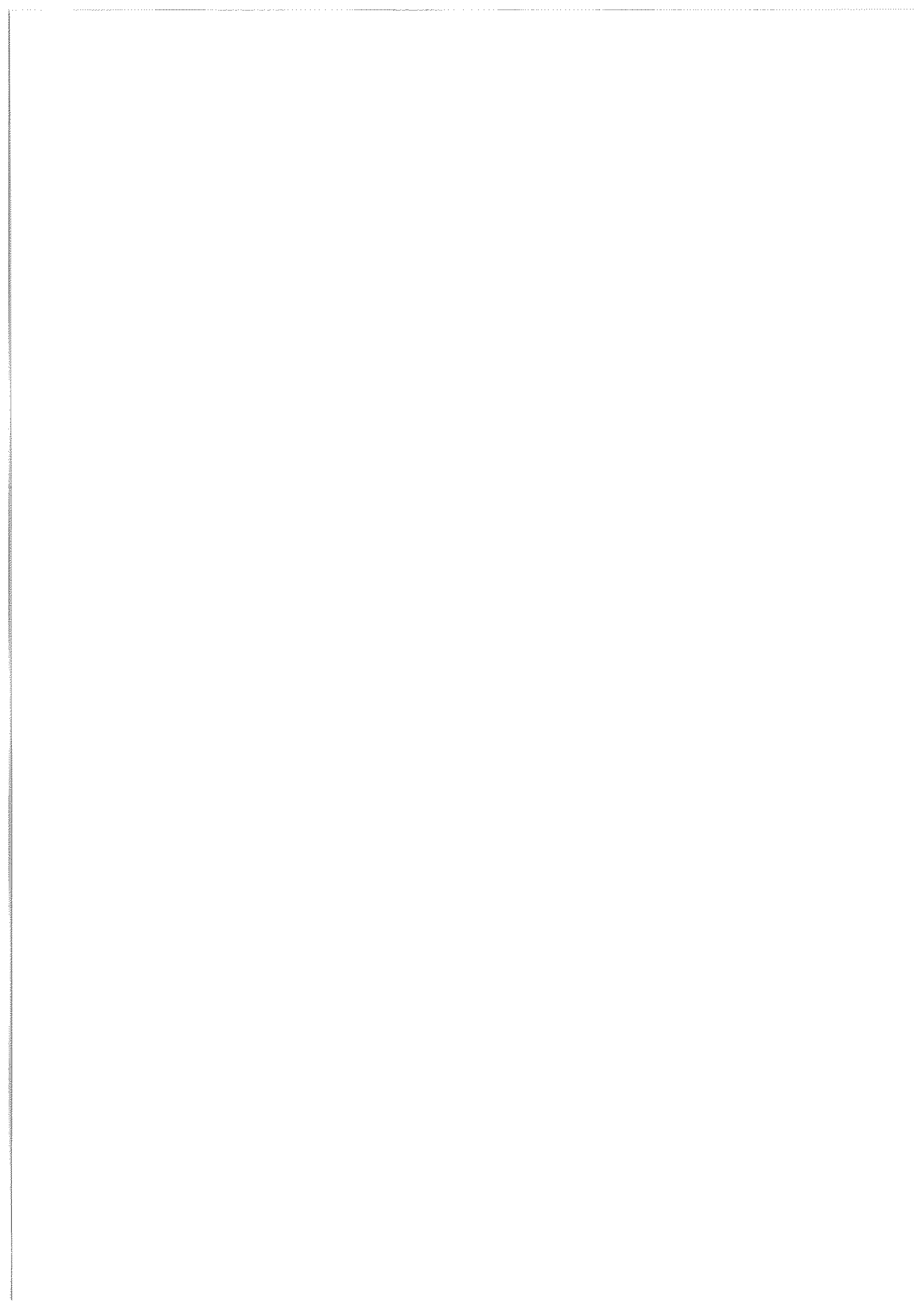
Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people





**Submission to Consultation on Proposed Amendment to Regulations
under the Medicines Act 1981 - Fluoride (2014)**

askmedsafe@moh.govt.nz

08/01/2015 06:52 p.m.

From:

To: "askmedsafe@moh.govt.nz" <askmedsafe@moh.govt.nz>

History: This message has been replied to.

SUBMISSION FORM

I do not (delete whichever does not apply) give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:

Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name

Email

Address

Question 1. *Do you support the proposed amendment? If not why not?*

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2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
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NO. Fluoride and its compounds are **not** used to 'treat' community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I do not (delete whichever does not apply) wish to speak to my submission.



**Submission to Consultation on Proposed Amendment to Regulations
under the Medicines Act 1981 - Fluoride (2014)**

askmedsafe

08/01/2015 06:55 p.m.

History:

This message has been replied to.

To
Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
Wellington 6145

SUBMISSION FORM

I do not give permission for my personal details to be released to persons under the Official Information Act 1982.

**Submission to Consultation on Proposed Amendment to Regulations under the
Medicines Act 1981 – Fluoride (2014)**

“It is proposed that a new regulation be made under section 105(1)(i) that:
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Name:

Email:

Address:

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NO. Fluoride and its compounds are **not** used to ‘**treat**’ community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat**

people.

I do wish to speak to my submission.

Kind Regards



**Submission to Consultation on Proposed Amendment to Regulations
under the Medicines Act 1981 - Fluoride (2014)**

askmedsafe@moh.govt.nz

08/01/2015 07:06 p.m.

History: This message has been replied to.

SUBMISSION FORM

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

“It is proposed that a new regulation be made under section 105(1)(i) that:

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Name:

Email:

Address

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I do not wish to speak to my submission.





No to water fluoridation

: askmedsafe

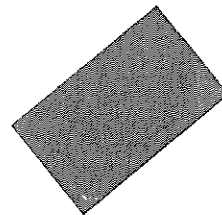
08/01/2015 07:29 p.m.

History:

This message has been replied to.

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Name: [REDACTED]
 Email: [REDACTED]
 Address [REDACTED]



Question 1. *Do you support the proposed amendment? If not why not?*

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I do / do not (delete whichever does not apply) wish to speak to my submission.

Post to:

Regulations under the Medicines Act 1981 Consultation
 Medsafe
 Clinical Leadership Protection & Regulation
 Ministry of Health
 PO Box 5013
 Wellington 6145

This email has been checked for viruses by Avast antivirus software.
www.avast.com



fluoride

: askmedsafe

08/01/2015 07:33 p.m.

History: This message has been replied to.

SAFE WATER ALTERNATIVE NEW ZEALAND (SWANZ) Submission

Both sides have a genuine desire to improve the health of children's teeth and both sides agree that:

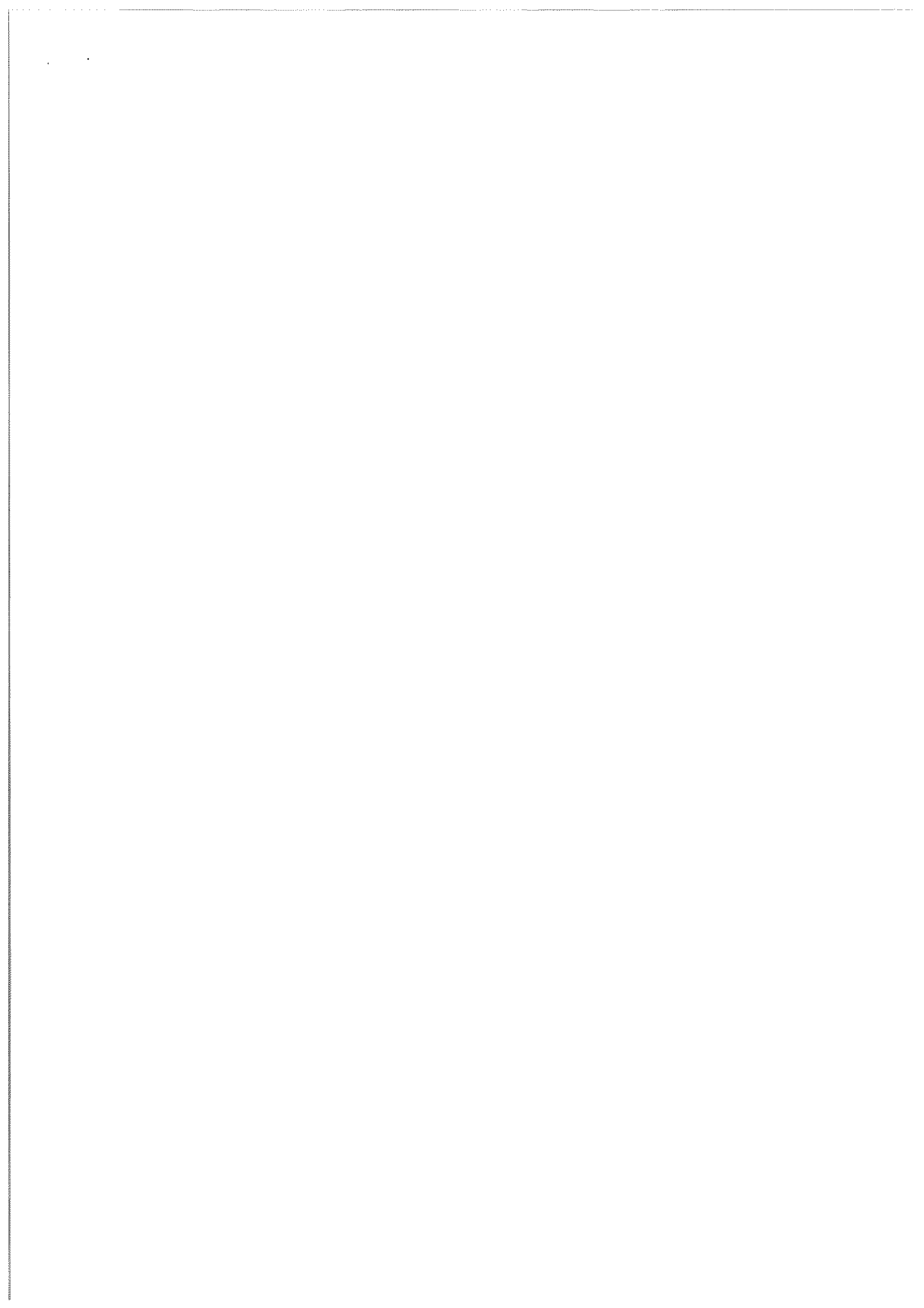
- Fluoride is most effective when applied directly to the teeth
- Poor diet and sugary drinks are the real cause of tooth decay in children
- Poor oral hygiene, i.e. the failure to brush teeth twice a day, is another major cause of tooth decay

On the weight of evidence presented at the Hamilton tribunal there were six factors that influenced the final decision to remove fluoride from the Council's water supply:

1. Application by toothpaste or other means that directly affect the tooth surface are much more effective at reducing tooth decay than fluoridation of water supplies.
2. Fluoridation is wasteful – of the 224 litres of water used by the average person each day, less than two litres is used for drinking – 99% goes down the drain (i.e. of the \$48,000 per year spent on fluoridation, only \$480 ends up being fit for purpose)
3. Communities around the world are rejecting the practice – most of Europe does not fluoridate.
4. There is strong evidence that fluoride should not be ingested at all by babies under six months old and bottle-fed babies are therefore at greater potential risk.
5. While fluoridation may have some benefits for some, it isn't good for everyone and fluoridation of the water supply affects personal choice. It is also cheaper for people to get fluoride as needed, and in an effective manner, than it is for people to avoid it from the public water supply.
6. Statistical evidence that fluoridation potentially causes harm.

Every study/review over the past 50 years has concluded more primary research is needed into the safety and efficacy of water fluoridation. Until that research has been done the issues around fluoridation will never be settled.

Co-ordinator SWANZ
Hamilton NZ





Submission Regulations under the Medicines Act 1981 Consultation

askmedsafe@moh.govt.nz

08/01/2015 07:36 p.m.

History:

This message has been replied to.

Regulations under the Medicines Act 1981 Consultation

Medsafe

Clinical Leadership Protection & Regulation

Ministry of Health

SUBMISSION FORM

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:

Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name:

Email: :

Address:

Question 1. Do you support the proposed amendment? If not why not?

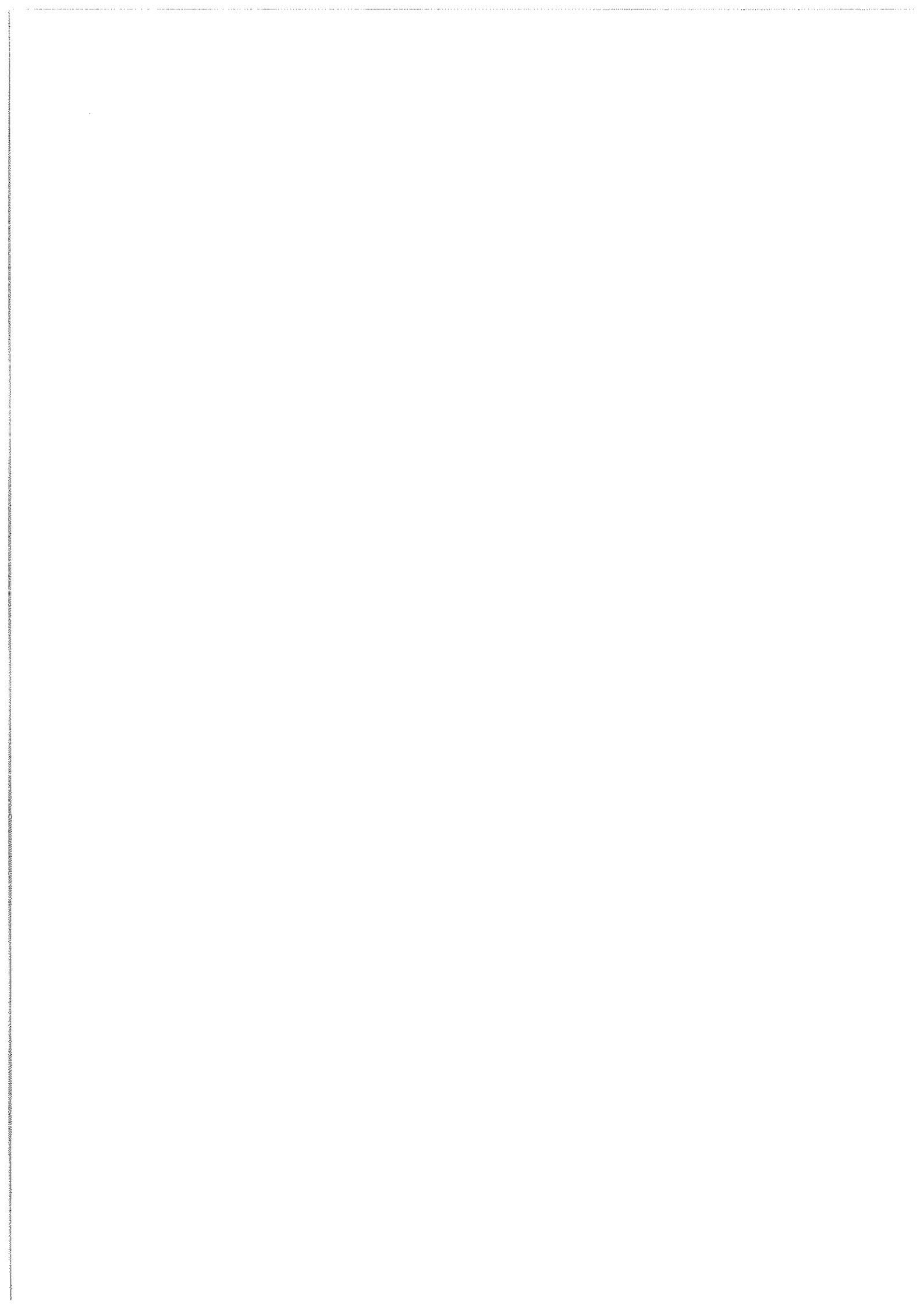
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NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission.



1172



fluoride & alzheimer's disease

j

to:

askmedsafe

08/01/2015 07:41 p.m.

Hide Details

From: " " " " " "

To: <askmedsafe@moil.gov.in> ,

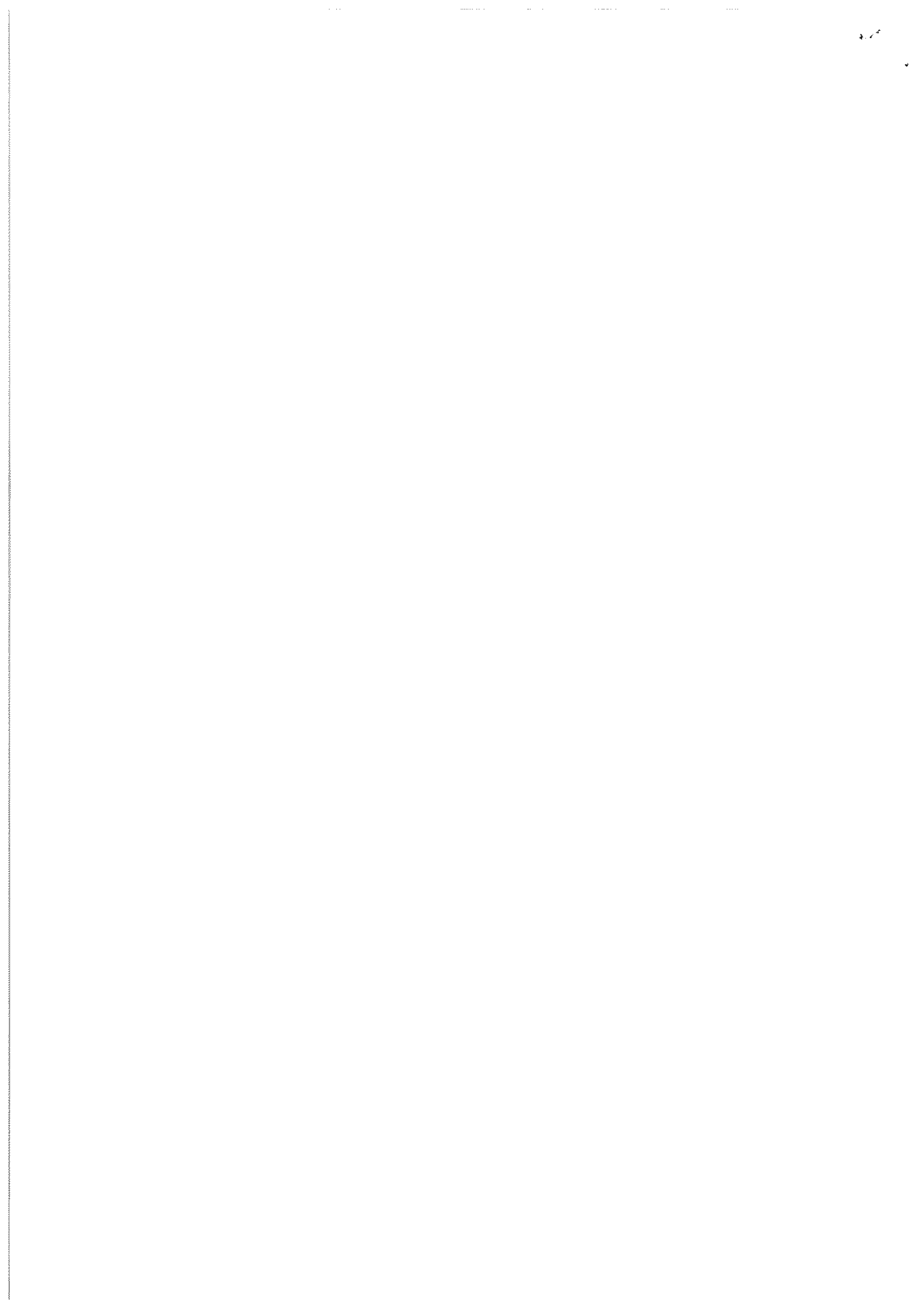
History: This message has been replied to.

1 Attachment



002.jpg

One of the many reasons fluoride should not be imposed on us in the water supply.



Alzheimer's Disease

On the increase – and often avoidable

There has been a staggering increase in Alzheimer's Disease (AD) in recent decades, mostly caused by Western governments. These 'authorities' have permitted and encouraged the doping of our water supplies with silicofluorides, which have been proven over and over again to cause AD (see *Chapter 19, Water Woes*).

The evidence against fluoridated water is compelling and has been a matter of public knowledge for nearly a century, yet we citizens in Western democracies sit back like sheep, permitting our governments to force us, through taxation, to pay for our own poison! Rather like the way the Chinese government makes family members pay for the bullet they use to execute their loved ones. Here, the middle class can afford to buy filters for their drinking water but the poor are on their own. Only the wealthy can afford the luxury of filtering their water at source so they will not have to bathe in a known neurotoxin.

I'm angry, and I don't apologise for that, and hope you agree with me that we shouldn't have to fight to keep hazardous wastes out of our water supply! We must protest, because nothing will break the government/industry stranglehold until we do.

Of course, silicofluoride is not the only cause of AD. The *December 1996* issue of *Neurology* reported on a study showing a substantially increased risk of AD in occupations which exposed workers to high levels of electromagnetic radiation. Such people will be well advised to find some way to protect themselves, as their risk is *four times higher than that of the general public* (see *Chapter 26, Remedies*). If on top of this risk, these workers are also exposed to fluoride, I don't like their chances.

Because we cannot see electromagnetic radiation, it is easy for governments and industry to 'pooh-pooh' concerns, and even make statements such as, "There is no peer-reviewed literature supporting these outlandish claims." But this is a bald-faced lie. *Neurology* is the official journal of the American Academy of Neurology, and is one of the most respected scientific journals in the world.





Fluoride? NO

skmedsafe

08/01/2015 07:43 p.m.

History:

This message has been replied to.

SUBMISSION FORM

I do give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

“It is proposed that a new regulation be made under section 105(1)(i) that: Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies.” Medsafe

Name:

Email:

Address:

Question 1. *Do you support the proposed amendment? If not why not?*

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Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are **not** used to ‘**treat**’ community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

*I do not wish to speak to my submission. **But I wish to add** that as a regular visitor to NZ, I have been very pleased to have water that tastes great, and does not cause health problems.*

SUBMISSION FORM

Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

Name:	<p style="text-align: center;">RDH BSC MPA</p> <p>President Elect International Federation of Dental Hygienists</p> <p>Dental Council of NZ for 6 years, currently Faculty at the University of Sydney School of Dentistry. Former Faculty at the University of Otago and Auckland University of Technology</p>
If this submission is made on behalf of an organisation, please name that organisation here:	Not submitting on behalf of an organisation
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Dental professional
<p>Question 1</p> <p><i>Do you support the proposed amendment? If not, why not?</i></p>	<p>NO</p> <p>Due to the availability of Topical fluoride compounds in toothpastes that are pure stannous fluoride and have been shown to be effective in the reduction of dental decay. HFA and SSF are byproducts of fertiliser production and consumers should not be subjected to being forced to swallow them in their drinking water. Long term effects are unknown and could prove detrimental/harmful to overall health.</p>

	These compounds should be classified as POISONS if anything, and certainly not deregulated
<p>Question 2</p> <p><i>Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?</i></p>	<p>NO. All fluoride compounds should remain classified as medicines.</p> <p>Please refer to this website.</p> <p>http://fluoridealert.org/articles/50-reasons/</p> <p>Even the US FDA classifies fluoride as a DRUG!!!!</p> <p>Declassifying this element is madness!!</p>

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you consider should be properly withheld under this legislation, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

If information from your submission is requested under the Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box:

- I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

SUBMISSION FORM

I do not give permission for
my personal details to be released to persons under the Official
Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:

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medicines for the purpose of the Act when they are manufactured and
supplied or distributed for the purpose of fluoridating community water
supplies." Medsafe

Name:

Email:

Address:

Question 1. Do you support the proposed amendment? If not why not?

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every New Zealander to be safe from the indiscriminate use of medicines

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specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the
purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission.



Submission

o: askmedsafe

08/01/2015 08:03 p.m.

From:

To: askmedsafe@minh.govt.nz,

History: This message has been replied to.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

“It is proposed that a new regulation be made under section 105(1)(i) that: Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies.” Medsafe

Name: .

Email .

Address: .

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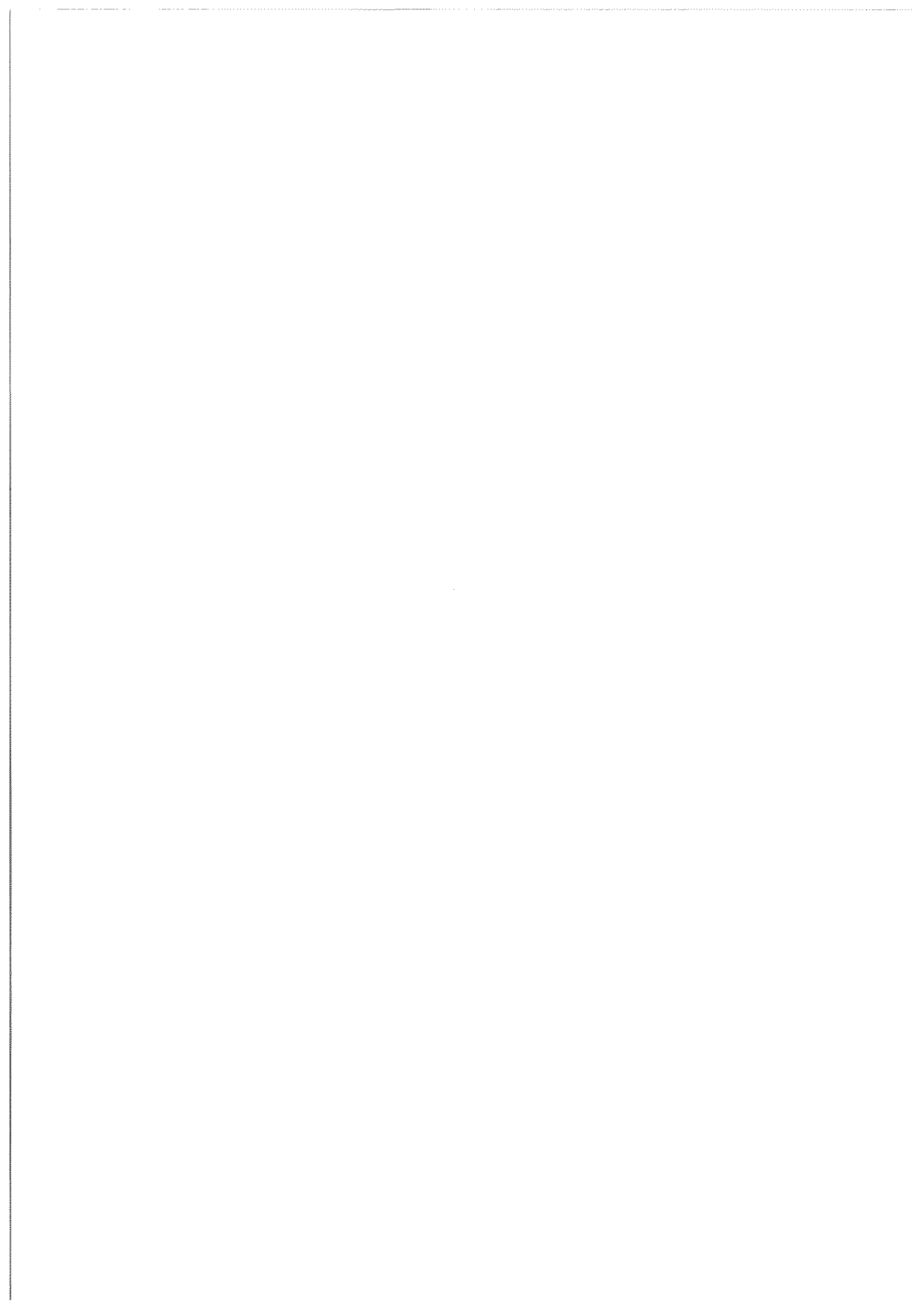
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--

Cheers





fluoride should NOT be allowed an exemption under NZ law

1 to: askmedsafe

08/01/2015 08:05 p.m.

History: This message has been replied to.

SUBMISSION FORM

I do give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

“It is proposed that a new regulation be made under section 105(1)(i) that: Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies.” Medsafe

Name: C
 Email:
 Address:

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I do not wish to speak to my submission.

yours faithfully,

has seen decreasing levels of dental decay in children.



Submission Proposede Amendment Fluoride/Medicines Act....

o: askmedsafe

08/01/2015 08:16 p.m.

History:

This message has been replied to.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

**Submission to Consultation on Proposed
Amendment to Regulations under the Medicines Act
1981 – Fluoride (2014)**

"It is proposed that a new regulation be made under section 105(1)(i) that:

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Nam

Email:

Address

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Post to:
Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
Wellington 6145

Email to: askmedsafe@moh.govt.nz



Fluoridation of Water Supplies in NZ
askmedsafe

08/01/2015 08:20 p.m.

History: This message has been replied to.

SUBMISSION FORM

I do not give permission for my personal details to be released to persons under the Official Information Act 1982
Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

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History: This message has been replied to.

SUBMISSION FORM

I do give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

“It is proposed that a new regulation be made under section 105(1)(i) that:

Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies.” Medsafe

Name

Ema

Address

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to “first do no harm”
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are **not** used to ‘**treat**’ community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I do not wish to speak to my submission.

I do give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

“It is proposed that a new regulation be made under section 105(1)(i) that:

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Name

Email

Address

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Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission.

Sincerely,

Post to:
Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
Wellington 6145

Email to: askmedsafe@moh.govt.nz



#1181
Duplications

Part 2 of 1181
~~1315~~

SUBMISSION FORM

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

Name: I
Email: ''
Address

Question 1. Do you support the proposed amendment? If not why not?

NO. I do not support the proposed amendment because:

1. A medicine is not defined by the dose used, but by the purpose for which it is administered -in this case these chemicals are added to the public water supply to treat dental disease. That makes fluoridating chemicals medicines.

In the last few years NZ health authorities have gone to some extraordinary lengths to continue their support and promotion of the outdated, unscientific and unethical practice of water fluoridation. But now they have reached a new low in their public relations tactics. They are attempting to change the language itself. Under the NZ Medicines Act they are trying to maintain that fluoride is a medicine in tablet form but not at the concentrations used in water fluoridation programs. But this is absurd. A medicine is not defined by the dose used, but by the purpose for which it is administered

If one looks up the word "medicine" in any major dictionary in the English language the definition is very simple and clear. A medicine is "a substance that is used to treat, prevent or mitigate a disease." In other words it is defined by its purpose. It is not defined by the dose used or even by whether it works or not.

Fluoride chemicals (HFA, SFA, NaF) are added to the water supply – in the few countries that practice water fluoridation – in order to fight tooth decay, which is a disease.

See,
Caries as a Disease of Civilization (Chapter XI, Blackwell Scientific Publications, The physiology and biochemistry of the mouth (4th Ed) by G Neil Jenkins)

This makes these fluoride compounds medicines by universal definition. To claim that somehow these are no longer medicines in the doses delivered via water fluoridation is nonsense. Assuming that fluoride at some higher dose was considered by NZ's Medicines' Act was a medicine, lowering the dose to a level of approximately 1 ppm used in water fluoridation could do two possible things:

a) it could lower its effectiveness and b) it could reduce its toxic side effects, but it would not change the purpose for which these substances were added to the water supply. At whatever dose used in tablet form, or whatever the concentration added to water (0.6 ppm, 0.7ppm, 1.0 ppm or 1.2 ppm) the purpose remains the same: to fight tooth decay. Therefore they remain medicines and water fluoridation remains medical treatment.

For the NZ Ministry of Health to attempt to change the definition of fluoride as used in water fluoridation from anything else but a medicine would make its support of this unscientific and unethical practice even more embarrassing than it already is. The effort to change the language itself represents the last desperate exercise in the application of arbitrary governmental power in support of a bankrupt policy. Clearly reason and scientific argument have failed. It is consistent with a series of steps taken recently in NZ to keep the practice of water fluoridation going at all costs.

2. Fluoride is not a water treatment chemical to treat the water (like chlorine) but simply to use the water supply to deliver medical treatment.

3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"

4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission

1182

~~1782~~



Re: Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 ? Fluoride (2014)

askmedsafe

09/01/2015 10:02 a.m.

History: This message has been replied to.

Corrections made. Thanks.

~~-----

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On 2015-01-08, at 12:09 PM, askmedsafe@moh.govt.nz wrote:

Thank you for your submission

<Mail Attachment.gif>

From: _____
To: askmedsafe@moh.govt.nz, _____
Date: 08/01/2015 08:29 p.m.
Subject: Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

I do give permission for my personal details to be released to persons under the Official Information Act 1982
Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name: _____
E-mail: _____

Address: _____

Question 1. *Do you support the proposed amendment? If not why not?*

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NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF), the purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission.

Post to:

Regulations under the Medicines Act 1981 Consultation

Medsafe

Clinical Leadership Protection & Regulation

Ministry of Health

PO Box 5013

Wellington 6145

▼▼

Statement of confidentiality: This e-mail message and any accompanying attachments may contain information that is IN-CONFIDENCE and subject to legal privilege.

If you are not the intended recipient, do not read, use, disseminate, distribute or copy this message or attachments.

If you have received this message in error, please notify the sender immediately and delete this message.

This e-mail message has been scanned for Viruses and Content and cleared by the Ministry of Health's Content and Virus Filtering Gateway

**SUBMISSION FORM**

: askmedsafe

08/01/2015 08:46 p.m.

History:

This message has been replied to.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that: Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name: -

Email.

Address

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I do not wish to speak to my submission.



Consultation on Proposed Amendment to Regulations under the Medicines Act 1981

: askmedsafe

08/01/2015 08:51 p.m.

History: This message has been replied to.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:

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Name ***

Email

Address:

Question 1. *Do you support the proposed amendment? If not why not?*

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NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission.

	<p>effective. Certainly not allowing fizzy or fruit juice at school would be a start.</p> <p>What about healthy people who drink a lot of water. They don't want that much fluoride passing through their system. It is bound to cause health problems in some people. It is a poison in high doses.</p> <p>This is a sticking plaster health solution rather than a real cure! Mouth hygiene by way of proper care and cleaning and lifestyle low sugar diet choices is the real solution.</p> <p>I can't help thinking this seems to be a solution to assist 'laziness', especially of some parents.!</p> <p>Please don't allow fluoride to be put in Christchurch's pure artesian water. If you do, I will be going back to the well.</p>
<p>Question 2</p> <p><i>Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?</i></p>	<p>No fluoride containing compounds should be in Christchurch water supplies.</p>

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you consider should be properly withheld under this legislation, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

If information from your submission is requested under the Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box:

- I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.



FW: Submission

askmedsafe@moh.govt.nz

08/01/2015 09:05 p.m.

From:

To: "askmedsafe@moh.govt.nz" <askmedsafe@moh.govt.nz>

History: This message has been replied to.

Submission from

Subject:

SUBMISSION FORM

I/ do not (delete whichever does not apply) give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that: Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name:**Email:****Address:**

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

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2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
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Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are **not** used to 'treat' community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I do / do not (delete whichever does not apply) wish to speak to my submission.

Email to: askmedsafe@moh.govt.nz





submission

askmedsafe

08/01/2015 09:16 p.m.

History: This message has been replied to.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982
 Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:

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Name:

Email:

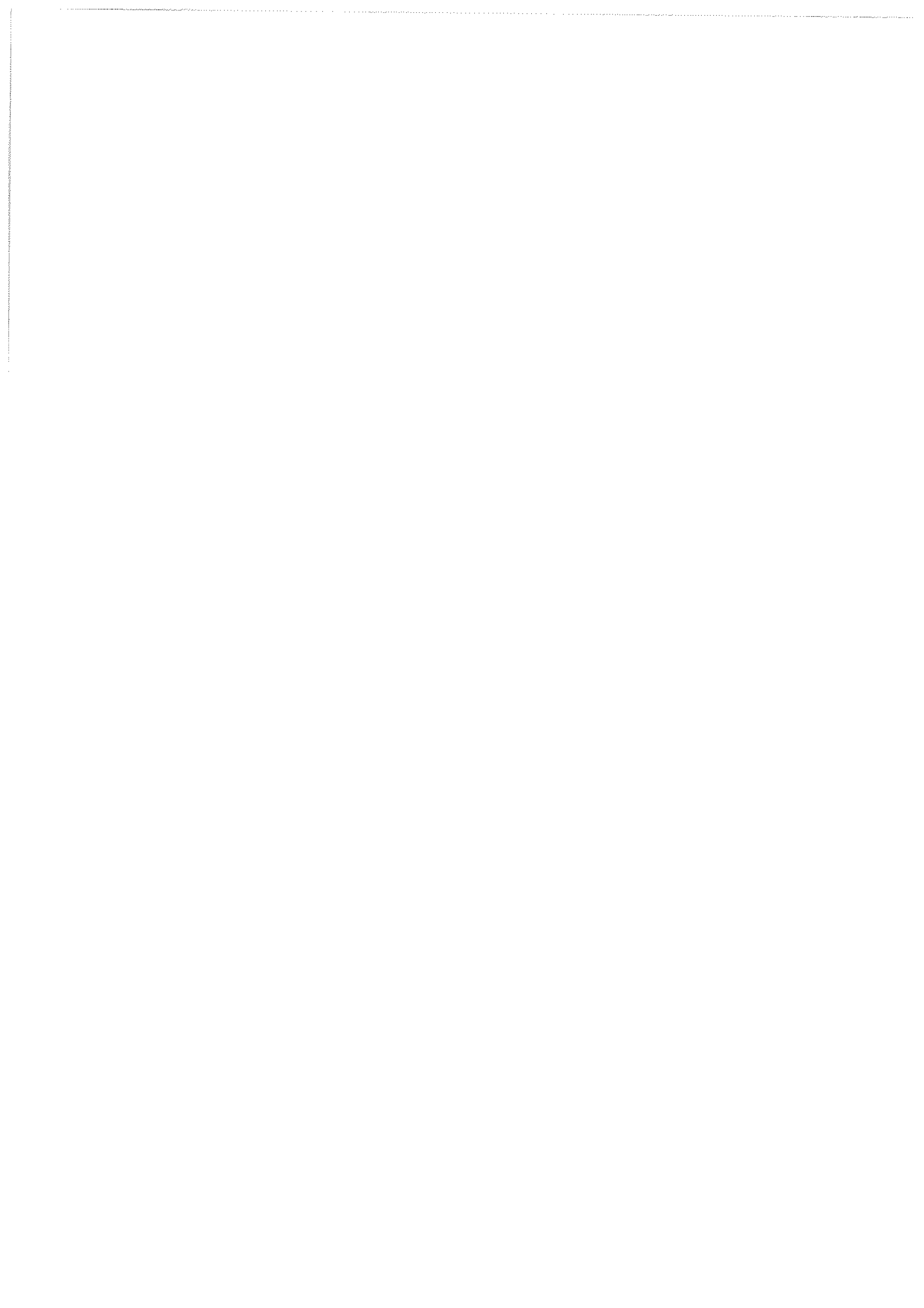
Address:

Question 1. Do you support the proposed amendment? If not why not?
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NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people
 I do not wish to speak to my submission.



**Fluoride - Medicines Act Amendment Submission**

to: askmedsafe

08/01/2015 09:17 p.m.

History: This message has been replied to.

Written Submission from

I do not give permission for my personal details to be released to persons under the Official Information Act 1982.

I am an individual who bitterly opposes the addition of fluoridation chemicals to drinking water, and oppose any attempt to make any of those chemicals exempt from the Medicines Act.

Consultation on Proposed Amendment to Regulations under the Medicines Act 1981

I am 100% opposed to any attempt to exempt fluoride chemicals from the Medicines Act.

I am stunned that the Ministry of Health is attempting to manipulate their own stringent guidelines for therapeutic substances. For many years, the MoH has sought to make a medicine out of anything that attempts to claim a therapeutic effect. If any natural nutritional substance makes any claim of benefit, the MoH jumps up and down.

Yet in this case, the MoH is wanting the law to state that fluoride chemicals be exempt from the heavily promoted therapeutic claim for reducing dental cavities. That is exactly the type of therapeutic claim the MoH insists must be included as a medicine, and yet now they want to exclude this one from that very process.

That is bullying at its most blatant, and the MoH should be ashamed of itself for even considering this action, although many people can clearly see that they are losing this battle, and they clearly see this as their only avenue to shut out opposition to this arrogant practice.

Fluoridation of drinking water is one of the most controversial all over the world. In almost every country, region, and community, there is considerable action against the fluoridation of water supplies. Dentists, doctors and many other medical and scientific experts throughout every country oppose this practice, and it is very clear that this current action is the MoH's only option to force this atrocious practice on more people. It is using its might and power to abuse the rights of so many people to refuse medical treatment, which is what fluoridation is.

The MoH's own statistics clearly show that fluoridation does not work, yet because of their huge budget, and their bulldozing over the top of community groups, and professional experts, they win most (thankfully not all) fights by communities to stop this practice. It is sheer power that they utilise to win, and yet the community groups keep winning. Now it seems the MoH has only one action left, and that is the law.

The fact that a bottle of fluoride pills would remain a medicine, yet fluoride used in public drinking water would be exempt is just ludicrous. Any sensible person, whatever their profession should see the precedent this is setting, for something that other options are available. This could very well lead the MoH to add any other chemical for therapeutic effect to drinking water, and that concept is very dangerous.

It is extremely ironic that it is MedSafe that is responsible for the collection of submissions. Medsafe is responsible for medicines, and if fluoride chemicals are not considered medicines, why is Medsafe involved?

In this instance, the law is not the right vehicle, and the MoH must not be allowed to ride roughshod over its own policy's to get its own way. It is clearly a sledgehammer in an attempt to crack a nut. It is wrong, selfish, irresponsible and reprehensible.

The MoH must not be allowed to win this, and Cabinet must not allow this travesty to occur.

The only option is for this amendment to be consigned to the rubbish bin, and the MoH be blocked from this course of action in the future.

End

This email has been checked for viruses by Avast antivirus software.
--

<u>v</u>

**proposed amendment to medical law**

to: askmedsafe

08/01/2015 09:25 p.m.

History:

This message has been replied to.

To whom it may concern

I strongly oppose the proposed amendment which would exempt the fluoridation of water from medical law.

It is obvious that since fluoride is added to water for the alleged purpose of reducing dental caries it can be regarded as medication

To allow fluoride exemption status would set a dangerous precedent which could legalize the addition of other substances with no recourse against possible abuse.



Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

: askmedsafe

08/01/2015 09:32 p.m.

History:

This message has been replied to.

I do give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

“It is proposed that a new regulation be made under section 105(1)(i) that: Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies.” Medsafe

Submitter details:

Name

Email

Address

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to “first do no harm”
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Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are **not** used to ‘**treat**’ community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I do not wish to speak to my submission.

Regards





SUBMISSION FORM

askmedsafe

08/01/2015 09:36 p.m.

History:

This message has been replied to.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:

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Name

Email:

Address:

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NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission.





Fluoride

to: askmedsafe@moh.govt.nz

08/01/2015 09:58 p.m.

History: This message has been replied to.

I do not (delete whichever does not apply) give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

“It is proposed that a new regulation be made under section 105(1)(i) that:

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Name

Email

Address:

Question 1. Do you support the proposed amendment? If not why not?

NO. I do not support the proposed amendment because:

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I do not (delete whichever does not apply) wish to speak to my submission.

Post to:

Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation

Ministry of Health
PO Box 5013
Wellington 6145

Email to: askmedsafe@moh.govt.nz

SUBMISSION FORM

Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	2015 / india@...
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Consumer interested in my own & the public's health
Question 1 <i>Do you support the proposed amendment? If not, why not?</i>	No, I don't support the amendment. Fluoride is not at all necessary for the safety of our water supply. It is used in an attempt to treat health conditions, so it is a medicine. The public should not be medicated with no choice in the matter. If any doubt at all exists in the safety of substances for long term ingestion, I believe we should follow the precautionary principle & not force people to drink it!
Question 2	No, I don't think any fluoride-containing

<i>Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?</i>	compounds should be named in the regulation as they would all be medicines used to treat people, not to treat the water supply.
--	---

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Fluoridation Submission Form
skmedsafe

08/01/2015 10:02 p.m.

From:

To: askmedsafe@moh.govt.nz,

History: This message has been replied to.

Submission Form.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

“It is proposed that a new regulation be made under section 105(1)(i) that: Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies.” Medsafe

Nam

Email

Address:

Question 1. *Do you support the proposed amendment? If not why not?*

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NO. Fluoride and its compounds are **not** used to ‘**treat**’ community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I do not wish to speak to my submission.





Stop the exemption of fluoride from existing regulations...

askmedsafe

08/01/2015 10:16 p.m.

History: This message has been replied to.

SUBMISSION FORM

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that: Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name

Email: ;

Address:

Question 1. Do you support the proposed amendment? If not why not?

NO. I do not support the proposed amendment because:

- 1. Fluoride is not a water treatment like chlorine
- 2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
- 3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
- 4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. Are there other fluoride-containing

compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

I do / do not (delete whichever does not apply) wish to speak to my submission.



Fluoride

: askmedsafe@moh.govt.nz

08/01/2015 10:18 p.m.

History: This message has been replied to.

SUBMISSION FORM

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Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

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Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are not used to ‘treat’ community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission

Cheers

Sent from my iPhone





History:

This message has been replied to.

SUBMISSION FORM

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I do not wish to speak to my submission.

Sent from Yahoo Mail on Android





No to Flouride

askmedsafe

08/01/2015 10:43 p.m.

History: This message has been replied to.

SUBMISSION FORM

I do give permission for my personal details to be released to persons under the Official Information Act 1982
 Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

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 I do / do not (delete whichever does not apply) wish to speak to my submission.

Post to:

Regulations under the Medicines Act 1981 Consultation
 Medsafe
 Clinical Leadership Protection & Regulation
 Ministry of Health
 PO Box 5013
 Wellington 6145





SUBMISSION FORM

: askmedsafe@moh.govt.nz

08/01/2015 10:43 p.m.

Please respond

History: This message has been replied to.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

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Name

Email:

Address

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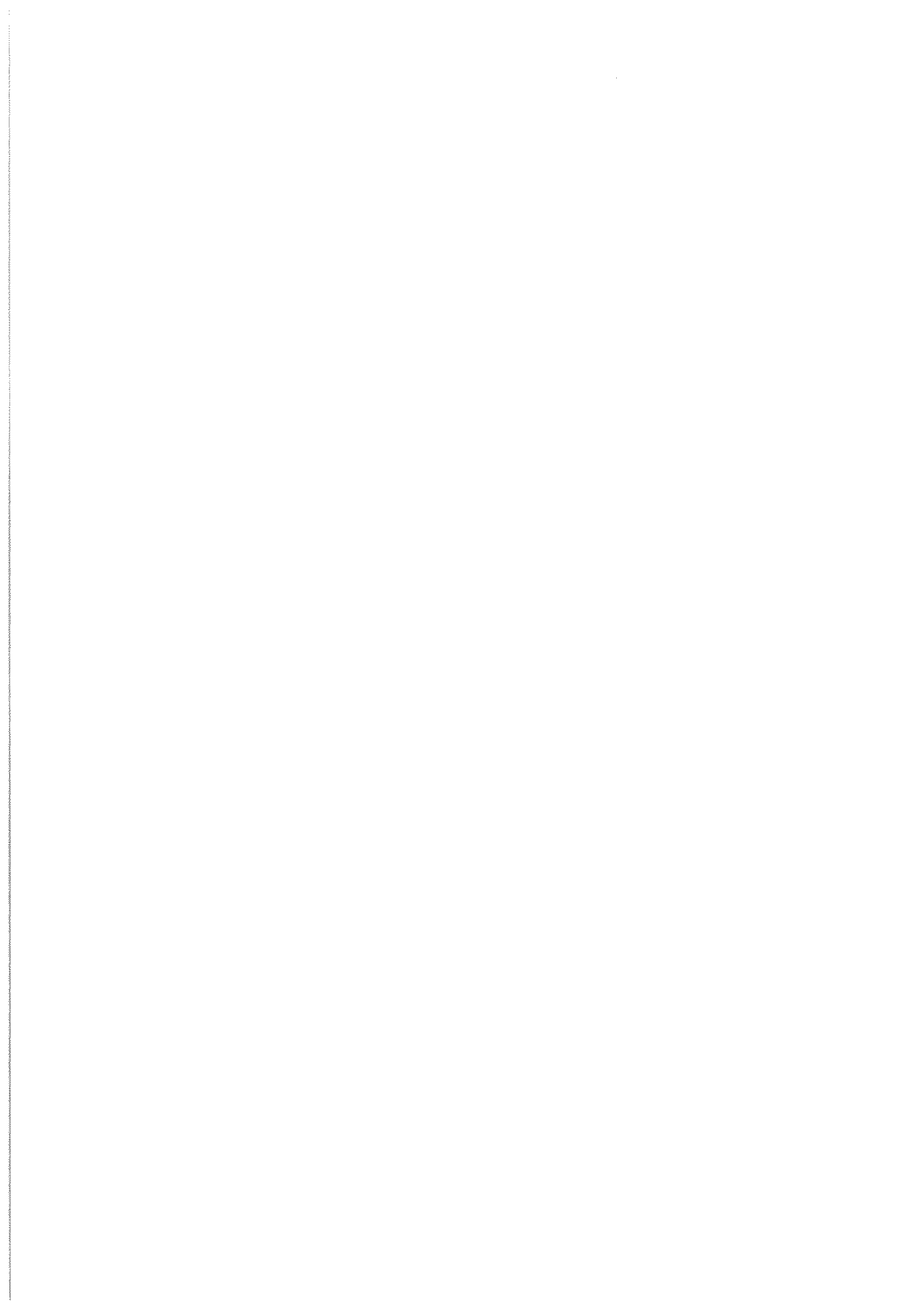
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NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission.





Fluoride

to: askmedsafe

Cc:

08/01/2015 10:51 p.m.

History: This message has been replied to.

I wish to make a submission regarding the proposal to exempt fluoride from the Medicines Act.

Judge Collins says in Para [29] of CIV-2014-485-004138 [2014] NZHC 2487 "The term concentration can be applied to any kind of chemical mixture. For present purposes concentration refers to the volume of a medicine in one litre of water. Schedule 1 of the Regulations states that "unless reference is made otherwise, every reference to a medicine in this Schedule applies ... only if the concentration of the medicine is greater than 10 milligrams per litre ...". "

Schedule 1 relates to Prescription medicines, Restricted medicines, and Pharmacy-only medicines; it does not relate to General medicines.

Judge Collins then falls into the trap of misunderstanding the limits of Schedule 1.

"[46] The concentrations of fluoride in domestic water supplies must not exceed 1.5 mg/l. When fluoride is added to domestic water supplies within the maximum allowable concentration of 1.5 mg/l the concentration of fluoride in domestic water supplies will be well below the concentration threshold required for fluoride to be a medicine in Schedule 1 of the Regulations.

[47] When viewed in the context of the maximum allowable concentrations of fluoride in domestic water, and the concentrations of fluorides that are classified as medicines in Schedule 1 of the Regulations, I am drawn to the conclusion that the definition of "medicine" in the Act cannot include fluoride when it is added to domestic water supplies to produce a concentration of no more than 1.5 mg/l."

The Judge then says in para [49] "I am required to interpret the meaning of "medicine" in the Act in context which includes the Regulations and the Health Act 1956. This approach leads to the conclusion that the concentration threshold for fluoride in Schedule 1 of the Regulations is so vastly higher than the maximum allowable concentration of fluoride in domestic water supplies that, when fluoride is added to domestic water at the authorised levels, it falls outside of the definition of "medicine" in the Act. "

He falsely uses an exemption that relates only to Schedule 1 medicines which can only be sourced via a prescription from a Registered Medical Practitioner or from a licensed pharmacy. Schedule 1 does not relate to general medicines.

Judge Collins then concludes in para 50 by saying that fluoride in water is a medicine but is exempt by the Schedule 1 10 mg/l exemption.

"[50] It follows from my reasoning that fluoride would be a medicine under the Act if it was added to domestic water supplies in concentrations of 10 mg/l or more."

I oppose the proposal to use regulation to exempt fluoridated water from being a medicine for several reasons.

Firstly, I believe the reason provided to the Minister for circumventing due process is spurious at best. To say that 'consultation' is being

undertaken at the same time as drafting, so that an alleged Court deadline relating to an appeal has all the hallmarks of a faux consultation. No analysis is provided to warrant the exemption; just a desire to head off an appeal.

Secondly, I believe that given this is setting a precedent that provides a mechanism for mass medication, the consultation process should have extended beyond organisations that the Ministry thinks have an interest. This is not a case where a single drug made by a select group of manufacturers prescribed to a limited number of people is being exempt. It is a process to legalise mass medication.

Thirdly, I believe that Judge Collins has misunderstood Schedule 1 in the Medicines Regulations, and has applied a threshold of 10 mg/l to general medicines when neither the Act itself nor the regulations provide such a threshold for general sale medicines.

The consultation process is a sham, the law has been misinterpreted, and the proposed exemption would create a precedent that legitimises mass medication.

I submit that the proposed exemption be submitted to proper consultation and that the public be made aware of the consequences of setting legal precedence for mass medication.

Please find attached two documents which form part of this submission.

The JUDGMENT OF COLLINS J in

CIV-2014-485-004138
[2014] NZHC 2487

and Health Report 20141527 dated 20 November 2014

Risk & Policy Adviser



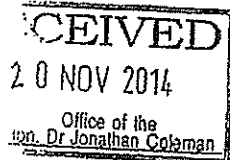
New Health New Zealand Inc v Attorney-General.pdf



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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.

**IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY**

**CIV-2014-485-004138
[2014] NZHC 2487**

UNDER the Judicature Amendment Act 1972 and
the Declaratory Judgments Act 1908

IN THE MATTER of an application for judicial review and an
application for a declaration

BETWEEN NEW HEALTH NEW ZEALAND INC
Plaintiff

AND ATTORNEY-GENERAL for and on behalf
of THE MINISTER OF HEALTH
Defendant

Hearing: 2 October 2014

Counsel: L M Hansen for Plaintiff
J Foster and M F Clark for Defendant

Judgment: 9 October 2014

JUDGMENT OF COLLINS J

Introduction

[1] I have concluded that Hydrofluorosilicic Acid (HFA) and Sodium Silico Fluoride (SSF) are not medicines under the Medicines Act 1981 (the Act) as currently used to fluoridate domestic water supplies in New Zealand.

[2] I am therefore dismissing an application by New Health New Zealand Inc (New Health) in which it seeks two declarations that:

1. When manufactured, sold to and supplied or distributed by local authorities for the purpose of community water fluoridation, HFA and SSF are medicines under the [Act].

2. The Ministry of Health is required to take all necessary steps to ensure the manufacture, distribution, sale and supply of HFA and SSF complies with the [Act] and Regulations.

[3] I shall:

- (1) explain the background to this proceeding, including its genesis in a related case;
- (2) examine the relevant legislation;
- (3) set out my analysis of the law and the reasons for my decision; and
- (4) summarise my conclusions.

Background

Water fluoridation

[4] Trace elements of fluoride are naturally present in some water supplies. In some communities, particularly in the United States, the natural concentration levels of fluoride in water are so high that steps have to be taken to reduce fluoride in those communities' water supplies. This is called de-fluoridation.

[5] In contrast, the process known as water fluoridation increases the concentration of fluoride in water. This process was first commenced in New Zealand in 1954 when water fluoridation was introduced in Hastings. Water fluoridation is primarily achieved through the introduction of HFA and SSF into water supplies by local authorities.

[6] Water fluoridation is usually undertaken after domestic water supplies have been treated and cleaned by adding a number of chemicals, including chloride. Fluoridation is achieved by adding measured quantities of HFA and SSF which, when dissolved in water, release fluoride ions, thereby increasing the concentration of fluoride ions in water.¹

¹ First Affidavit of D B Menkes, 23 June 2014 at [10].

[7] HFA is a by-product of the manufacture of phosphate fertiliser. Phosphate rock, which contains fluoride and silicon is treated with sulphuric acid. This produces two gases which are then exposed to water to form HFA. SSF is produced by adding either sodium carbonate or sodium chloride to HFA. For convenience, I will, when possible, refer in the balance of this judgment to HFA and SSF as fluoride even though they are really compounds which contain fluoride.

[8] The Drinking Water Standards for New Zealand (the Drinking Water Standards) are set by the Ministry of Health (the Ministry) under s 690 of the Health Act 1956. In setting the Drinking Water Standards the Ministry relies on advice from an expert committee which in turn has based its recommendations on World Health Organisation (WHO) guidelines. The Drinking Water Standards set the maximum allowable concentration level of fluoride in domestic water supplies in New Zealand.

[9] The maximum allowable level of fluoride in domestic water supplies in New Zealand is 1.5 milligrams per litre (1.5 mg/l). This maximum allowable concentration level for fluoride was set in 1984 and was based upon a WHO guideline issued in 1984. The WHO guideline has not changed since it was promulgated and was calculated on the basis of a person consuming two litres of water a day over a lifetime. In New Zealand the maximum allowable levels of fluoride in domestic water is consistent with those in domestic water supplies in Australia and England, and much lower than the maximum allowable level of fluoride in the United States which is set at 4 mg/l.²

Purpose of fluoridation

[10] The sole purpose in placing fluoride into water is to prevent and reduce tooth decay. The Ministry of Health believes that introducing fluoride into water is "... a safe, effective and affordable way to prevent and reduce tooth decay".³ The Ministry of Health says that:⁴

² Affidavit of P F Prendergast, 7 July 2014 at [46]-[47].

³ Affidavit of S S Jessamine, 7 July 2014 at [13].

⁴ Above n 3.

... Other public health authorities and medical science bodies and international organisations, including the New Zealand Medical Association, the New Zealand Dental Association, the World Health Organisation and the World Dental Federation share the view that fluoridation of drinking water supplies is [an] effective way of preventing and reducing tooth decay.

[11] When fluoride is dissolved in water the increased concentration of fluoride ions affects mineralisation of tooth enamel, thereby preventing tooth decay.⁵ Thus, the addition of fluoride to domestic water supplies aims to prevent or reduce dental decay by a pharmacological process.

[12] There are others who do not share the Ministry of Health's views about the positive effects of fluoride being added to community water supplies. New Health is an interest group which was established in 2005 to promote "the best interests and health freedoms of consumers".⁶ New Health opposes the adding of fluoride to community water supplies. Mr Sloan, the Chairman of New Health, has produced three affidavits in which he refers to a number of reports including:

- (1) a report prepared at the University of York in 2000 (the York report);
- (2) a report prepared by the New Zealand National Research Council in 2006 (NRC report);
- (3) an affidavit from Dr Kathleen Thiessen in October 2013; and
- (4) a report prepared in 2011 by a European based organisation, the Scientific Committee on Health and Environmental Risks (SCHER report).

[13] In his first affidavit Mr Sloan explains that New Health is opposed to fluoridation of water supplies by New Zealand local authorities for reasons which include:⁷

- (1) fluoridation removes consumers' freedom of choice;

⁵ First Affidavit of D B Menkes, 23 June 2014 at [21].

⁶ First Affidavit of P D Sloan, 1 April 2014 at [4].

⁷ First Affidavit of P D Sloan, 1 April 2014 at [10].

- (2) fluoride is potentially harmful to health;
- (3) fluoridating water supplies is not an effective way of providing fluoride for the purposes of preventing dental decay;
- (4) fluoridation conflicts with core principles of contemporary pharmacology; and
- (5) the fluoride added to water supplies in New Zealand is obtained from the phosphate fertiliser industry and contains heavy metal contaminants including arsenic and lead.

[14] The efficacy and safety of fluoridation of water is a topic that engenders strong debate and disagreement. There has been a raft of litigation over the introduction of fluoride to domestic water supplies in New Zealand⁸ and many other western countries.⁹ However, I do not have to address those issues in this proceeding. My task is to interpret the Act and decide if fluoride falls within the definition of “medicine” in the Act when used for the purpose of fluoridating community water supplies.

Genesis to this proceeding

[15] In *New Health New Zealand Inc v South Taranaki Council*,¹⁰ New Health challenged the lawfulness of community water fluoridation. In that case New Health said that adding fluoride to domestic water supplies:

- (1) constituted treatment for the purposes of s 11 of the New Zealand Bill of Rights Act 1990 (NZBORA) and that consumers of fluoridated

⁸ *Attorney-General of New Zealand v Lower Hutt City Corp* [1964] AC 1469 (PC); *New Health New Zealand Inc v South Taranaki District Council* [2014] NZHC 395, [2014] 2 NZLR 834; *Safe Water Alternative New Zealand Inc v Hamilton City Council* [2014] NZHC 1463.

⁹ See David Shaw “Weeping and Wailing and Gnashing of Teeth: The legal fiction of water fluoridation” (2012) *Medical Law International* 12; Dean Farrer “Fluoridation: Compulsory Medication of Municipal Water Supplies?” (1973) 5 *Urb Law* 504; Jeff Wurzburg and Corrine Propas Parver “Community Fluoridation around the Nation: Significant Case Law and Legislation” (2013) 7 *Health Law and Policy Brief* 1, 2.

¹⁰ *New Health New Zealand Inc v South Taranaki District Council*, above n 8.

water had a right to refuse treatment associated with drinking fluoridated water;¹¹

- (2) was not authorised by the Local Government Act 2012;
- (3) required ministerial approval under s 94(1) of the Act because it was a “therapeutic food”; and
- (4) was not authorised by the Health Act 1956.

[16] All of these arguments were rejected by Rodney Hansen J. In addressing the claim based on s 11 of the NZBORA Rodney Hansen J said:¹²

... although the addition of fluoride [to water] does no more than to elevate it to levels which often occur naturally, it is nevertheless a process undertaken for the purpose of preventing or arresting a disease ... the process of fluoridation is undertaken for a therapeutic purpose.

[17] This aspect of Rodney Hansen J’s judgment has been focused upon by New Health to support its claim for declarations that fluoride is a medicine within the meaning of the Act when added to community water supplies for the purposes of treating or preventing tooth decay.

[18] Rodney Hansen J’s observation that fluoride additives are added to water for therapeutic purposes was consistent with the view of Lord Jauncey in *McCull v Strathclyde Regional Council*¹³ in which he said that fluoride, when added to water, is a “medicinal product” within the meaning of s 130 of the Medicines Act 1968 (UK).

¹¹ **11 Right to refuse to undergo medical treatment**

Everyone has the right to refuse to undergo any medical treatment.

¹² *New Health New Zealand Inc v South Taranaki District Council*, above n 8, at [79].

¹³ *McCull v Strathclyde Regional Council* [1983] SC 225 (CS).

Relevant legislation

Overview

[19] The importation, manufacture, distribution and use of chemicals including those used as medicines or to make medicines are governed by a range of statutes and regulations. Acts such as the Hazardous Substances and New Organisms Act 1996, the Health Act 1956 and the Misuse of Drugs Act 1975 regulate a wide-range of drugs and dangerous substances. HFA and SSF are hazardous substances under the Hazardous Substances and New Organisms Act 1996. That Act regulates the importation of those chemicals and how they can be modified, transported and stored.¹⁴

[20] Other statutes and regulations control the way in which products can be manufactured, supplied to and administered to humans. In addition to the Act, statutes and regulations which fall into this category include the Food Act 1981, the Dietary Supplements Regulations 1985 and the Medicines Regulations 1984 (the Regulations).

Medicines Act 1981

[21] The Act regulates medicines, related products and medical devices in New Zealand.

[22] Medicine is defined in s 3 of the Act. The relevant part of the definition provides:

(1) In this Act, unless the context otherwise requires, medicine—

(a) means any substance or article that—

- (i) is manufactured, imported, sold, or supplied wholly or principally for administering to 1 or more human beings for a therapeutic purpose; and
- (ii) achieves, or is likely to achieve, its principal intended action in or on the human body by pharmacological, immunological, or metabolic means...

¹⁴ Affidavit of P F Prendergast, 7 July 2014 at [44].

[23] Certain items are specifically excluded from the definition of “medicine” in the Act. Items that are excluded include any food as defined in s 2 of the Food Act 1981, or “... any substance or article of a kind or belonging to a class that is declared by regulations not to be a medicine for the purposes of this Act”.¹⁵

[24] “Administer” is defined in s 2 of the Act to mean:

... administer to a human being, either—

(a) Orally ... by introduction into the body in any other way;

...

and every reference in this Act to administering a substance or article is a reference to administering it either in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, some substance in which it is to be administered.

[25] “Therapeutic purpose” is defined in s 4 of the Act. The relevant portion of that definition provides:

In this Act, unless the context otherwise requires, therapeutic purpose means

...

(a) Preventing, ... alleviating, treating, curing ... a disease, ailment, defect ...; or

(b) Influencing, inhibiting, or modifying a physiological process

...

[26] The Act regulates and places restrictions on the sale, supply and administration of five categories of medicines:

(1) new medicines;

(2) prescription medicines;

(3) restricted medicines;

(4) pharmacy-only medicines; and

¹⁵ Medicines Act 1981, s 3(1)(c)(vi).

- (5) general sale medicines.

[27] The regulation of new medicines under the Act is not relevant to the issue I have to consider. For present purposes it is only necessary to explain that:

- (1) prescription medicines; and
- (2) restrictive medicines; and
- (3) pharmacy-only medicines

are identified by regulations or notices issued under s 106 of the Act. General sale medicines are medicines that may be lawfully sold, other than as pharmacy-only, prescription and restricted medicines.¹⁶ General sale medicines are identified in a list of such medicines published by the Director-General of Health.¹⁷

Medicines Regulations 1984

[28] Fluorides are identified in Parts 1, 2 and 3 of Schedule 1 to the Regulations as prescription medicines, restricted medicines and pharmacy-only medicines.

Concentrations of fluorides

[29] The term concentration can be applied to any kind of chemical mixture. For present purposes concentration refers to the volume of a medicine in one litre of water. Schedule 1 of the Regulations states that “unless reference is made otherwise, every reference to a medicine in this Schedule applies ... only if the concentration of the medicine is greater than 10 milligrams per litre ...”.

Dosages of fluorides

[30] The Regulations then categorise fluorides, generally by reference to doses and dosages. A dose is a quantity of a medicine.¹⁸ The term “dosage” refers to the

¹⁶ Medicines Act 1981, s 99(2).

¹⁷ Section 99(1).

¹⁸ Derived from the definition of “dose”; Lesley Brown (ed) *The New Shorter Oxford English Dictionary* (4th ed, Oxford University Press, New York, 1993).

rate of application of a dose of medicine.¹⁹ Footnotes 20, 21 and 22 set out in full the classification of fluorides as pharmacy-only, restricted and prescription medicines. It is sufficient to say at this juncture that, subject to certain exceptions, fluorides are classified as:

- (1) Prescription medicines:²⁰ when used in medicines used for internal use containing more than 0.5 milligrams per dose unit containing 15 milligrams or less per litre or per kilogram.
- (2) Restricted medicines:²¹ when used in liquid medicines for external use containing 5.5 grams or less and more than 1 gram per litre or per kilogram and when sold in packets approved by the Minister or the Director of Health for distribution as restricted medicines.
- (3) Pharmacy-only medicines:²² when used in medicine used for internal use containing more than “0.5 milligrams or less per dose unit ... except in medicines containing 15 milligrams or less per litre or per kilogram”.

[31] The Director-General has categorised fluorides as a general sale medicine.²³ With certain qualifications that are explained in footnote 23 a fluoride is a general

¹⁹ Derived from the definition of “dosage”; Lesley Brown (ed) *The New Shorter Oxford English Dictionary*, above n 18.

²⁰ Fluorides; for internal use in medicines containing more than 0.5 milligrams per dose unit except in medicines containing 15 milligrams or less per litre or per kilogram; except in parenteral nutrition replacement preparations; for external use in medicines containing more than 5.5 grams per litre or per kilogram except when supplied to a dental professional registered with the Dental Council.

²¹ Fluorides; for external use in liquid form in medicines containing 5.5 grams or less and more than 1 gram per litre or per kilogram and when sold in packs approved by the Minister or the Director-General for distribution as restricted medicines; for external use in non-liquid form in medicines containing 5.5 grams or less and more than 1 gram per litre or per kilogram, except in medicines containing 1.5 grams or less and more than 1 gram per litre or per kilogram; except when supplied to a dental professional registered with the Dental Council.

²² Fluorides; for internal use in medicines containing 0.5 milligrams or less per dose unit; except in parenteral nutrition replacement preparations; for external use in liquid form in medicines containing 1 gram or less per litre or per kilogram and when sold in packs approved by the Minister or the Director-General for distribution as pharmacy-only medicines except in medicines containing 220 milligrams or less per litre or per kilogram and in packs containing not more than 120 milligrams of total fluoride; except when supplied to any dental professional registered with the Dental Council; except in medicines containing 15 milligrams or less per litre or per kilogram.

²³ For external use in liquid form in medicines containing 220 milligrams or less per litre or per

sale medicine when it is used for external use in liquid form in medicines containing 220 milligrams or less per litre or per kilogram.

[32] For completeness I note that reg 58A states that dentrifice products,²⁴ which are primarily toothpastes and mouth washes, are not medicines provided that:

- (i) the dentrifice product does not contain a medicine specified in Schedule 1; and
- (ii) the dentrifice product is not claimed to be for use in relation to any therapeutic purpose other than one or both of the following:
 - (A) preventing dental decay;
 - (B) improving oral hygiene.

Analysis

[33] In approaching my task I have focused upon three questions:

- (1) is fluoride added to domestic water supplies for a therapeutic purpose?
- (2) is fluoride “administered” to a human being when it is added to domestic water supplies?
- (3) does the “context otherwise require” me to conclude that fluoride, when added to domestic water supplies, is not a medicine within the meaning of the Act?

kilogram and in packs containing not more than 120 milligrams of total fluoride, which have been approved by the Minister or the Director-General for distribution as general sale medicine; for general use in non-liquid form and medicines containing 1.5 grams or less per litre or per kilogram and, when containing more than 1 gram per litre or per kilogram, sold in packs approved by the Minister or the Director-General for distribution as general sale medicine; in medicines containing 15 milligrams or less per litre or per kilogram; in parenteral nutrition replacement preparations; Medsafe “Database of Medicine Classifications” (14 July 2014) Medicine Classification <www.medsafe.govt.nz/profs/class/classification.asp>

²⁴ “Means any substance or mixture or substances used or represented for use for the purpose of cleaning the mouths or teeth (natural or artificial) of human beings, and includes any denture fixative”; Medicines Act 1981, s 2.

Therapeutic purpose

[34] The purpose of adding fluoride to domestic water supplies leads inevitably to the conclusion that the process of fluoridating domestic water falls within the definition of “therapeutic purpose” in the Act. This is because fluoride is added to domestic water supplies in order to “prevent”, “alleviate” and “treat” tooth decay, which is a “disease” or “ailment”. Water fluoridation is also designed to “inhibit” the “physiological process” of tooth decay.

[35] In addition, the placing of fluoride in domestic water supplies achieves its intended action on human beings by a pharmacological process. I am therefore satisfied that introducing fluoride into domestic water supplies is undertaken for therapeutic purposes and satisfies the requirements of s 3(1)(a)(ii) of the definition of “medicine” which I have set out in paragraph [22].

To administer

[36] Ms Foster, senior counsel for the Attorney-General said that the lynchpin of her client’s case was that fluoride is not administered to any person within the meaning of the Act when it is added to domestic water supplies. She submitted that although HFA and SSF are chemicals that are used to increase the fluoride levels in water they cannot be said to be manufactured or supplied to be administered to a human being. This argument was based on the contention that HFA and SSF in their undiluted form cannot be administered to a human being for therapeutic purposes because if they were so administered the consequences would be fatal. It is fluoridated water, rather than HFA and SSF that is administered to humans.

[37] The deficiency with this aspect of Ms Foster’s argument is that it does not take account of the full definition of “administer” in the Act. The definition of “administer” includes administering a substance “either in its existing state or after it has been dissolved in, or diluted or mixed with some substance in which it is to be administered”.

[38] HFA and SSF are dissolved and diluted in water to enable fluoride to be consumed at very low concentrations by human beings.

[39] Accordingly, I am satisfied fluoride is administered to human beings, albeit at very low concentrations, when it is added to community water supplies for therapeutic purposes.

Context

[40] Parliament prefixed the definition of “medicine” in the Act with the words “unless the context otherwise requires”. The same qualification precedes other definitions in the Act, including the definitions of “administer” and “therapeutic purpose”.

[41] Although Parliament elected not to refer to “context” when it passed s 5(1) of the Interpretation Act 1999,²⁵ it is widely accepted that legislation today should be interpreted in light of its context.²⁶ This approach parallels what Lord Steyn described as the “pendulum” swing “towards purposive methods for construction”²⁷ which is now firmly entrenched in this country in s 5(1) of the Interpretation Act 1999. A contextual approach requires Judges to ascertain the meaning of legislation by referring, where necessary, to the broader legislative and policy contexts.²⁸ A leading example of this approach can be seen in *L D Nathan & Co Ltd v Hotel Association of New Zealand*²⁹ in which low-strength beer was held not to be “liquor” as defined in s 2 of the Sale of Liquor Act 1962 when viewed in the broader legislative and policy context of the definition of “liquor”. A contextual approach is essential “in order to make an Act work as Parliament must have intended”.³⁰

[42] Ms Hansen, counsel for New Health advanced a contextual argument which requires careful analysis. Ms Hansen explained that fluoride tablets, which, when sold as a pharmacy-only medicine, contain 1.1 milligram of sodium fluoride. She submitted that ingesting two 1.1 milligram sodium fluoride tablets supplies a person

²⁵ Interpretation Act 1999, s 5(1):

The meaning of an enactment must be ascertained from its text in the light of its purpose.

²⁶ *Agnew v Pardington* [2006] 2 NZLR 520 (CA) at [32]; JF Burrows & RI Carter *Statute Law in New Zealand* (4th ed, LexisNexis, Wellington, 2009) at 232.

²⁷ *R (Quintavella) v Secretary of State for Health* [2003] 2 AC 687 at 700.

²⁸ *9 Cornwall Crescent London Ltd v The Mayor and Burgesses of the Royal Borough of Kensington and Chelsea* [2005] EWCA Civ 324 at [52].

²⁹ *L D Nathan & Co Ltd v Hotel Association of New Zealand* [1986] 1 NZLR 385 (CA).

³⁰ See for example, *Northland Milk Vendors Association Inc v Northern Milk* [1988] 1 NZLR 530 (CA) at 538.

with the approximate amount of fluoride he or she ingests when he or she drinks one litre of water fluoridated to the maximum allowable level.³¹

[43] Ms Hansen pointed out that there are no controls over how much water a person can drink and that when viewed in this context, fluoridated water should not be treated any differently from pharmacy-only fluoride tablets which plainly are a medicine.

[44] It will be apparent Ms Hansen's argument relies upon the dosages of fluoride prescribed in Schedule 1 of the Regulations.

[45] The defect in Ms Hansen's approach is that it ignores the threshold concentration required for substances to be medicines in Schedule 1 of the Regulations. As I have explained in paragraph [29], Schedule 1 of the Regulations specifies that every reference to a medicine in the Schedule only applies if the concentration of that medicine is greater than 10 mg/l.

[46] The concentrations of fluoride in domestic water supplies must not exceed 1.5 mg/l. When fluoride is added to domestic water supplies within the maximum allowable concentration of 1.5 mg/l the concentration of fluoride in domestic water supplies will be well below the concentration threshold required for fluoride to be a medicine in Schedule 1 of the Regulations.

[47] When viewed in the context of the maximum allowable concentrations of fluoride in domestic water, and the concentrations of fluorides that are classified as medicines in Schedule 1 of the Regulations, I am drawn to the conclusion that the definition of "medicine" in the Act cannot include fluoride when it is added to domestic water supplies to produce a concentration of no more than 1.5 mg/l.

[48] I appreciate the approach I have taken focuses upon concentrations of fluoride and not dosages and that there is no legal limit placed on how much fluoridated water a person can consume. However, because fluoridated water is not

³¹ Affidavit of D B Menkes, 23 June 2014 at [26].

administered in dosages the only practical way fluoride can be measured and regulated in domestic water supplies is by referring to concentrations.

[49] I am required to interpret the meaning of “medicine” in the Act in context which includes the Regulations and the Health Act 1956. This approach leads to the conclusion that the concentration threshold for fluoride in Schedule 1 of the Regulations is so vastly higher than the maximum allowable concentration of fluoride in domestic water supplies that, when fluoride is added to domestic water at the authorised levels, it falls outside of the definition of “medicine” in the Act.

[50] It follows from my reasoning that fluoride would be a medicine under the Act *if* it was added to domestic water supplies in concentrations of 10 mg/l or more.

[51] While I am confident my conclusion is correct, the Ministry may wish to consider recommending a Regulation that exempts HFA and SSF from the definition of “medicine” when those compounds are used to fluoridate water.

Conclusions

[52] When HFA and SSF are added to domestic water supplies in New Zealand to produce fluoride concentrations within the current allowable level of 1.5 mg/l they are not medicines within the meaning of the Act.

[53] The application for declarations is dismissed.

[54] Under normal circumstances the Attorney-General would be entitled to costs on a scale 2B basis. However, I take the view that because New Health has advanced legitimate arguments in the public interest, this is one of those rare situations where an award of costs is not appropriate.³²

³² *Gibbs v New Plymouth District Council (No 2)* HC New Plymouth CIV-2004-443-115, 5 October 2006.

D B Collins J

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