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

I do / ~~do not~~ (delete whichever does not apply) 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

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

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
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My interest in this topic is as a Health Professional, a Consumer and as a concerned grandmother.

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

Reasons I oppose fluoridation chemicals bing added to public water.
Hydrofluorosilicic acid (i.e. Hexaflurosilicic acid or sodium silica fluoride) is a toxic waste from the phosphate fertilizer industry. It is not pharmaceutical grade fluoride.

It is supplied by Orica Ltd, previously named Imperial Chemical Industries, formed in 1928, which made explosives for the gold rush. You can read their list of chemical accidents on Wikipedia. http://en.wikipedia.org/wiki/Orica This multinational corporation's income was US$6.7 billion last year.

Fluoridation chemicals are linked to Cancer, Premature Births, Hip Fractures, Thyroid Disease, Lowered IQ, Alzheimer's ...and more. There are many scientific peer reviewed studies indicating harm.

Fluoridation has NEVER been registered as safe by any health authority in the world. To quote Medsafe's website - **"There is no universal acceptance of the positive health effects of the addition of fluoride to drinking water supplies."**

Fluoride is NOT a nutrient, most of the world classifies it as a drug.
Ministry of Health classifies it as a Medicine.

Fluoridation chemicals do NOT reduce dental decay.
Dental decay has reduced in all countries WITH or WITHOUT fluoridation.

An estimate is that Watercare Ltd pays Orica Ltd approx. $453,644.47 per year to purchase Hydrofluorosilicic acid. *(Calculated on population of Hamilton which spent $48,000pa on fluoride, compared to the population of Auckland.)*

People would be grateful to have that sum reduced from their water bills and buy fluoride toothpaste if they wish.

Most of that water does not come in contact with children's teeth – most fills the washing machine and flushes the toilet.

The Ministry of Health claims to be using Hydrofluorosilicic acid in the tap water so it can come in contact with children's teeth to strengthen them.

Teeth are made from Calcium, Vitamin C and Protein. Would you consider adding those nutrients to the tap water to strengthen peoples teeth of all ages? If the consumption of those supplements is a personal choice, then so should fluoride also be a personal choice.

Is it ETHICAL to mass medicate people with Hydrofluorosilicic acid, (a toxic waste from the phosphate fertilizer industry) through the water supply?

Only 22 NZ Councils of 67 still use fluoridation chemicals.

When asked to provide even one Scientifically Peer Reviewed study that proved Hydrofluorosilicic acid was 100% safe and effective for human consumption, the Ministry of Health was unable to come up with any evidence.

Under the Bill of Human Rights I have the right to refuse drugs and chemicals into my body.

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

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

1054

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1057

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1058

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1059

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

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I was a teacher of young children at Ngaruawahia school in the 1950s. In those days, with no fluoride anywhere, it was the Maori children who had the better teeth. Why do Maori children now have worse teeth? Surely diet is the cause, not the presence or absence of fluoride.

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1061

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

askmedsafe 08/01/2015 06:24 a.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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Emai
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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.

Regards.

~~1395~~
1062

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Medsafe
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Ministry of Health
PO Box 5013
Wellington 6145

Email to: askmedsafe@moh.govt.nz

1063

Fluoride

: askmedsafe@moh.govt.nz 08/01/2015 08:31 a.m.

History: This message has been replied to.

SUBMISSION FORM
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Submission

ɔ: askmedsafe@moh.govt.nz 08/01/2015 08:46 a.m.

History: This message has been replied to.

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fluoride petition
S skmedsafe 08/01/2015 08:53 a.m.
History: This message has been replied to.

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Fluoride submission
to: askmedsafe 08/01/2015 08:55 a.m.
History: This message has been replied to.

FLUORIDE SUBMISSION
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Toothpaste containing fluoride is readily available to perform the same function. Fluoridation of the water is unnecessary and is harmful to certain groups in the population, particularly infants.

I do not wish to speak to my submission.

1067

against fluoride exemption!!
askmedsafe@moh.govt.nz 08/01/2015 08:56 a.m.

History: This message has been replied to.

SUBMISSION FORM

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

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Many times before, history has shown that if people interfere in nature, trying to "fix" things, they forget the long term downside. Adding fluoride DOES rob people of their free choice as there are many ways of using fluoride by choice. Fluoride is NOT an essential element and has a narrow treatment band. There are risks involved, again, risks people can hardly avoid as there is no choice.

In Holland an Belgium, both countries highly respected for their level of research and medical standard, BOTH have stopped fluoridising water and statistics show NO larger toothdecay. This is managed by PROPER education and PROPER healthcare. This is what is needed to keep this a healthy country of choice.

Kind regards,

Fluoride Submission

to: askmedsafe 08/01/2015 08:56 a.m.

History: This message has been replied to.

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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.

NZ Floridation

to: askmedsafe 08/01/2015 09:00 a.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:

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.

/

1070

Flouridation of the Public Water Supply

to: askmedsafe 08/01/2015 09:02 a.m.

History: This message has been replied to.

Dear Sir,

I have followed the Fluoride debate since 1961 when my late father, in his capacity as County Medical Officer of Health (Boston, Lincolnshire, UK) received some free samples of a Fluoride Toothpaste.

It is difficult for those with entrenched positions to change their view on many topics but, at this traditional time of goodwill, my feeling is that it is time for the whole concept of fluoride / fluoridation to be reassessed and in a completely dispassionate way.

A project not from the point of view of the dental and medical professions, or of their professional bodies, but from the view-point of chemists, biochemists and most of all from toxicologists.

Little attention is ever given to the accumulation of fluoride in the body from whatever source, including water supply (especially in those areas where it is added), toothpaste and mouthwashes.

Medical practitioners always specify the dosage of drugs prescribed and specify the frequency as to when they should be taken: why then is no consideration given to the possibility (probability?) of over-dosage.

In the UK, packaging containing fluoride toothpaste cautions parents to supervise children to ensure that they do not swallow any of this flavoursome product – does this not tell us something?

Yours faithfully,

UK

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

to: askmedsafe 08/01/2015 09:05 a.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: I
Email:
Address: 1

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.

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:	F
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 *Do you support the proposed amendment? If not, why not?*	No. See attached submission below.
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?*	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; Brent Phillips

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.

1073

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

askmedsafe 08/01/2015 09:20 a.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:

I do not support the proposed amendment because:

Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
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"

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**

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: 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:1

Question 1. *Do you support the proposed amendment?* **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 (delete whichever does not apply) wish to speak to my submission.

Email to: askmedsafe@moh.govt.nz

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

askmedsafe@moh.govt.nz 08/01/2015 09:31 a.m.

Please respond t

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: 1

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.

1076

Submission about drinking water fluoridation

To: askmedsafe 08/01/2015 09:38 a.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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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.

Best regards.

The Conscious Choice Movement Generational Accountability Worldwide

ph +64

Fluoridation

askmedsafe 08/01/2015 09:49 a.m.

History: This message has been replied to.

Submission Form

I 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
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 my submission.

Proposed Regulation on Fluoride
C' ɔ: askmedsafe 08/01/2015 09:51 a.m.

History: This message has been replied to.

Submission made by
(
V
Phone (

8th January 2015

We do NOT support the proposed ammendment to provide an exemption for fluoride containing substances.

Our reasons are:-

1. The "Background and rationale" on the Medsafe web site states "the addition of fluoride compounds to community drinking water supplies (is) for the purpose of preventing and reducing tooth decay". Water does not have tooth decay, people do. Therefore flouride containing substances added to water supplies are for the treatment of a medical condition and should properly be classified as "medicine" and subject to the provisions of the Medicines Act.

2. The addition of flouride containing substances to drinking water is supposed to be carefully regulated as to concentration "a maximum of 1.5 milligrams per litre of water". This is because it is widely recognised by medical authorities that the ingestion of higher levels of fluoride (including accumulation from other sources) has serious health consequences.

For Example - This excerpt from the U.S. Department of Health & Human Services website -

"HHS' proposed recommendation of 0.7 milligrams of fluoride per liter of water replaces the current recommended range of 0.7 to 1.2 milligrams. This updated recommendation is based on recent EPA and HHS scientific assessments to balance the benefits of preventing tooth decay while limiting any unwanted health effects. These scientific assessments will also guide EPA in making a determination of whether to lower the maximum amount of fluoride allowed in drinking water, which is set to prevent adverse health effects."

It should be noted that the recommended level is under half that used by New Zealand health authorities.

3. Medsafe's own website contains a statement of updated definitions for medicines.
http://www.medsafe.govt.nz/Medicines/policy-statements/definition-of-med.asp

"Important Changes to the Definition of Medicines and Medical Devices Effective 1 July 2014

Therapeutic purpose - means any of the following purposes, or a purpose in connection with any of the following purposes:

1. preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury; or
2. influencing, inhibiting, or modifying a physiological process;

Medicine - means any substance or article that -

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

If "water for injection" is classified as a "medicine" under the medicines act, then certainly "flouride containing substances" for the treatment of dental decay should be, and as such should properly be regulated under the act.

We make note that question 2 in your consultation contains a factual error which in our view makes it invalid. Chlorine is used to treat community water supplies. Fluoride containing substances are not.

1079

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

I to: askmedsafe@moh.govt.nz 08/01/2015 09:54 a.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."

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**

Kind regards

1080

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

to: askmedsafe@moh.govt.nz 08/01/2015 09:55 a.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

Nam
Ema
Addre

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. This is a common interpretation clearly made in many modern countries.
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" as well as to invoke the individual's right to "informed consent"
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. This would be truly opening a "Pandora's box" of future problems

New Zealand , if this measure is taken, would become a laughingstock among nations. This is clearly an attempt to gain a specific end through redefining the meaning of medicine. Medication is an intentional process that is irrelevant of the compound being used and the dose quantity. It is ridiculous to try to define whether something is a medicine merely by its dose! By the way, being "manufactured and supplied or distributed for the purpose of fluoridating community water supplies" is exactly medication. Oxford would object to this attempted re-definition!

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.

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

Bill Albrecht 68 Grandcourt Drive Nepean, ON, K2G 5W9 (613) 224-8815 Cell (613) 298-5525 "To love is to admire with the heart; to admire is to love with the mind." Theophile Gautier (1811-1872) Poet and novelist

****

1081

Fluoride
PSGR to: askmedsafe 08/01/2015 09:58 a.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

Please find attached a submission from Physicians and Scientists for Global Responsibility on fluoride.

We look forward to receiving your acknowledgement. Thank you.

behalf of the
Trustees of Physicians and Scientists for Global Responsibility New Zealand Charitable Trust

c, MSc, MB, ChB, Dip.Obst. (Auckland), FRNZCGP, ND

(Hons), MPhil., S

MB, BCh, BAO, DCH, DRCOG, DGM, MRCGP (UK), FRNZCGP

e BSc (Hons), PhD, Mus.B, LTCL, AIRMTNZ, Scientist,

MBBS, FACAM, FACNEM, Director, E

ris, MBChB, Dip Obs, CNZSM., CPCH, CNZFP; DMM, FRNZCGP, C

n, B.Vet.Med., retired veterinarian,

PhD, Coordinator F

s, BSc, PhD,

, BSc, MBChB, Dip.Rel.Studies, Dip.Obst., DCH, FRNZCGP, FIBCMT (USA), FACNEM, M
Forensic Medicine (Monash), G

, Businesswoman retired,

Physicians and Scientists for Global Responsibility
PO Box 8188
TAURANGA 3145
+64 7 576 5721

www.psgr.org.nz

Ends Submission on behalf of PSGR 7 1 2015.pdf

Ministry of Health
New Zealand Medicines and Medical Devices Safety Authority
PO Box 5013
WELLINGTON 6145

SUBMISSION

MEDSAFE PROPOSED AMENDMENT TO MEDICINES ACT 1981 FOR THE CLAIMED PURPOSE OF ENABLING FLUORIDATION OF PUBLIC WATER SUPPLIES TO BYPASS STATUTORY SAFETY REQUIREMENTS IN THAT ACT AND IN THE HEALTH AND DISABILITY SERVICES (SAFETY) ACT 2001

The Secretary
Physicians and Scientists for Global Responsibility
PO Box 8188
TAURANGA 3145
Telephone +64 (0)7 576 5721 (www.psgr.org.nz)

Medsafe proposed amendment To Medicines Act 1981
for the claimed purpose of enabling fluoridation of public water
supplies to bypass statutory safety requirements in that Act and in
the Health And Disability Services (Safety) Act 2001

1.0 Introduction

1.1 This Submission is made for and on behalf of Physicians and Scientists for Global Responsibility (PSGR).

1.2 The purpose of PSGR is to promote education, research and analyses so as to facilitate public debate on and awareness of issues of science, medicine and technology.

1.3 Thus, PSGR has a particular role in matters of the public interest – especially in cases where there are arguably issues of public safety involved.

1.4 Therefore, PSGR has a need to take action when it considers that a proposed government action appears to be irresponsible, contrary to the public interest and otherwise possibly contrary to the purposes of established statutory law and administrative law principle.

1.5 PSRG considers the proposed Medsafe amendment to the Medicines Act 1981 to qualify under the action-required headings set out in 1.4 above.

2.0 The Health & Disability (Safety) Act 2001

2.1 The Health & Disability (Safety) Act 2001 at Section 3 requires the Ministry of Health (MoH) to:

(a) promote the safe provision of health and disability services to the public; and

(b) enable the establishment of consistent and reasonable standards for providing health and disability services to the public safely.

2.2 Parliament's purpose and intent is arguably very clear. It is not therefore 'open' to a 'business unit' of the MoH (i.e. Medsafe) to advance an amendment to the Medicines Act 1981 when there is clear evidence that its proposed amendment has an arguably material probability of endangering public safety and health as well as being contrary to the public interest.

2.3 An advisor to PSGR on machinery of government and public law matters requested Medsafe (on 12 December 2014) to provide documentation setting out clearly the issue that its amendment seeks to address together with its Regulatory Impact Analysis (RIA) and its associated Regulatory Impact Statement (RIS) as well as its compliance with the requirements set out by the Regulations Review Committee of the House of Representatives

as well as compliance with the Legislative Advisory Committee Guidelines (LAC Guidelines) so that PSGR would be in a position to make a properly informed approach to making a submission within the time-frame requested by Medsafe.

2.4 However, Medsafe did not provide any of that documentation that is reasonably required to demonstrate that due care has identified all relevant considerations and that such considerations have been accorded due weight in the formulation of a proposed amendment.

2.5 It therefore seems to be a reasonable assumption that Medsafe had not formulated its proposed amendment to the Medicines Act 1981 with any due regard to the disciplines required by due process.

2.6 It is a matter of note and concern to PSGR that Medsafe responded with a delaying tactic – a decision to regard the request for required documentation as being a request under the Official Information Act 1982, thus triggering a delay for its required response that would extend to 3 February 2015; too late for that documentation (if it exists) to be available to inform PSGR submission and other submitters in time for them to comply with Medsafe's date for submissions.

2.7 Such a delay in the provision of required documentation renders impossible informed submissions.

2.8 Thus, submitters are left with attempting to undertake some of the work of those in the MoH and Medsafe who are supposed to have complied with their duty of care prior to advancing their proposed amendment for submissions.

2.9 In the view of PSGR, such conduct by MoH is not only reprehensible from the point of view of compliance with Parliamentary standards and principles that are supposed to inform safe and effective regulation, they are also an affront to the fiduciary obligation that the Crown is supposed to observe so as to be seen to act with utmost good faith towards the general public that it is supposed to serve.

2.10 Notably, the documentation that was reasonably requested is of the essence to inform the relevant Parliament organisations and the general public about any proposed amendment to an important statute.

2.11 Thus, PSGR regards the matter of the MoH approach to this amendment as being appropriate for formal complaints to the control agencies within the machinery of government.

2.12 Notwithstanding an intention to proceed with such complaints, PSGR now sets out further reasons why MoH cannot proceed lawfully with such a proposed amendment.

3. Relevant tests of risks and safety

3.1 Formulation of public policy (a species of delegated regulation) – such as the MoH policy encouraging the fluoridation of NZ public water supplies – requires similar rigour for its formulation as that for formulating a statutory provision.

3.2 That rigour requires MoH to identify 'all relevant considerations' in its research and then to accord each relevant consideration 'an appropriate weight'.

3.3 Necessarily, considerations relating to public safety and the broader public interest (e.g. economic damage that could be caused) are particularly relevant considerations because a primary statute – the Health & Disability Services (Safety) Act 2001 at section 2, (a) and (b) establishes that purpose.

3.4 Such relevant considerations may meet three relevant tests as to level of solidity of evidence about any safety concerns:-

3.4.1 the scientific test (circa 95 per cent certainty that something is safe);

3.4.2 the legal test (circa greater than a 50 per cent chance that there is a material risk); and

3.4.3 the precautionary principle test that is invoked if there is a reasonable suspicion that there may be widespread harm caused by a proposed action.

3.5 It is submitted that the established MoH policy of promoting fluoridation of NZ public water supplies is firmly captured and rendered unlawful by at least the second and third tests.

3.6 If the strength of the evidence is such as to make the established MoH policy on fluoridation of public water supplies unlawful, then arguably it follows that the Medsafe proposed amendment to the Medicines Act 1981 is thus also rendered unlawful.

3.7 Therefore the balance of this submission – primarily in the form of Attachments - sets out some of the peer-reviewed scientific research findings and (in Attachment B) strategic issues relating to public safety and the public interest.

3.8 It is submitted that these relevant considerations arguably more than qualify that the MoH practice of adding fluoride to NZ public water supplies is both a hazardous and ineffective policy – and should not therefore now also be 'enabled' by Medsafe's proposed amendment to the Medicines Act 1981.

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ATTACHMENT A

EVIDENCE OF MoH UNSAFE FLUORIDATION POLICY & EVIDENCE OF QUESTIONABLE EFFICACY OF THAT POLICY:

1. Introduction

1.1 The New Zealand Ministry of Health (MoH) has had a long-standing policy that has pursued addition of fluoride[1] to New Zealand public water supplies solely for the claimed purpose of giving effect to a belief that to do so imparts medicinal properties to that water which MoH apparently considers will cause a significant reduction in the incidence of dental carries.

1.2 Therefore, by the tests of reasonable logic, statutory definition and purpose, MoH policy to insert fluoride into public water supplies is to employ fluoride as a 'therapeutic substance' and therefore 'a medicine' subject to discretionary decisions made according to provisions in the Medicines Act 1981.

1.3 The dominant purpose and intent of New Zealand statutes relating to health is dominated by considerations of achieving a high level of public safety in relation to approval of claimed medicinal products.

1.4 Since the Crown is bound to observe provisions in the cluster of statutes relating to health matters, it is also arguably required to comply with those relevant statutes.

1.5 Such compliance involves due care to matters of public health and safety – and particularly identifying all such 'relevant considerations' as well as transparently giving due weight to each such relevant consideration.

1.6 Such a required approach also applies to the formulation of the MoH policy (subordinate legislation) of encouraging fluoridation of public water supplies (and its periodic review of that policy).

1.7 Equally, the same approach is required to apply to any use of MoH statutory administrative powers to propose statutory or regulatory changes or amendments: i.e. such changes or amendments must be consistent with the purpose and intent of related statutes. The MoH current proposed amendment to the Medicines Act 1981 is of that species.

1.8 The current MoH proposed amendment to that Act would arguably bypass, in an arbitrary and absurd manner, the purpose and intent of relevant NZ health statutes.

1.9 As an administrator of health statutes, the MoH is in a special position of fiduciary obligation and trust with respect to the public that it is supposed to serve and protect. It would be unreasonable for the MoH to claim that it does not have much of a duty of care because it can give the public access to an arguably sham 'consultation process' about its proposed administrative approach to the use of its statutory powers.

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1 Fluoride added to public water supplies is an industrial waste product that is contaminated with various toxic metals – many of which are bio-accumulative and mutually-synergistic in their toxicity.

1.10 This Attachment A sets out, in its predominant first part, an illustration of a number of relevant safety issue considerations associated with the established MoH policy of fluoridation of public water supplies. Arguably, any one or group of the associated referenced papers and authorities should be sufficient to cause MoH to abandon its fluoride policy – and therefore also abandon its associated tactic to pursue its proposed amendment to the Medicines Act 1981 that appears to seek to make 'lawful' a clearly unsafe and damaging use of fluoride as a medicine.

1.11 Towards the end of this Attachment A, it sets out compelling authorities that indicate that the MoH claimed efficacy for an association between its policy of fluoridating public water supplies and a reduction of dental carries in the population is a 'belief' and that it is not based upon any proven basis that such fluoridation of public water supplies brings about any statistically significant reduction in the incidence of dental carries.

1.12 This Attachment A finishes with a brief conclusion and a recommendation.

2. Absurdity

2.1 The purpose of the aggregate of the provisions incorporated in the Medicines Act 1981 may reasonably be described as 'designed to protect people from the risk of exposure to unsafe medicines'.

2.2 Therefore unsafe and arbitrary use of medicines is an offence under the Act.

2.3 For the MoH to argue that the multiple adverse health effects of fluoride and its industrial waste co-contaminants can be safely added to public water supplies is an absurdity.

2.4 Therefore, the move by the MoH to seek a statutory amendment for the purpose of giving statutory authority to its established fluoridation policy places the rule of law and the foundations of peoples' trust in the credibility and authority of Parliament in jeopardy.

2.5 Under New Zealand constitutional law it is not lawful to invite Parliament to do an absurd thing – making an unsafe amendment to an Act intended to protect peoples' safety.

2.6 There is no evidence to suggest that putting fluoride into drinking water is safe for people who drink it or for the environment area in which waste-water disposal accumulates the many toxic metals that the fluoridated water contains.

2.7 However, this submission includes references to many authoritative references that point to the dangers to health and environmental safety of the substances that are involved.

3.0 Lack of safety data

3.1 A number of government-appointed bodies have all raised concerns about a lack of any safety data relating to fluoridation of public water supplies:-

3.1.1 The U.S. Agency for Toxic Substances and Disease Register (ATSDR) in 1993 and 2003.

3.1.2 The "York Report" a British National Health Service investigation (McDonagh et al.

2000).

3.1.3 The National Research Council (NRC-USA) 2006.

3.1.4 The Scientific Committee on Health and Environmental Research (SCHER-EU) in 2011.

3.2 Following is a quotation from the ATSDR: "*very limited human and animal data were located to evaluate the immunological effects of fluoride.*"

3.3 And a further quote from the NRC report: "*The existing data base does not permit a complete assessment of the immunotoxic potential for fluoride.*"

3.4 All of the organisations referred to in 3.1 above requested that definitive research had to be done into the potential for adverse health effects.

3.5 Not surprisingly, governments that have established policies to fluoridate public water supplies (e.g. America, Australia, New Zealand and the Republic of Ireland) have been reluctant to undertake such research. Nevertheless, health officials in these countries have repeatedly provided to their respective Governments and public unfounded assurances about the safety of their policies – and persistently refused to consider relevant evidence about the likely harm that their policy may be causing.

3.6 But as biological sciences have been advancing, so has the evidence of the probability of such harm.

3.7 It is arguably unconscionable that policy administrators should continue to refuse to review their policies against the growing weight of evidence that their established policies to fluoridate public water supplies have a likely greater than 50 per cent probability of causing harm to people and the environment.

4.0 Disease incidence correlated with water fluoridation

4.1 In February 2013 a report was presented to the Government in Ireland that was titled: "*Public Health Investigation of Epidemiological data on disease and mortality in Ireland related to water fluoridation and fluoride exposure*".

4.2 This presentation compared the incidences of 28 diseases in the Republic of Ireland (RoI) with both unfluoridated Northern Ireland (NI) and the EU. (Waugh D. available at: www.enviro.ie).

4.3 Notably, the RoI has had mandatory water fluoridation for 50 years. Although it has to be acknowledged that epidemiological studies cannot prove cause and effect, they do reveal statistical correlation; and such correlations are evidence of a required 'relevant consideration' for public policy formulation relating to public safety issues and regulation.

4.4 Here are some examples of some of the correlations contained in that RoI presentation.

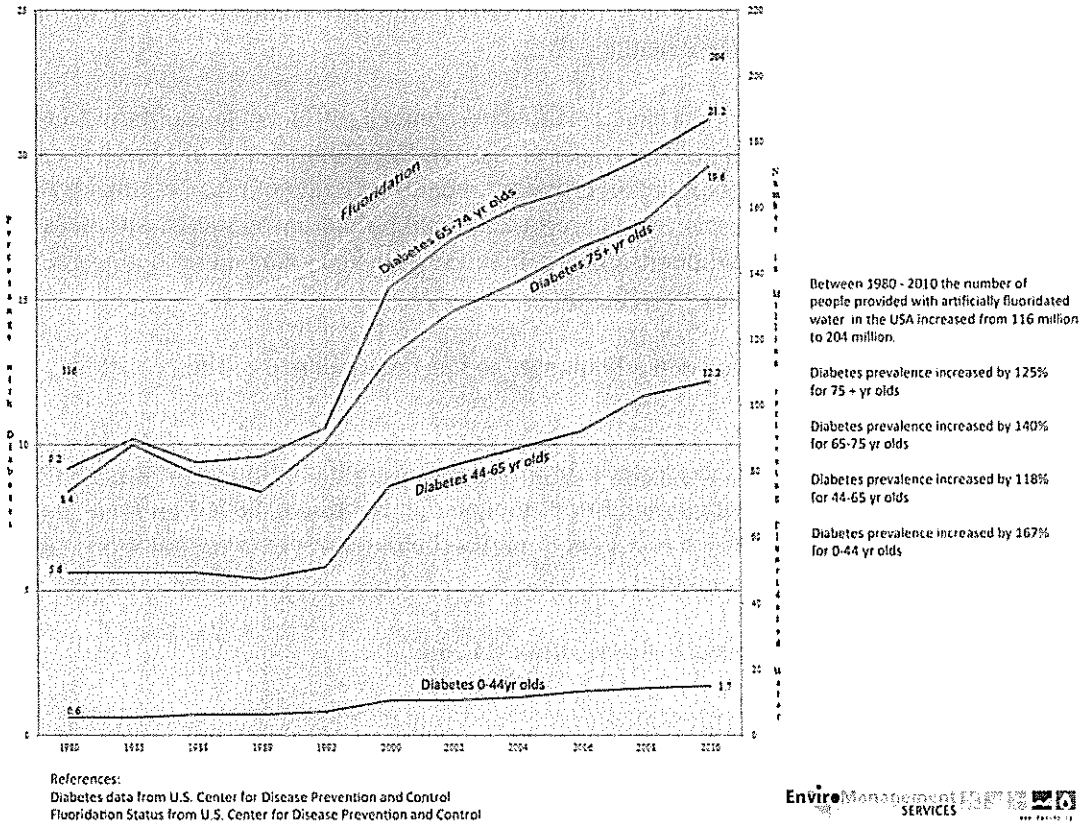
4.4.1 Comparing the Republic of Ireland with Northern Ireland, the incidence of Type 2

diabetes was 60 per cent higher in the fluoridated Republic. New Zealand is also experiencing a current epidemic of diabetes according to NZ government statistics. In 1996 there were 81,000 diagnosed cases: by 2009 there were greater than 270,000 diagnosed cases.

A similar pattern of increase in diabetes occurs in both the USA and Australia. It is reported that Pacific Islander and Maori populations have three times higher rates of diabetes than Caucasians.

The U.S. increase in diabetes appears to be associated with the increase in water fluoridation as shown below.

CHANGES IN NUMBER OF PEOPLE PROVIDED WITH ARTIFICIALLY FLUORIDATED WATER IN USA AND INCREASE IN DIABETES PREVALENCE BETWEEN 1980-2010



4.4.2 Endocrine/metabolic disorders including hypothyroidism and immunological disorders were all markedly elevated in the Republic compared with N Ireland. That evidence would be consistent with fluoride being a known endocrine disrupter (*State of the Science of Endocrine Disrupting Chemicals,* UNEP / WHO report 2012) and "an endocrine disruptor in the broad sense of altering normal endocrine function." (NRC 2006).

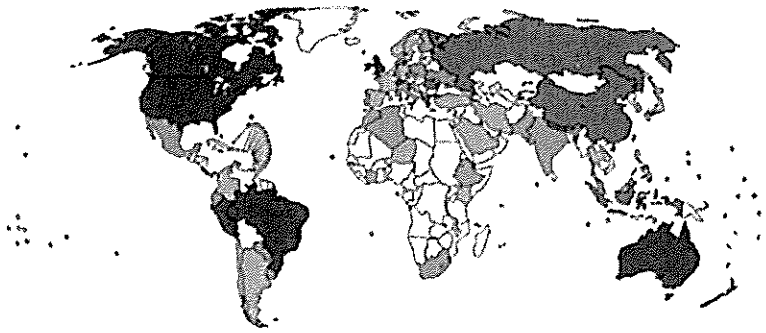
4.4.3 Admission rates for Chronic Obstructive Pulmonary Disease (COPD) were highest for the Republic at 364 per100,000. The rate for NZ is similar at 319 per 100,000. Australia is also similar at 312. By comparison the EU is <200 per100,000 for the (OECD 2012).

4.4.4 Asthma rates in the Republic were double those seen in N Ireland. The Republic's figure was the highest in the EU – ref. the ISAAC study (1998).

4.4.5 Asthma incidence world-wide shows that all of the fluoridating countries share equally elevated rates (Masoli 2004). [See map below.]

The world map of the prevalence of asthma is based on these the ECRHS and ISAAC studies combined. The map clearly identifies that the highest prevalence worldwide of asthma is to be found in fluoridated countries including Australia, New Zealand, United States, Canada, Brazil and Ireland.

World map of the prevalence of clinical asthma



Proportion of population (%)

- ≥10.1
- 7.6–10.0
- 5.1–7.5
- 2.5–5.0
- 0–2.5
- No standardized data available

4.4.6 Deaths in males from ischaemic heart disease were highest in the USA with NZ next followed by Canada and then the RoI (WHO 2011).

4.4.7 NZ leads the world for sudden infant death syndrome (SIDS) per 100,000; next in sequence are the USA, Argentina, Australia and the RoI.

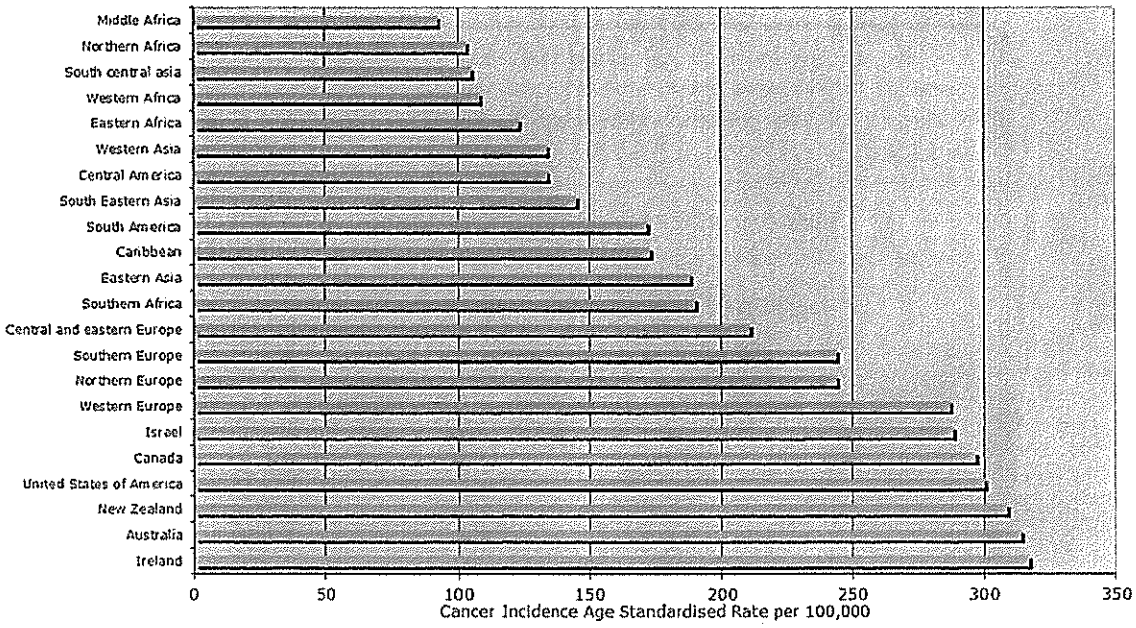
4.4.8 Infants that are still breast fed at six months of age are less than 10 per cent in the Republic whereas in the EU the figure is more than 40per cent. RoI infants would therefore have significantly greater fluoride exposure and increased risks of neurotoxicity and lowered I.Q. - a well-documented adverse effect of fluoridated water (Choi et al 2012). The US EPA website includes fluoride in the 100 chemicals having "substantial" evidence of developmental neurotoxicity.

4.4.9 The RoI has the highest rates in the EU for prostate, ovarian, colon, rectal and pancreatic cancers as well as Non-Hodgkin's lymphoma (all of which are notably of concern in NZ).

4.4.10 A statistically significant increase in uterine cancer was also detected following water fluoridation during the American occupation of Okinawa, Japan, between 1945 and 1972 (Tohyama 1996).

4.4.11 The following chart demonstrates the overall increased cancer incidence in the fluoridating countries (orange bars are fluoridating countries) [Note: Israel is ceasing fluoridation in 2015].

Highest Incidence of Cancer. All cancers excluding non-melanoma skin cancer-Estimated Incidence both sexes. GLOBOCAN 2008, IARC -31.5.2013



5.0 Higher rates of osteosarcoma

5.1 In all four of the long-term fluoridating countries, compared with the rest of the world, osteosarcoma rates are also significantly elevated.

5.2 Significantly, the NRC scientific committee highlighted the carcinogenic potential of fluoride and unanimously concluded that fluoride appeared to have the potential to initiate and promote cancers including: "Osteosarcoma presents the greatest *a priori* plausibility as a potential cancer target site, the NTP animal study findings of borderline increased osteosarcomas in male rats, and the known mitogenic effect of fluoride on bone cells in culture (NRC (2006) p275).

5.3 Notably, Bassin's landmark study showing >500 per cent increased risk of osteosarcoma in boys if exposed to fluoridated water during the mid-childhood growth spurt occurring between age 6 and 8 years has not been refuted (Bassin 2006).

5.4 A recent paper has also confirmed elevated serum fluoride levels in patients with osteosarcoma compared to healthy controls (Kharb 2013).

5.5 The elevated rate of bone cancers that are mainly osteosarcoma occurs in two peaks: one in young men (where it is frequently fatal); and another peak in the elderly where the comparative increased incidence is even more marked at treble the rates seen in non-fluoridated populations of the mainland Europe.

5.6 Age-specific rates for NZ confirmed this pattern with peaks reaching 3 per 100,000 in both teenagers and the 65-85 age cohort (NZ Health Dept. statistics accessed 2013) with the

latter age cohort exceeding the latest Australian rates of 1.8 per 100,000 compared to 0.4 per 100,000 for the EU (Mirabello 2009). New Zealand's lower soil selenium levels may make NZ people more susceptible to cancerous effects of fluoride.

6.0 Fluoride - the common denominator of multi-system diseases

6.1 From the foregoing swathe of evidence, reason suggests that there is a likely greater than 50 per cent probability that fluoridation of public water supplies is linked with the markedly-higher incidence of multi-system disease.

6.2 Fluoride is a known endocrine disrupter (*State of the Science of Endocrine Disrupting Chemicals,* UNEP / WHO report 2012) and from the NRC (2006) "an endocrine disruptor in the broad sense of altering normal endocrine function."

6.3 Notably, American adults ingest daily an average of 3mg of fluoride and a 1-3 year old (under 14kg) over 1.5mg/day - or double an amount that would alter thyroid function (EPA 2010).

7.0 Industrial waste disposal

7.1 Water fluoridation uses hexafluorosilicic acid (H_2SiF_6) and its sodium salt (Na SiF) almost exclusively. They are hazard substances - HazChem class 7.

7.2 These fluoride forms are recovered ('scrubbings') from gaseous emissions following treatment of phosphate ores with sulphuric acid.

7.3 Such scrubbings are contaminated with variable amounts of lead, arsenic, beryllium, vanadium, cadmium, and mercury. Therefore, because of the different chemicals used, old studies based on the use of natural calcium fluoride are irrelevant.

7.4 Disposal of such highly-toxic and corrosive chemicals from the super-phosphate fertiliser production was a major problem until approval was orchestrated in the USA to permit dilution into municipal water supplies in the 1940s and 50s (Kauffman 2005).

7.5 If the fertiliser production companies had to store or destroy such unwanted and dangerous chemicals, it is likely that the cost of fertiliser would rise significantly. It has been fortunate for them that governments have turned a blind-eye to health and safety considerations and allowed these mainly bio-accumulative toxins to accrue in peoples' bodies and in the environments around municipal waste-water disposal sites.

8.0 Lack of safety testing

8.1 Such silico-fluoride and toxic metal fertiliser-production waste products added to public water supplies have never been tested for their likely adverse effects on peoples' health and safety and upon the environment associated with waste-water disposal.

8.2 The Republic of Ireland and NZ both have generally 'soft' water supplies that have low calcium levels.

8.3 Low calcium levels increase potential toxicity of fluoride added to water supplies.

8.4 Fluoride is a halogen that has a particularly high negative electron charge: that gives it a bias to be highly reactive with other substances – for example, aluminium cooking utensils and lead in brass plumbing fittings.

8.5 Increasing peoples' bio-accumulation of aluminium and lead would be a most serious matter; sufficient to invoke the precautionary principle or, more likely, to meet the legal test of a greater than 50 per cent probability of causing harm.

8.6 Such factors would more than offset any MoH claimed benefit of any minuscule reduction in the incidence of dental carries caused by sugar-laden diets in a proportion of the population.

9.0 Health effects

9.1 Chronic exposures to sodium fluoride – on its own - may cause damage to kidneys, lungs, the nervous system, heart, gastrointestinal tract, cardiovascular system, bones and teeth (2008 MSDS Sodium fluoride NaF 100% - sciencelab.com Texas. Accessed July 2013).

9.2 But, because fluoride is aggressive in its association with other toxic substances like lead and aluminium, it seems reasonable to suspect that reported adverse health effects of its use in public water supplies may be due to a variety (or combination) of various silicofluoride compounds.

9.3 Arsenic, lead and mercury form three of the bio-accumulative and synergistic contaminants in the fluoride mix that is added to public water supplies by the MoH fluoridation policy.

9.4 The deliberate addition of an arsenic contaminated substance at any level would not normally be permitted.

9.5 Where is the MoH research that shows that the synergistic factors between bio-accumulative toxic substances are not 'a relevant consideration' and that such factors and metal-stripping abilities of fluoride pose no health and environmental safety issues of any material weight?

9.6 Fluoride is the most bioactive of the halogens (fluorine, chlorine, bromine and iodine).

9.7 That means that fluoride by preferential uptake decreases dietary iodine availability.

9.8 Because the majority of the NZ population is already iodine (and selenium) deficient, further iodine depletion will have potentially serious adverse health effects - not only on peoples' thyroid function but also on the health of breasts with subsequent risks of fibrocystic breast disease (FBD) and cancer. It is noteworthy that daily high dose iodine supplementation is an effective treatment for FBD.

9.9 Why is it that the MoH refuses to say that it has considered such factors; that has given them due weight to each of them; and that it has done so while advancing compelling and documented reasoning available to the public?

9.10 Regarding a fluoride-iodine association, Susheela and associates commented : "*Our findings further strengthen the possibility that fluoride is often responsible for thyroid hormone*

alterations normally ascribed to iodine deficiency disorder." And:"*The role of excess fluoride in aggravating health problems in children by inducing iodine deficiency disorders appears to be either overlooked or has remained largely unnoticed.*" *(Susheela et al. 2005)*

9.11 A physiological review of fluoridation was published recently that demolished MoH claimed benefit for fluoride being responsible for material reduction in dental carries as a result of fluoridated public water supplies.

9.12 That same review also revealed widespread adverse effects including serious cardiovascular adverse events due to fluoride-induced hypocalcaemia (Sauerheber 2013).

9.13 According to Sauerheber, industrial fluoride at blood levels typically found in residents of fluoridated cities is recognized as a neurotoxin, a non-physiologic mitogen, a general enzyme inhibitor, and a permanent bone perturbant during chronic consumption (Sauerheber 2013).

9.14 Support for adverse cardiovascular effects also appeared in a 2012 paper that concluded "*An increased fluoride uptake in coronary arteries may be associated with an increased cardiovascular risk*" (Li et al.2012).

9.15 Finally, although there is international epidemiological evidence associating asthma with fluoride, the following local NZ example is pertinent.

9.15 New Plymouth ceased fluoridation in 2011: subsequently, the hospital asthma admission rate has fallen by approximately 50 percent in following years to 2014 (Taranaki DHB Figures obtained under OIA July 2014). [See Table below.]

Summary Table	
Year	# of Asthma Discharges
2003	75
2004	77
2005	79
2006	54
2007	45
2008	62
2009	86
2010	88
2011	52
2012	32
2013	42

Cessation of fluoridation

9.16 In 2007 in the Republic of Ireland, following a nationwide 30 per cent reduction in water fluoride concentration (to 0.7 from 1.0ppm), there was a 27 per cent decline in hospital admissions for asthma among children under 15 years of age; the largest decline was observed among children aged 0-4years.

10.0 Minimal reduction in dental decay

10.1 Currently, the MoH claims what appears to be an impressive 25 per cent reduction in dental decay from its policy of adding fluoride to public water supplies. But, in practical terms, this translates to only a reduction of less than one dental surface of a child's 128 dental surfaces. [In earlier times the MoH had claimed that its policy achieved a 40 per cent reduction.]

10.2 This unimpressive low reduction in dental carries on teeth surfaces has been repeated in American and Australian dental research that sought to measure fluoride benefits. The actual data research results were as follows:- Brunelle and Carlos 1990 (**0.6 surface**); Spencer AJ and Slade 1996 (**0.3 surface**); and Armfield and Spencer 2004 (**1.5 surfaces**).

10.3 Furthermore, the latest findings (Slade and Spencer 2013) on lifelong - 45 years - exposure in Australia, showed that fluoridation of public water supplies had a maximum benefit of 1 tooth saved – but even that result was at the margin of questionable statistical relevance.

10.4 Notwithstanding that a policy of fluoridation of public water supplies apparently results in such minuscule reductions in dental carries, policy proponents continue to mislead and deceive government decision-making – apparently intentionally - by using a percentage figure rather than an absolute measure.

10.5 Meanwhile, officials in fluoridating countries continue to ignore the probability of serious adverse health and environmental effects of their policy of adding fluoride to public drinking water. There is, consequently, no proper risk/benefit assessment to inform proper and trust-worthy public policy formulation and use of statutory powers.

10.6 Arguably, that conduct is a serious breach of government fiduciary obligation (and trust that the public necessarily resides in its machinery of government); a breach of the principles of constitutional and administrative law; and a breach of the purpose and intent of established statutory provisions relating to health and safety of people and the environment.

10.7 In addition, the established MoH policy to pursue fluoridation of public water supplies as a route to making what turns out to be – at most - a minuscule reduction in dental carries ignores the fundamental dietary cause of dental carries and its portent for resulting in even more serious disease. That may perhaps be reasonably described as gross negligence.

11.0 Dietary link with dental caries

11.1 During the 1950-60s Ralph Steinman, Professor of Dentistry at Loma Linda University, California, published over 20 relevant primary animal research papers. He was the co-discoverer of the hypothalamic-parotid endocrine axis that controls the rate of fluid movement through the dentine (Steinman and Leonora 1968).

11.2 Steinman demonstrated that dental caries mainly resulted from chronically elevated levels of sugars in the blood.

11.3 Systemic sucrose resulted in the normal caries-protective retrograde dentinal fluid movement ceasing and even reversing. This reversal facilitated bacterial invasion of the several kilometres of dentinal tubules per tooth.

11.4 Physiological failure therefore preceded structural failure that Steinman also showed

occurring in the dentine prior to enamel breakdown (Steinman 1971).

11.5 The dental "fluoride bomb" where much of the underlying tooth has already decayed by the time a pinhole appears in the fluoride-hardened enamel is entirely consistent with Steinman's research.

11.6 This delayed caries detection occurs in the young adult at a time when the unexpected and significant financial costs are even more burdensome.

11.7 Dental caries therefore appears to be a systemic disease that is eminently controllable by diet and not a fluoride-deficiency condition.

11.8 Notably, the Maori population on their ancestral diet and drinking "fluoride-deficient" waters had less than 1:1000 teeth showing any decay until adopting foods of commerce based on white flour and sugar.

11.9 That shift in diet and the incidence of dental caries then increased to 40 per cent within a generation (Price 2010).

11.10 A 1.5L bottle of cola in a supermarket that some children drink on a daily basis is cheaper than bottled water but contains 162 grams - or about 40 teaspoons - of sugar. Even a tin of baked beans contains significant quantities of sugar. It is a substance that predisposes people to obesity and diabetes Type 2.

11.11 Thus, government officials in any administration that simply focus policies on addressing symptoms (i.e. dental caries) of serious and potentially life-threatening dietary habits may arguably and reasonably be regarded as negligent.

11.12 In November 2014 the Annual Report of the (UK) Government Chief Scientific Adviser, Mark Walport entitled: *Innovation: Managing Risk, Not Avoiding It. Evidence and Case Studies* was published. Professor Andrew Stirling was an invited contributor for a chapter in which he stated in section 2 Policy and the Politics of Choice: *"History presents plenty of examples of innovation trajectories that later proved to be misguided – for instance involving asbestos, benzene, thalidomide, dioxins, lead in petrol, tobacco, many pesticides, mercury, chlorine and endocrine-disrupting compounds, as well as chlorofluorocarbons, high sulphur fuels and fossil fuels in general. In all these and many other cases, delayed recognition of adverse effects incurred not only serious environmental or health impacts, but massive expense and reductions in competitiveness for firms and economies persisting in the wrong path"* (Stirling 2014).

12.0 Recommendation

That the MoH should withdraw this application to make an amendment to the Medicines Act 1981 and that the MoH directs that fluoridation of public water supplies should cease.

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ATTACHMENT B

MoH FLUORIDATION OF PUBLIC WATER SUPPLIES POLICY: ECONOMIC AND OTHER STRATEGIC RELEVANT CONSIDERATIONS

1. Introduction

1.1 Policies made pursuant to a statute are a species of subordinate legislation. To be lawful, policies cannot be formulated such as to contravene a statutory purpose or otherwise not be reasonably in the public interest.

1.2 Arguably, therefore, if there is no documented evidence that a policy has been formulated taking into account all relevant considerations, then it would be absurd for Parliament to be asked to pass an amendment to a related act in order to facilitate a likely deficient and unlawful policy.

1.3 It seems plain from correspondence with the Ministry of Health (MoH) that it made an arguably arbitrary policy decision, many decades ago, to fluoridate public water supplies. Arbitrariness may reasonably be suspected because the MoH has failed to produce documentation that shows that it identified all relevant policy considerations and that it was consequently able to give due weight and acceptable reasoning in its documentation relating to all such relevant matters.

1.4 Such a gross deficiency in due process is reasonably likely to have resulted in a materially deficient or possibly an unlawful policy: 'an error in making findings of relevant fact'; and 'an error inconsistent with relevant legislative purpose and intent'.

1.5 Such a circumstance is hardly a proper and lawful foundation for advancing a directly-associated amendment to an associated act for the express purpose of enabling delivery of the possibly deficient and illegal policy.

1.6 Such MoH conduct gives the appearance of being 'arbitrary'; possibly 'unlawful and illegal'; and therefore likely to have a high probability of producing results contrary to statutory purpose and the public interest.

1.7 The MoH has been unable to produce to date and in a timely manner for these submission purposes any documentation that demonstrates that it took into account relevant:

1.7.1 accumulative biological risks to health;

1.7.2 accumulative risks to environmental safety; and

1.7.3 possible serious and accumulative adverse economic and strategic risks to the national interest.

1.8 The MoH has simply persisted in a claim that its policy is necessary because MoH claims that fluoride in public water supplies has a material beneficial effect on reduction of dental carries – (although that claim is not supported by the facts as set out in the preceding Attachment A).

1.9 The MoH seems to have decided that it can rely upon simply taking comfort in adopting 'water treatment standards' imported from overseas entities. But there is no evidence that those so called 'standards' were formulated with any due regard to all relevant safety considerations (such as those examples set out in this submission).

1.10 Also, as mentioned in Attachment A, NZ people have relevant characteristics of low calcium levels that risks fluoride in water supplies being more toxic. Yet MoH has not advanced any evidence that it has taken into account such relevant factors in its adoption of 'standards' for fluoridation of NZ water supplies.

1.11 Now, the MoH is proposing to seek an amendment to the Medicines Act 1981 so as to set aside fluoridation of public water supplies from the safety provisions of that Act – despite established health statutes emphasising that the purpose and intent of the health statutes that the MoH administers is focussed primarily upon securing *protection* of the health and safety of New Zealanders.

1.12 While MoH appears to be seeking that amendment to enable implementation of its established policy to encourage fluoridation of public water supplies, the seeking of that amendment draws into focus whether or not the MoH established *policy* is in the public interest; and whether or not the amendment complies with the purpose and intent of the established health statutes.

1.13 It would arguably be absurd for MoH to claim that its proposed *amendment* does not rely upon its long-established *policy* to encourage delivery of fluoridation of public water supplies.

1.14 However, the MoH has not been able to advance to the PSGR advisor on machinery of government matters any of the required regulatory impact assessment (RIA) and regulatory impact statement (RIS) documentation that is supposed to show to the control agencies in government and to the general public that the MoH policy formulation considered all

relevant matters and that it gave those matters due weight with acceptable and documented reasoning when it formulated its policy. [See para 1.20 for details about requests for documentation.]

1.15 Thus there is arguably no documented sound policy foundation to support the MoH proposed advance of a statutory amendment proposal to Parliament.

1.16 Therefore, it follows that the principal Parliamentary committees concerned with maintaining quality of regulatory matters – the Regulations Review Committee and the Legislative Advisory Committee – will not be informed in the manner that they require for proper purview of such an amendment.

1.17 In addition, Government policy requires regulatory impact assessments and associated statements to be produced: thus it seems that the Treasury's Regulatory Impact Assessment Team (RIAT) will apparently have no relevant documentation to assess for the carrying out of its task on this amendment and related policy matter.

1.18 Similarly, it seems that the Law Society will not be equipped with adequate documentation so that it may undertake properly its statutory observer role.

1.19 Also, there is arguably no proper documented basis for enabling timely consultation with the general public about this proposed amendment.

1.20 A written request for such documentation was made on behalf of PSGR on 12 December 2014. MoH did not comply with that request indicating in a reply that it wished to treat the request as an OIA procedural matter; MoH also advised that such treatment would result in a delay; and the extent of the likely OIA delay would mean that the adequacy or otherwise of the MoH documentation relating to this matter could not inform the PSGR submission (or other submissions) about MoH consideration (or non-consideration) of relevant matters.

1.21 Such a MoH response raises a suspicion that the MoH had not carried out the required regulatory impact assessment prior to advancing its proposed amendment.

1.22 Such conduct by MoH – coupled with the MoH timing of its public consultation and submission matter to occur over the Christmas/ New Year holiday period - seems to suggest that the MoH was intent upon a cynical and possibly bad faith course to push through the amendment that it wanted in what might reasonably be described as an unaccountable, arbitrary, unlawful and tyrannical manner.

1.23 On examination, it is clear that the imported 'water treatment standards' that MoH adopted within its policy to encourage fluoridation of public water supplies did not take into account the due spectrum of risks as set out in paragraph 7.1 above – and in particular long-term and

accumulative effects and strategic implications for the national interest.

2. Second-order effects of fluoride in water supplies

2.1 It is arguably not adequate for MoH to formulate a policy on fluoridation of public water supplies without having due regard to (and documenting) such reasonably relevant factors as:

2.1.1 elemental chemical synergy effects on people (e.g. mercury with lead); and

2.1.2 bio-accumulative effects of introduced toxic substances and their synergistic effects on people; and

2.2.3 similar effects associated with safety of concentrated waste-water disposal into the environment.

2.2 For example, the typical form of fluoride fluorosilicic acid or hydrofluorosilicic acid (HFS) used for fluoridation of public water supplies contains the following additional substances – some of which are particularly toxic as well as bio-accumulative and synergistic with one another (increasing their toxicity) in both people and the environment. (Source of the table below is Prayon Rupel S.A., Belgium – a supplier to NZ.)

Substance	Max. allowable level (MAL) micrograms/l
Arsenic	5
Barium	200
Beryllium	0.4
Cadmium	0.5
Chromium	10
Copper	130
Nickel	10
Lead	1.5
Antimony	0.5
Selenium	5
Thallium	0.2
Mercury	0.2

2.3 A 10 fold difference in arsenic levels between HFS batches (4.9-56.0ppm) has been confirmed that could potentially exceed standard safety levels when diluted and there are

currently no routine measurements for metal content per batch (Mullinex PJ 2014). Notably, the Maximum Contaminant Level Goals (MCLG) are set at 0ppm for both arsenic and lead (US EPA 2012)

2.4 Mercury, lead, arsenic and cadmium are accumulative and particularly synergistic in both their neurotoxicity and their cytoxicity. (ATSDR2004 and Mullinex PJ 2014)

2.5 Fluoride in water supplies has the capacity to strip aluminium from kettles and cooking pots with increased risk of neurotoxicity from elevated aluminium levels (Isaacson RL et al 1997 and Varner JA et al 1998) .

2.6 Fluoride in water supplies has the capacity to strip lead from plumbing systems – particularly if water disinfection is also added in the form of chlorine (and that is usually the case in most large municipal water supply systems) (Maas RP et al. 2007).

2.7 Lead in brass plumbing systems is usually stabilised and contained by formation of lead oxide and lead dioxide coatings. When chlorine is used as a disinfection agent it tends to disrupt those protective coatings; but the addition of fluoride strips those protective coatings away allowing remaining fluoride to burrow into the lead concentrated on the outer skins of brass fittings. (Maas RP et al. 2007).

2.8 Children exposed to silicofluoride treated water have elevated blood lead levels and about double that of children in non-fluoridated communities. (Coplan MJ et al 2007) .

2.9 Where is the MoH documentation that shows that it has considered all of these categories of likely toxicity in a reasonable way and given them due weight in its formulation of its policy to add fluoride to public drinking water?

2.10 Yet these few factors illustrated above are not an exhaustive list of the likely scale of the combined accumulative and synergistic effect of toxicities associated with the addition of fluoride to public water supplies.

3. Third-order adverse effects of fluoride in drinking water

3.1 There is mounting evidence that fluoride in drinking water together with other common contaminants causes both direct and indirect brain damage *in utero* as well as accumulative material damage to a person's brain during their lifetime. That evidence points to effects that range from materially-lowered IQ and brain-functioning disorders ranging from ASD through to early Alzheimer's disease (AD) (Grandjean P. 2014).

3.2 Municipal waste water from fluoridated water supplies tends to be disposed of in a concentrated area where the range of toxic materials referred to in para 2.2 above will tend

to bio-accumulate in soils, underground aquifers and flow into streams, lakes and river systems.

3.3 Such waste water concentration issues arguably trigger issues of compliance with the purpose and intent of the Resource Management Act 1991. MoH does not seem to have advanced any documentation that shows that it has considered the potential for such third-order adverse effects on the environment when it formulated its fluoridation policy. Yet, there is arguably a statutory duty for MoH to comply with statutory purposes set out in such statutory instruments because they bind the Crown.

3.4 It is submitted that the MoH policy on adding fluoride and its associated toxic substances into public water supplies to the likely inter-generational detriment of peoples' health as well as detriment to the environment should, long ago, have caused MoH to set aside any reasoned pursuit of its idea to advance a policy of fluoridating public water supplies in New Zealand - on the grounds that the risks well out-weighed any possible gains.

3.5 It is not acceptable to administrative law for the MoH to deny evidence of 'a reasonable probability' of significant harm to people and the environment by continuing to claim 'that the present scientific evidence' (i.e. evidence of 95 per cent certainty) has not yet proven that fluoridation of public water supplies in unsafe'. That is arguably a spurious, misleading and unlawful position for the MoH to take.

3.6 It should be clear to the MoH that the available science *does* indicate a reasonable probability of significant inter-generational harm to both people and the environment being caused by its established policy to fluoridate public water supplies.

3.7 Arguably, there is sufficient scientific evidence, for MoH policy formulation purposes, to require the engagement of the precautionary principle and in many instances of the currently available science engagement of the legal test (greater than a 50 per cent probability) of a reasonable probability of harm. Qualification for either test should, arguably, require MoH to abandon its fluoridation policy.

3.8 For the MoH to further persist with its policy would be against the public interest and therefore illegal.

3.9 Thus, it is arguably an absurdity that the MoH is currently pursuing an 'enabling' amendment to the Medicines Act 1981 so as to advance its grossly-faulted and illegal policy to fluoridate New Zealand public water supplies.

4.0 Recommendation

a) That the Ministry of Health should withdraw its policy to pursue fluoridation of public water supplies.

b) That the Ministry of Health should withdraw its application to make an amendment to the Medicines Act 1981 apparently aimed at enabling advancement of its policy to fluoridate public water supplies contrary to safety provisions for medicines that feature in that Act and contrary to the purpose and intent of related health statutes.

* * * * * * *

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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:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Water bill payer
Question 1 *Do you support the proposed amendment? If not, why not?*	**No.** The **"Background and rationale for the proposed amendment"** does not give any rationale whatsoever. It is complete nonsense. It does however confirm that these chemicals are added to the water supply, ostensibly for a claimed therapeutic purpose. They are therefore medicines by definition. As "safety and effectiveness" is claimed so often by the promoters of these industrial chemicals, then the correct avenue would be to put them through the Medsafe medicine approval process.
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?*	This question is mis-worded. The water supply is being used as a delivery vehicle for a medicine to PEOPLE, at an uncontrolled dose.

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:
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: 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. 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"

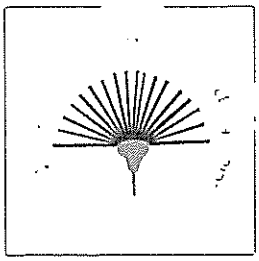
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

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.

1084



8 January 2015

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

CLINIC

PHONE

FAX

EMAIL

WEB

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

I am concerned that Medsafe proposes the above amendment and do not support it because:

1. Fluoride is not a water treatment and is added to water as a treatment of dental caries and is therefore a medicine.

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

3. 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 medicine.

4. 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 this submission.

Yours faithfully

1085

Submission re Proposed Amendment to Regulations (Fluoridated Water)
To:
askmedsafe
08/01/2015 10:05 a.m.
Hide Details
From:
To: askmedsafe@moh.govt.nz,
History: This message has been replied to.

3 Attachments

Fluorosis.jpg WHO Dental decay rates.jpg fluoride fluorosis decay comparison.jpg

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

8 January, 2014

To Whom it May Concern:

I understand that the new regulation to be made under section 105(1)(i) proposes an amendment that states "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."

I do not support this amendment. Fluoride, we are told, is added to our water supplies as a treatment for dental caries, and this amendment undermines the right of New Zealanders to be safe from the indiscriminate use of medicine. Basically, it gives councils free rein to dump a toxin into our water supplies, purportedly for a medical purpose, without medical regulation. And there are medical consequences—some quite unintended—with the use of fluoride.

A couple of years ago, when the fluoride issue began to rise into consciousness in New Zealand, I did a little of my own research. This is what I found, and it inspired me to blog on the topic[i], which I essentially share here:

In New Zealand, a little over 60% of our country's drinking water has fluoride added to it[ii]. Here in the Wellington Region where I live, only Petone and the suburb of Korokoro have fluoride-free water. According to the Greater Wellington Regional Council, fluoride is added to the rest of the region's drinking water to bring it up to a level between 0.7 and 1.0 parts per million (ppm), at a cost of $195,000 annually[iii]. The 0.7-1.0 ppm figure is based on the Ministry of Health's recommendation,[iv] a level they consider optimum for dental health. In the U.S., the recommended

level is 0.7 ppm[v].

Fluoride is an industrial chemical. The most common form to be added to drinking water is Fluorosilicic acid[vi], a liquid by-product of the fertilizer industry. In Wellington they use sodium fluorosilicate[vii] which, being a powder, is easier to ship. Fluoride occurs naturally in some water supplies, especially in volcanic and hydrothermal areas[viii].

Fluoride was first added to a municipal water supply in 1945 when Grand Rapids, Michigan (USA) became the first city in the world to have their water artificially fluoridated. This followed an early dental discovery that teeth discoloured by unusually high natural levels of fluoride in some local water sources showed resistant to decay. Further research suggested that if fluoride was added to pure water, and levels were maximized around 1.0 ppm, the tooth staining (fluorosis) caused by the fluoride would be minimal and white (rather than brown), and teeth might become more decay-resistant[ix]. By 1960, many cities in the U.S. had introduced fluoridated water.

Other than its [assumed] advantage for dental health—more on that shortly—fluoride is not advocated for any other health benefit. In fact, concern has been raised in recent years about the health RISKS of excess fluoride consumption. The US EPA (Environmental Protection Agency) sets a maximum safety level of 4 ppm[x], which is twice what their senior scientist recommended (see the documentary Fluoridegate[xi]). The World Health Organisation (WHO) recommends a maximum of 1.5 ppm[xii]. Excessive consumption—and it is cumulative in the body over time—can lead to an increased likelihood of bone fractures and bone pain, and in children can caused pitted teeth and cosmetic tooth damage[xiii]. Although there have been attempts to establish whether or not drinking fluoridated water increases the risk of cancer, examination of population records has proven inconclusive. Rats, however, showed increased risk of bone and liver cancers when given only fluoridated water to drink (see Fluoridegate). And in a recent meta analysis of several studies, fluoride exposure was linked to lowered intelligence levels in children[xiv].

One concern is that we don't just get fluoride from our tap water, nor can we as individuals easily monitor the amount of fluoride we are consuming. Most of us brush with fluoride toothpaste, and if you read the back of the toothpaste tube it will say in bold print something like: **Do not swallow. Rinse well after brushing**. Fluoride is, after all, poisonous[xv]. But how much lingers and gets swallowed with your saliva? Many mouthwashes also have fluoride. So do many soft drinks, sports drinks, wines, and juices. Tea leaves concentrate any fluoride that was in the soil, and if you make tea with fluoridated water you're getting a double dose. Some pesticides that may have been used on your food contain fluoride. Some drugs are fluorinated. If your water is fluoridated, and you drink more of it in the summer when it's hot, you're getting more fluoride than you might do if the weather is cooler and you drink less. So it's hard to measure. One caution: if you are using infant formula, be sure to NOT use fluoridated tap water to mix baby's formula as the amount of fluoride your baby is likely to consume will exceed safe levels[xvi]. (I suspect few parents in New Zealand are aware of this.)

Lastly, I'd like to come back to the central issue: does fluoridated water actually decrease tooth decay? If it does, then countries with a high percentage of water fluoridation should have lower levels of tooth decay. Yet of the top seven countries[xvii] with the lowest tooth decay rates, only England fluoridates some of its water (around 11%) according to the WHO. Meanwhile, New

[iii] http://www.gw.govt.nz/fluoride-2/

[iv] Ibid.

[v] http://www.hhs.gov/news/press/2011pres/01/20110107a.html

[vi] http://en.wikipedia.org/wiki/Water_fluoridation

[vii] http://www.gw.govt.nz/fluoride-2/

[viii] http://en.wikipedia.org/wiki/Water_fluoridation

[ix] http://www.nidcr.nih.gov/oralhealth/topics/fluoride/thestoryoffluoridation.htm

[x] http://water.epa.gov/drink/contaminants/basicinformation/fluoride.cfm

[xi] http://topdocumentaryfilms.com/fluoridegate/

[xii] http://www.who.int/water_sanitation_health/publications/fluoride_drinking_water_full.pdf

[xiii] http://water.epa.gov/drink/contaminants/basicinformation/fluoride.cfm

[xiv] http://www.ncbi.nlm.nih.gov/pubmed/18695947

[xv] http://fluoridealert.org/studies/acute03/

[xvi] http://www.health.govt.nz/our-work/preventative-health-wellness/fluoridation/fluoride-and-health/infant-formula-and-fluoridated-water

[xvii] These countries are Denmark, Germany, England, Netherlands, Switzerland, Belgium, and Sweden. http://www.fluoridealert.org/issues/caries/who-data/

[xviii] http://www.fluoridealert.org/content/bfs-2012/

[xix] Ibid.

[xx] Ibid.

[xxi] See graph at http://fluoridealert.org/articles/fluorosis_vs_caries/

Zealand is one of just 11 countries worldwide where over half the population drinks fluoridated water. The other "50%+ fluoridated" countries are the U.S., Australia, Chile, Brunei, Guyana, Hong Kong, Malaysia, Singapore, Israel, and Ireland[xviii], and tooth decay rates remain higher in these countries[xix]. In Europe only 3% of the population drink fluoridated water[xx]. Surprisingly, the WHO has recorded a general drop in decay levels over time in all countries irrespective of water fluoridation.

Which begs the question...if fluoride is a toxic chemical, and fluoridation doesn't make any significant difference to rates of tooth decay, but it does cause dental fluorosis (visible tooth damage) [xxi], it may increase the risk of bone damage and cancer, and it impacts children's intelligence, AND it costs the taxpayers money to add it to our water...why in the world are we letting this stuff be put in our water supply?

I do not support this amendment, I do not support water fluoridation, and I do not wish to speak to my submission, but I do hope you will take my objection to this amendment into consideration. I do give my permission for my personal details to be released to persons under the Official Information Act 1982 regarding this issue.

Regards,

---

[i] http://s .ter.html

[ii] http://www.fluoridealert.org/issues/caries/who-data/

1086

Fluoride

to: askmedsafe 08/01/2015 10:05 a.m.

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:
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 peopleNaku Noa

1087

NZ wide fluoride submission

o: askmedsafe 08/01/2015 10:07 a.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 not wish to speak to my submission.

1088

re: fluoride as a medication

ɔ: askmedsafe 08/01/2015 10:09 a.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: r
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.

1089

Submission Form

ıskmedsafe 08/01/2015 10:15 a.m.

History: This message has been replied to.

SUBMISSION FORM
I do (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:
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 (delete whichever does not apply) wish to speak to my submission

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I'M PRO CHOICE
ɔ: askmedsafe@moh.govt.nz 08/01/2015 10:21 a.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:
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
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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 BELIEVE PEOPLE SHOULD HAVE THE CHOICE WETHER TAKING FLUORIDE FOR THEIR OWN HELATH BENEFIT OR NOT! IT SHOULD NOT BE FORCED!

Fluoride Free NZ Submission Form
askmedsafe 08/01/2015 10:29 a.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)

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

1092

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: [illegible] [illegible] United States [illegible]	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc): Concerned citizen of the international community.	
Question 1 *Do you support the proposed amendment? If not, why not?* *No because fluoride is purported to prevent dental carries and is added to the water supply for that specific purpose therefore it must be categorized as a medicine under the act.*	

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*	

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.

Fluoridation of water

o: askmedsafe@moh.govt.nz 08/01/2015 10:45 a.m.

Please respond

History: This message has been replied to.

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.

1094

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

: askmedsafe 08/01/2015 10:59 a.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 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

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

skmedsafe@moh.govt.nz 08/01/2015 11:06 a.m.

History: This message has been replied to.

Dear Sir/ Madam,

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

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**

Yours,

1096

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

: askmedsafe 08/01/2015 11:07 a.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:

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.

Proposed changes to Exempt Fluoride as a medicine
: askmedsafe 08/01/2015 11:09 a.m.

History: This message has been replied to.

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

Dear Sir/Madam

Please find below my submission form opposing the proposed government changes to Medsafe.

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"
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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.

Yours faithfully

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

ɔ: askmedsafe 08/01/2015 11:12 a.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

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
5. The World Health Organization in its Specialist Report on Low-Dose Endocrine Disruptors (2012) stated explicitly that low doses of Fluoride cause Diabetes and Obesity as well as Thyroid Disease.
6. Israel banned water Fluoridation in August 2014 so that even communities that say they want it - can't have it. Their Health Minister is a qualified medical doctor.
7. Former Australian Federal Health Minister, member of relevant WHO committees, and medical doctor Dr Doug Everingham wants a global ban on Fluoridation

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. All Fluorides are toxic, bioaccumulative with demonstrable harm and should be banned from water supplies.

I do not wish to speak to my submission.

NZ wide fluoride submission

o: askmedsafe 08/01/2015 11:16 a.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)

"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

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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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 08/01/2015 11:18 a.m.

cc: j.coleman

History: This message has been replied to.

Dear Medsafe

SUBMISSION ON PROPOSAL THAT HFA AND SSF ARE NOT MEDICINES FOR THE PURPOSES OF THE MEDICINES ACT WHEN THEY ARE MANUFACTURED AND SUPPLIED OR DISTRIBUTED FOR THE PURPOSE OF FLUORIDATING COMMUNITY WATER SUPPLIES

QUESTION 1: DO YOU SUPPORT THE PROPOSED AMENDMENT? IF NOT, WHY NOT?

ANSWER TO QUESTION 1

I oppose the proposed amendment for the following reasons:

1 = No Regulation should be made exempting HFA and SSF from being medicines until the Court of Appeal has determined whether or not HFA and SSF are medicines under the Medicines Act.

2 = If HFA and SSF are medicines they should not be exempt from the Medicines Act.

3 = If HFA and SSF are not medicines there is no need for the exemption.

4 = The Medicines Act is designed to ensure the safety, quality and efficacy of medicines. HFA and SSF should be subject to these controls.

5 = These controls will ensure that people are not exposed to uncontrolled doses of fluoride from an industrial grade and heavy-metal contaminated fluoride substance.

6 = If fluoride tablets are not recommended for babies, toddlers and pregnant women, these sub-populations should not be ingesting fluoridated water.

7 = No protection against dental decay is provided by swallowing fluoride; consequently HFA and SSF should not be swallowed.

8 = Those people who believe there is a benefit in ingesting fluoride can buy sodium fluoride tablets from a pharmacy.

QUESTION 2: ARE THERE ANY OTHER FLUORIDE-CONTAINING COMPOUNDS USED TO TREAT COMMUNITY WATER SUPPLIES THAT SHOULD BE SPECIFICALLY IN THE REGULATION? IF SO, WHAT ARE THEY?

ANSWER TO QUESTION 2: NO.

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

Yours sincerely