

SUBMISSION

The Ministry of Health is seeking submissions, *by 9 January 2015*, on a proposed amendment to the regulations (Medicines Regulations 1894) made under the Medicines Act 1981.

The proposed amendment would have the effect of providing legal clarity that the fluoride substances used to treat drinking water are not medicines.

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

The consultation link is on the Medsafe website and is also being provided to local government, the New Zealand Dental Association and the New Zealand Medical Association:

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

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.

Impacts of the proposed amendment

The proposed amendment would have **no regulatory impact** on:

- manufacturers and suppliers of medicines containing fluorides

manufacturers and suppliers of fluorides used to treat community drinking water supplies.

The benefit of the proposed amendment is that it would preserve the status quo and provide legal clarity about the regulatory status of fluoride compounds used to treat community water supplies.

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:	N/A
Please provide a brief description of the organisation if applicable:	N/A
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	consumer
Question 1 <i>Do you support the proposed amendment? If not, why not?</i>	Yes
Question 2 <i>Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?</i>	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.

How to make a submission

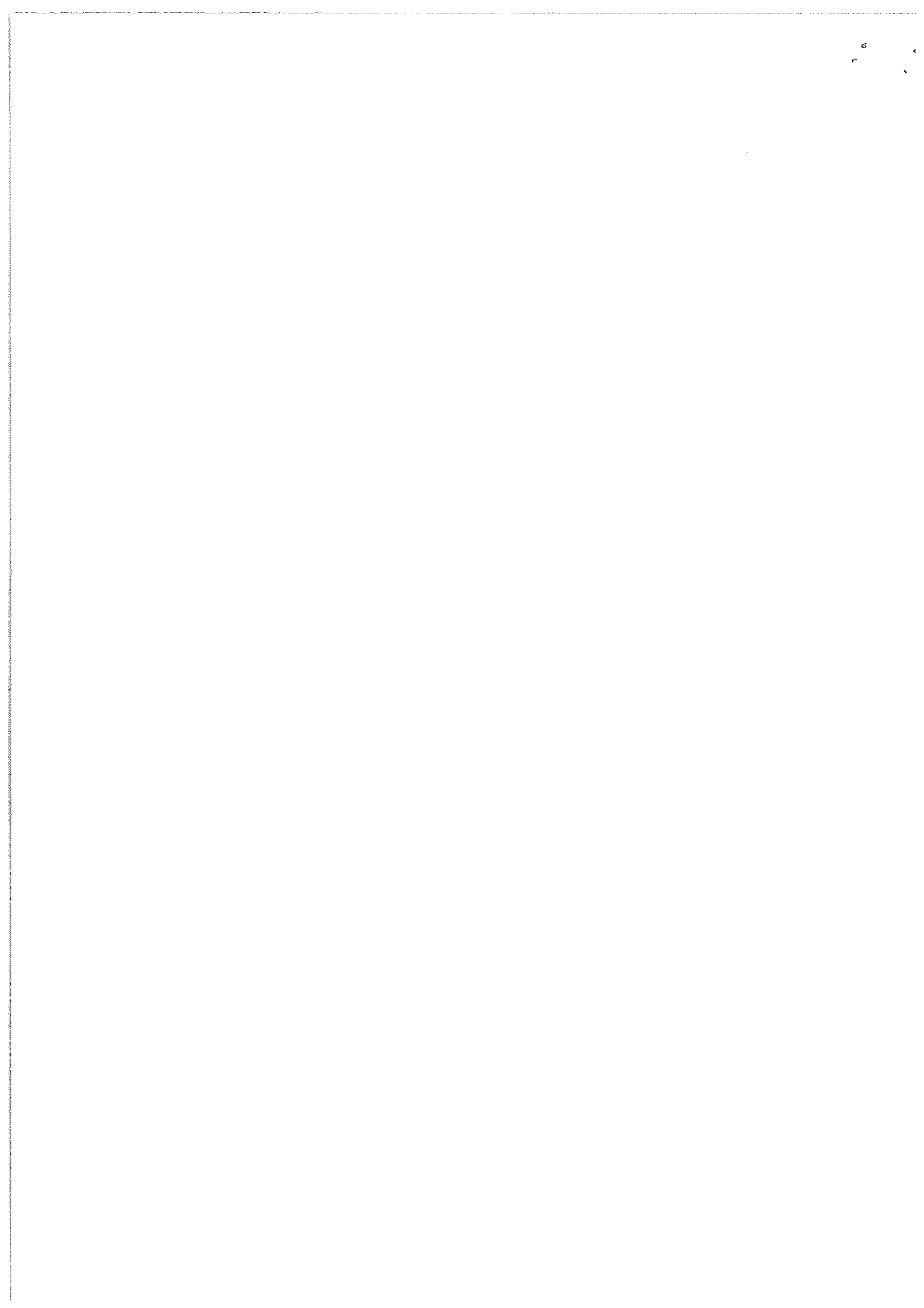
Please send your submission to:

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

or

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

The closing date for submissions is 9 January 2015.



SUBMISSION

The Ministry of Health is seeking submissions, *by 9 January 2015*, on a proposed amendment to the regulations (Medicines Regulations 1894) made under the Medicines Act 1981.

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Change proposal

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

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Impacts of the proposed amendment

The proposed amendment would have **no regulatory impact** on:

- manufacturers and suppliers of medicines containing fluorides
- manufacturers and suppliers of fluorides used to treat community drinking water supplies.

The benefit of the proposed amendment is that it would preserve the status quo and provide legal clarity about the regulatory status of fluoride compounds used to treat community water supplies.

SUBMISSION FORM

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

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If this submission is made on behalf of an organisation, please name that organisation here:	Personal only
Please provide a brief description of the organisation if applicable:	N/A
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Health professional working in public health
Question 1 <i>Do you support the proposed amendment? If not, why not?</i>	I support the amendment as stated
Question 2 <i>Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?</i>	

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.

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How to make a submission

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Regulations under the Medicines Act 1981 Consultation

Medsafe

Clinical Leadership Protection & Regulation

Ministry of Health

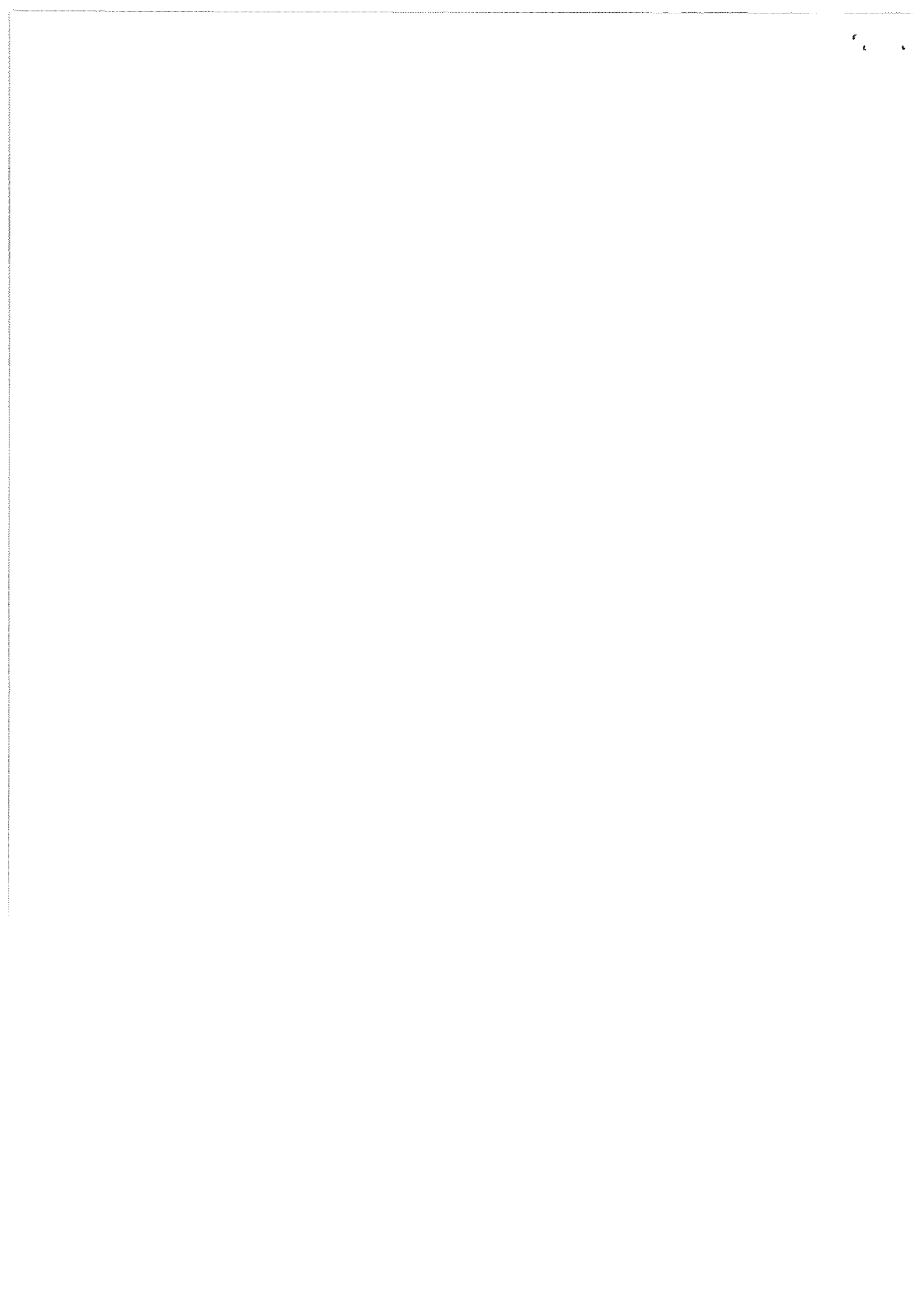
PO Box 5013

Wellington 6145

Or

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

The closing date for submissions is 9 January 2015.



203



Fw: Proposed Fluoride introduction

to:

askmedsafe@moh.govt.nz

23/12/2014 06:02 p.m.

Hide Details

From: S

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

Please respond to ' "

1 Attachment



10356323_379008028913311_96262334127894281_n.jpg

On Tuesday, 23 December 2014 5:48 PM, S

After fully investigating what Fluoride actually is and how its been covertly introduced int world water supplies, i perceive it is a dangerous cancer causeing chemical that should not be introduced to New Zealand's water supply. I see no evidence of it having any benefit in regard to tooth decay also.

Yours truly

S

You all must be unaware of how dangerous fluoride is and where it originates from.



Public Health South

Dunedin: Private Bag 1921, Dunedin 9054
Ph: 03 476 9800 Fax: 03 476 9858

Invercargill: PO Box 1601, Invercargill 9840
Ph: 03 211 0900 Fax: 03 211 0899

Queenstown: PO Box 2180, Wakatipu, Queenstown 9349
Ph: 03 450 9156 Fax: 03 450 9169

SUBMISSION ON PROPOSED AMENDMENT TO REGULATIONS UNDER THE MEDICINES ACT 1981

To: Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
WELLINGTON 6145
askmedsafe@moh.govt.nz

Details of Submitter: Public Health Service of the Southern District Health Board

Address for Service: Public Health South
Southern District Health Board
Private Bag 1921
DUNEDIN 9054

Contact Person: Leanne Liggett
leanne.liggett@southerndhb.govt.nz
03 211 0900 ext 723

Our Reference: 14Dec06

Date: 24 December 2014

Introduction

Southern District Health Board (Southern DHB) presents this submission through its Public Health Service. This Service is the principal source of expert advice within Southern DHB regarding matters concerning Public Health. Southern DHB has responsibility under the New Zealand Public Health and Disability Act 2000 to improve, promote and protect the health of people and communities. Additionally there is a responsibility to promote the reduction of adverse social and environmental effects on the health of people and communities. With 4,250 staff, we are located in the lower South Island (South of the Waitaki River) and deliver health services to a population of 308,500.

Given this responsibility, we feel it is important that we comment on the proposed amendment to the regulations (Medicines Regulations 1894 made under the Medicines Act and this submission follows the format and structure of the consultation documents.

Submission

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

The Southern DHB supports the proposed amendment to the Medicines Regulations.

Justice Collins has made it very clear in his ruling of 9 October 2014¹ that fluoride added to the drinking water supply is not a medicine, within the meaning of the Medicines Act, because the maximum allowable concentration in drinking water is 1mg/L and Schedule 1 of the Medicines Regulations specifies that every reference to a medicine in the schedule only applies if the concentration of that medicine is greater than 10mg/L.

However, the proposal to clarify 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” is a sensible and appropriate measure in the opinion of the Southern DHB.

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?

The US Center for Disease Control^{2,3} lists three fluoride compounds used as additives for community water fluoridation:

- Fluorosilicic acid: a water-based solution used by most water fluoridation programmes. Fluorosilicate is also referred to as hydrofluorosilicate, FSA, HFS or HFA.
- Sodium fluorosilicate: a dry additive, dissolved into a solution before being added to water. Sodium fluorosilicate is also known as sodium silico fluoride (SSF).
- Sodium fluoride: a dry additive, typically used in small water systems, dissolved into a solution before being added to water.

The proposal at present does not specifically list sodium fluoride. While Southern DHB understands it is not the preferred compound for community water fluoridation programmes for reasons of economics and handling, it may be used for small water systems.

Southern DHB recommends that it is also listed for the sake of completeness and clarity.

Please don't hesitate to contact the authors if we can be of any further assistance.



Dr Leanne Liggett
Public Health Analyst



Dr Tim Mackay
Clinical Leader, Oral Health Services

¹ New Health New Zealand v Attorney-General [2014] NZHC2487

² www.cdc.gov/fluoridation/factsheets/engineering/wfadditives.htm. Accessed 17 December 2014

³ <https://12240->

console.memberconnex.com/Folder?Action=View%20File&Folder_id=89&File=WATER%20FLUORIDATION%20ARTICLE_Pages%20from%20WATER_NOV-2014.PDF Accessed 10 December 2014



putting fluoride

to: askmedsafe@moh.govt.nz

23/12/2014 04:37 p.m.

Good Afternoon

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:

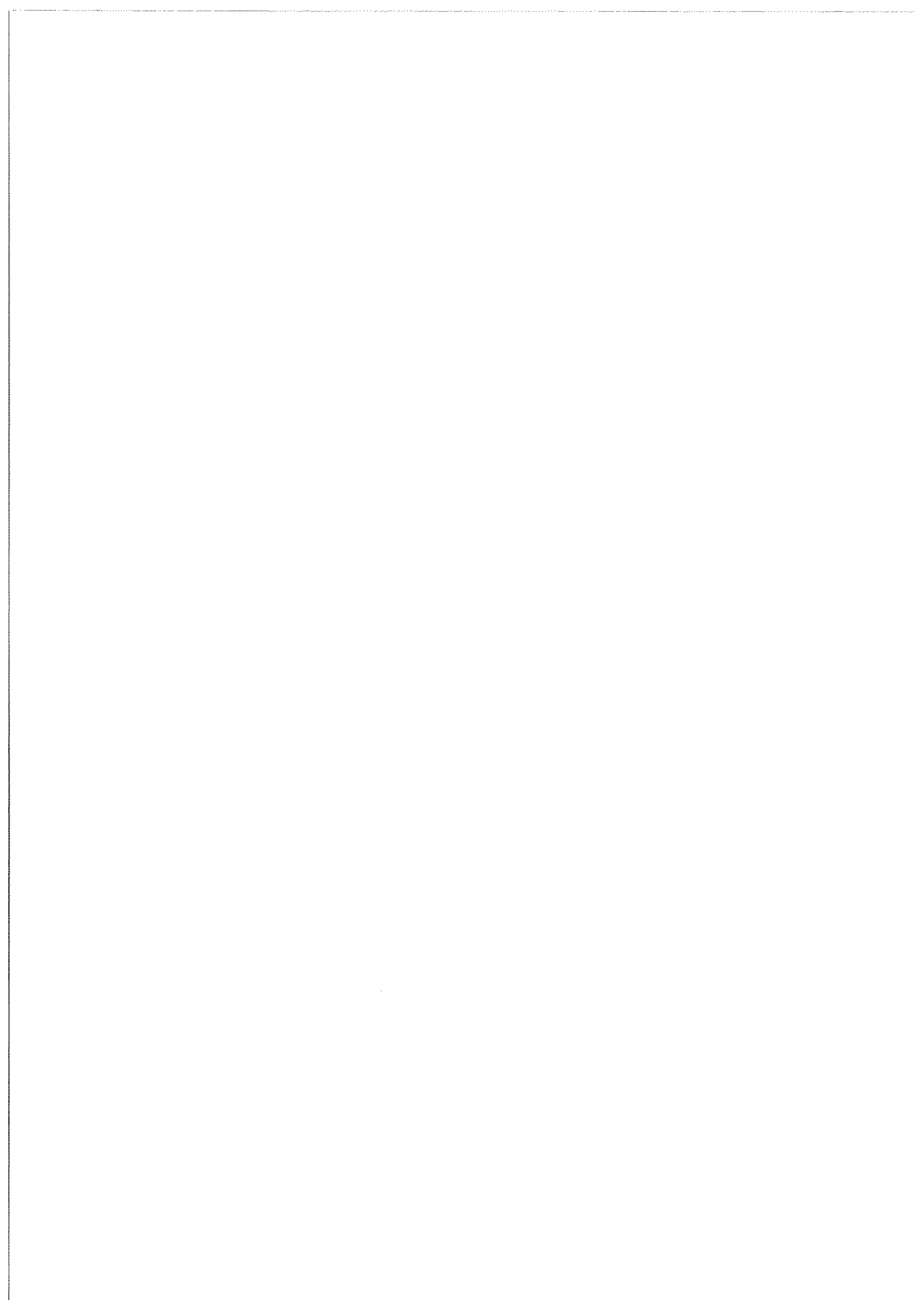
- 1. Fluoride is not a water treatment like chlorine
- 2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
- 3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health 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.

Sincere Regards



206



Submission Fluoride Poison

to:

askmedsafe

24/12/2014 08:24 a.m.

Hide Details

From:

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

Security:

To ensure privacy, images from remote sites were prevented from downloading. Show Images

Apologies, the first message had an incorrect address.....adjustment made with this submission. Regards, W.

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"

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 (CUFF) 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



This email is free from viruses and malware because avast! Antivirus protection is active.



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

to:

askmedsafe@moh.govt.nz

23/12/2014 03:36 p.m.

Hide Details

From:

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

Re: Regulations under the Medicines Act 1981 Consultation

Medsafe

Clinical Leadership Protection & Regulation

Ministry of Health

PO Box 5013

Wellington 6145

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

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Name

Email:

Address

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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. Evidence shows that Fluoride does do harm

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.

Thank-you for your attention to the contents herein.

Yours sincerely,

A man may die, nations may rise and fall, but an idea lives on. - John F Kennedy

208



FLUORIDE

to.

askmedsafe

24/12/2014 03:09 p.m.

Hide Details

From: "

To: <askmedsafe@moh.govt.nz>

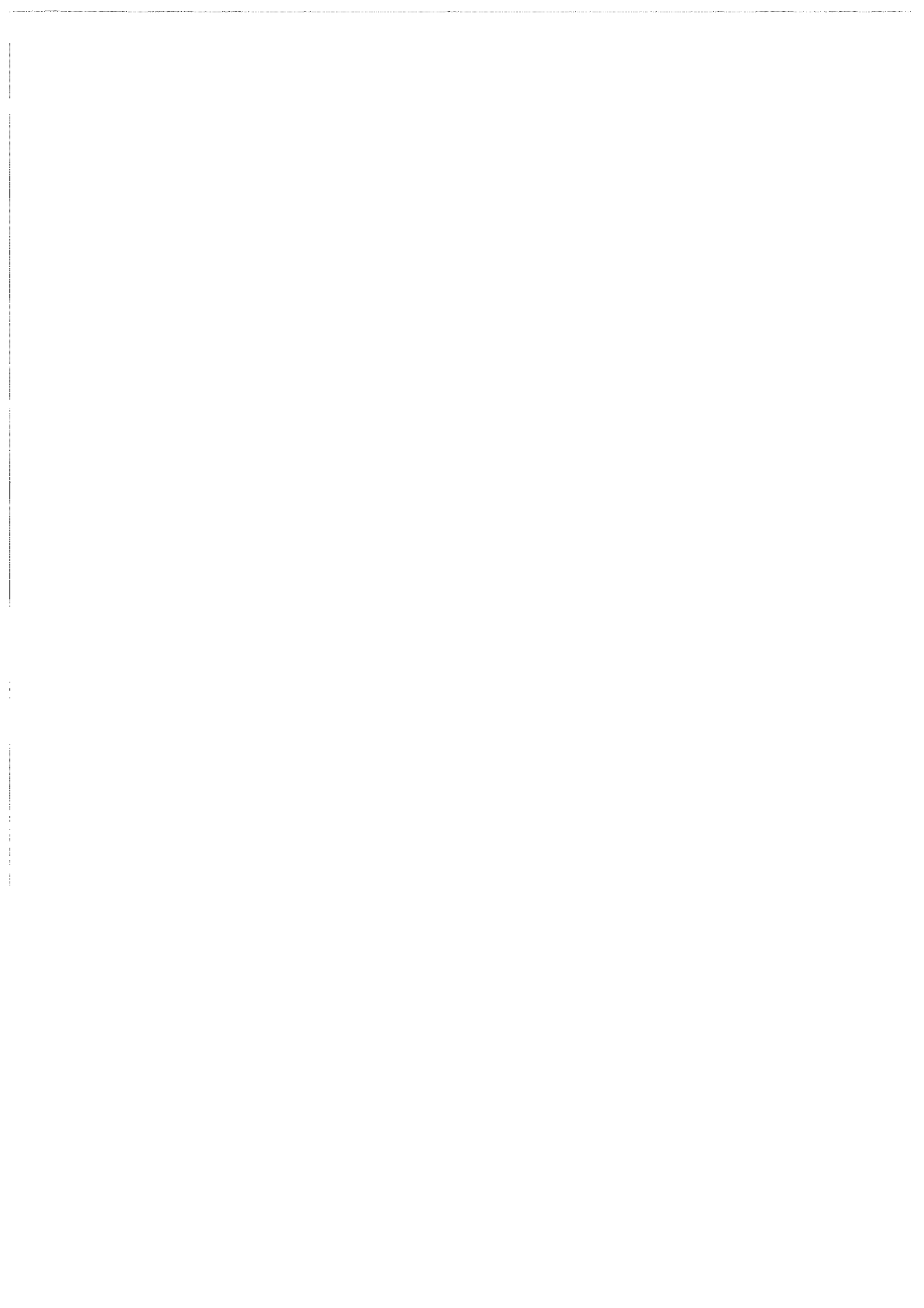
Dear sir, madam,

I am referring to the proposed legislation that would remove the possibility of public opinion from decision making by government regarding the fluoridation of water. It is incomprehensible given the volume of exquisitely sound and peer reviewed science denouncing the use of fluoride in drinking water as ineffective, undesirable and potentially exquisitely dangerous. The late New Zealand dentist, Dr. John Calquhoun, whose research work revealed so long ago that fluoridation was a useless pursuit, showed the shortcomings of this pointless exercise without even touching on the pernicious dangers of the substance. Currently, one of the foremost, and irrefutably meticulously researched, experts in this field, Prof. Paul Connett, has warned repeatedly of the potentially wicked ramifications of water fluoridation and there is a great deal of other research available to boot: <https://www.youtube.com/watch?v=R6eedSasQ8>

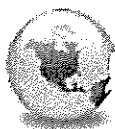
Yet here is our government blandly trying to bully through legislation that will remove the citizenry's democratic right to object to being effectively poisoned and medicated without their consent. It is draconian in the extreme and I hereby express my disgust and outrage over the proposed legislation.

Regards,

.....
.....
.....



209



Fluoride

to:

askmedsafe@moh.govt.nz

24/12/2014 12:13 p.m.

Hide Details

From:

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

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: Fluoride is not a water treatment like chlorine - **Fluoride is the only chemical added to water for the purpose of medical treatment.** The U.S. Food and Drug Administration (FDA) classifies fluoride as a drug when used to prevent or mitigate disease (FDA 2000). As a matter of basic logic, adding fluoride to water for the sole purpose of preventing tooth decay (a non-waterborne disease) is a form of medical treatment. All other water treatment chemicals are added to improve the water's quality or safety, which fluoride does not do. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine. Once fluoride is put in the water it is impossible to control the dose each individual receives because people drink different amounts of water therefore any amount added should fall within the medicines 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. 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 2014

to:

askmedsafe

26/12/2014 07:47 a.m.

Hide Details

From

To: askmedsafe@moh.govt.nz,

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

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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



211



Fluoride Submission

:

to:

askmedsafe@moh.govt.nz

25/12/2014 01:25 p.m.

Hide Details

From: :

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

Please respond to

Hello,

This is a submission to:

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

I am a sophisticated consumer of dental care, and have decades of experience with water filtration. My comments are based on my reading, and understanding as a consumer.

As dentists explain topical fluoride treatments, the concentrated fluoride can harden the enamel, as it is absorbed through the surface. Dentists also recommend fluoride in toothpaste; neither of these treatments are meant to be ingested.

These details indicate that dentists view fluoride as a 'medical' treatment; please retain fluoride on your medical list as it is presently. Sadly, one of the impacts of the proposed amendment is that it would actually obscure legal clarity about the medical status of fluoride compounds used to treat teeth.

Another aspect of my familiarity with fluoride stems from my experience with water filters. No conventional filters can reliably remove fluoride as added to municipal water systems. As you know, there are many companies that promote added fluoride, but there are very few individuals who feel the same way. Many people filter their drinking water, as a more economical approach than purchasing bottled water.

When fluoride is supplied via drinking water, there is no control regarding the amount of fluoride actually consumed, which will lead to either insufficient or excessive consumption. This approach is therefore not accepted in most countries in the world, and New Zealand should follow their lead.

Sincerely,

.



212



Proposed amendment to regulations - fluoride

to:
askmedsafe@moh.govt.nz
26/12/2014 09:43 a.m.
Hide Details
From:
To: "askmedsafe@moh.govt.nz" <askmedsafe@moh.govt.nz>,

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

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

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Name: ' '

Email

Address:

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I do not wish to speak to my submission.

213



Regulations under the Medicines

to:
askmedsafe@moh.govt.nz
27/12/2014 05:45 a.m.
Hide Details
From
To: "askmedsafe@moh.govt.nz" <askmedsafe@mon.govt.nz>,

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

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

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Name

Email

Address:

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fluoride and its compounds is to **treat people**

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Post to:

Regulations under the Medicines Act 1981 Consultation

Medsafe

Clinical Leadership Protection & Regulation

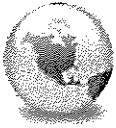
Ministry of Health

PO Box 5013

Wellington 6145

Email to: askmedsafe@moh.govt.nz

214



SUBMISSION FORM - Fluoride (2014)

to:
askmedsafe
24/12/2014 03:55 p.m.
Hide Details
F
To: askmedsafe@moh.govt.nz,

To Whom it May Concern,

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

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

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

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

Name: |

Email: |

Address: |

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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. This proposed amendment would set a precedent for adding other contaminants to NZ water supplies thereby placing the lives of all children and future generations at risk.
6. If children's dental health is top priority to Government health authorities, they would be advised to **prioritise the Restriction of sugar, soft drinks, confectionary and all sugar based produce from supermarkets. Why is do high-sugar beverages cost LESS than Water?**

<http://articles.mercola.com/sites/articles/archive/2012/09/09/ethanol-alcohol-and-fructose.aspx>

7. **Sugar is as addictive as Cocaine** and yet it is sold freely in all supermarkets, dairies and petrol stations. Many schools now look to healthy food options, realising the need to protect children's brains, intelligence and health. <https://www.facebook.com/video.php?v=292990907535892&set=vb.144320512402933&type=2&theater> .

YES- there is a problem with Oral Health in NZ Children but putting Fluoride in the water supply is NOT the answer!! To do so is to further compromise the health of the nation.

7. Provide Fluoride tablets FREE for those of limited awareness to take if they can be persuaded to, BUT **Please leave our drinking water unadulterated!** To impose toxic substances onto the public without their consent is tantamount to mass poisoning and threatens our

freedom of health.

First, Do No Harm!!

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 trust that you will take the trouble to follow the links and educate yourselves on the SCIENCE linking SUGAR to poor oral health for which the **misguided use of Fluoride** is being ineffectively used.*

I DO NOT SUPPORT THE PROPOSED AMENDMENT TO CHANGING THE WORDING OF FLUORIDE AS 'NOT A MEDICINE' FOR THE PURPOSE OF APPROVING IT FOR USE IN COMMUNITY WATER SUPPLIES.

In my opinion, THIS IS A FORM OF LEGAL MANOEUVRING DESIGNED TO MANIPULATE LEGALISED POISONING. WILL BROMIDE BE NEXT ON THE AGENDA IF THIS FOLLY GOES AHEAD???

carefully guide or manipulate (someone or something) in order to achieve an end.
synonyms: intrigue, plot, scheme, plan, lay plans, conspire, pull strings;

That this amendment was proposed by the Judicial body reviewing the case in NZ is shocking and inappropriate. The Medicines Act is designed to protect people from harm.

Yours sincerely,

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215



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

to:
askmedsafe
26/12/2014 08:10 p.m.
Hide Details
From
To: askmedsafe@moh.govt.nz,

"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 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**

I do not wish to speak to my submission.

Thanks

216



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

to:

askmedsafe@moh.govt.nz

26/12/2014 03:04 p.m.

Hide Details

From:

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

Please respond 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:

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Medsafe

Name

Email: t

Address

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When I removed the portion of fluoride from my diet that was coming from consuming flouridated tap water I experienced an extensive and quite rapid increase in the ability to think clearly. I am also diagnosed with aspergers which is a condition in which people are often already disadvantaged in terms of effective processing of minerals and/or are more sensitive to the effects of toxins. As a person representing the medical profession, it should concern you to ignore the effects that accumulated doses of toxins from multiple sources have on the much higher than previously recognised portion of the population who are now diagnosed with a condition that inhibits the body's ability to deal with toxins. Such an amendment would ignore these investigations and so endanger the health of this significantly growing portion of the population.

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

to:
askmedsafe
26/12/2014 12:45 a.m.
Hide Details
From
To: askmedsafe@moh.govt.nz, --

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

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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**

Further to the above, my research (using Medical and Dental journals), shows that fluoride is actually harmful to the human body when ingested via drinking water. I believe that fluoride is actually toxic (as it is a by-product of the fertilizer industry) and I do not want a toxic substance added to any public water supply.

The only nation in the European Union to still add fluoride to most public water is the Republic of Ireland (Eire), which actually has

*the highest rate of dental caries (cavities) in the whole EU. Adding fluoride to the water supply is **not** an effective method of reducing dental caries, and should be stopped immediately.*

Thank you,

218



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

to:

askmedsafe@moh.govt.nz

24/12/2014 10:06 p.m.

Hide Details

|

711-mail.com>

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

Submission from:

Name: 1

Email:

Address: 3

NB:

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

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

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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. I understand fluoride has been shown to have many unproductive health outcomes per articles such as these: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3491930/>, Science news 131:73, TV3 News on Sunday (21st) & many others.
6. Given these & other arguments pointing to the contentiousness of fluoridating public water supplies that largely forces everyone to ingest it, rather than risk unnecessary exposure to fluoride for the rest of the population, it would seem to make more sense to target an education campaign aimed at fluoride tablets being given to children (I was given them as a child)

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?

Putting aside the argument over the wording of this question - regarding whether there are other Fluoride-containing compounds used to 'treat' community water supplies (& that community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**); I suggest it is not so much a question of what compounds should or shouldn't be named in the regulation, as much as it is a question of how rigorous the testing is of any compound that goes into a community's water supply. Again, articles such as those above would seem to point to the existence of a significant body of material that points to some serious question marks over the safety of using adding any fluoride-containing compound to a community's water supply.

219



flouride

to:

askmedsafe@moh.govt.nz

27/12/2014 12:12 a.m.

Hide Details

From:

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

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:

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

Post to:

Regulations under the Medicines Act 1981 Consultation

Medsafe

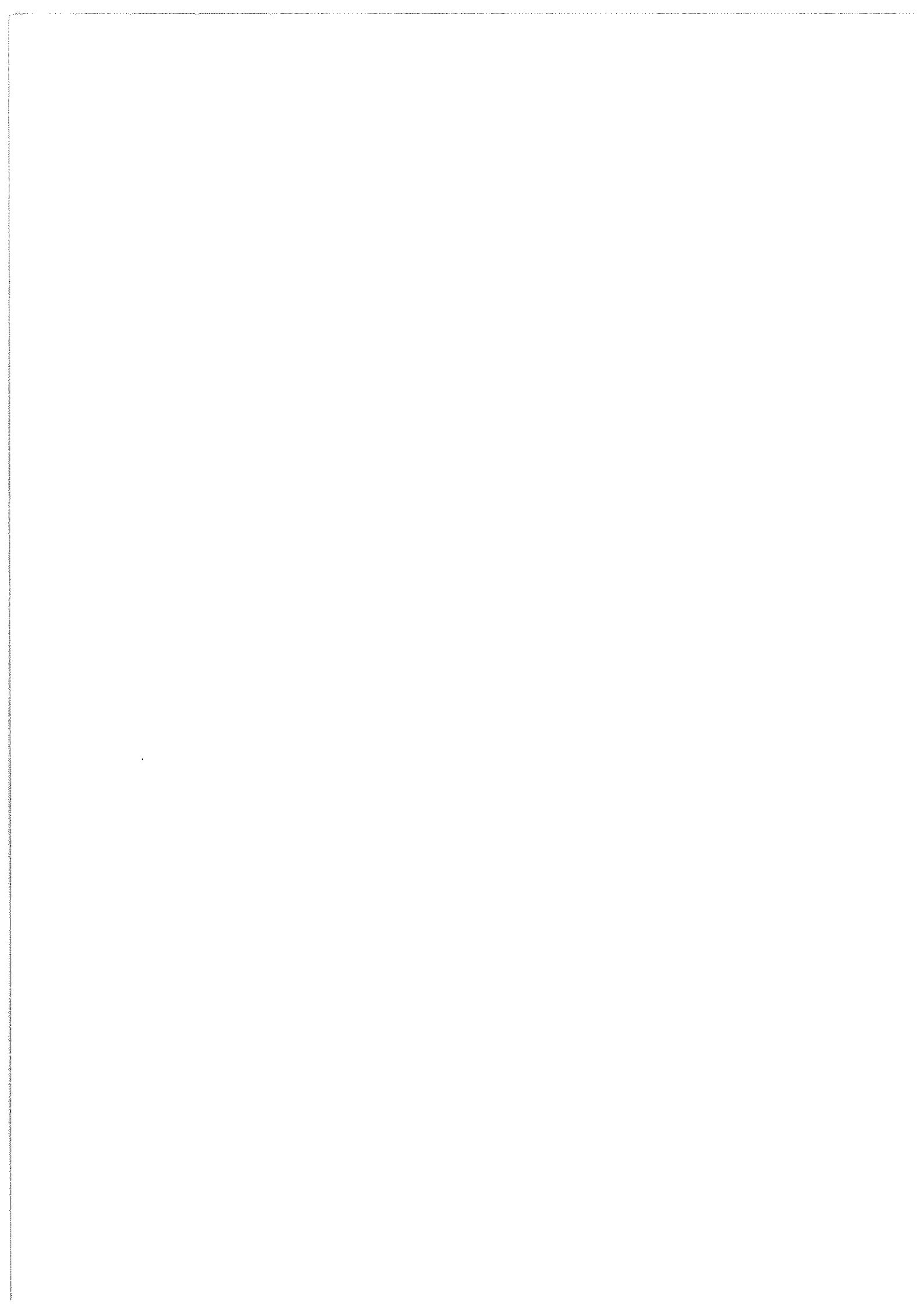
Clinical Leadership Protection & Regulation

Ministry of Health

PO Box 5013

Wellington 6145

Email to: askmedsafe@moh.govt.nz





Flouride

(

to:

askmedsafe

26/12/2014 09:46 p.m.

Hide Details

From:

To: askmedsafe@moh.govt.nz,

RE: Pending application to exempt fluoride (HFA and SSF) from the New Zealand Medicine's Act, with a closing date of 9th January 2015.

I understand that this bill means that no one would have the right to vote having their tap water free of fluoride. This seems to me an infringement of a citizen's right to make decisions which affect their health and the health of their children.

I understand that fluoride may have some positive effect in reducing the number of tooth cavities, but there are other ways, less evasive ways of using fluoride on teeth, and it is important to consider the overall effect of the chemical on the human body.

It has been established that fluoride is a pollutant and over time can cause a number of health issues.

One of the more important aspects of this is reducing the IQ in children and likely increasing the possibility of behaviour problems. I refer to a report released on July this year by a team of Harvard and Chinese scientists. This warned of fluoride's potential to reduce human intelligence. The researchers issued their warning after reviewing dozens of studies from the past two decades that have linked elevated fluoride exposure to reduced IQ in children.

The National Research Council issued a similar warning in 2006.

I feel this evidence is convincing enough to stop the introduction of fluoride into the public water supply, and certainly to prevent this bill coming into law

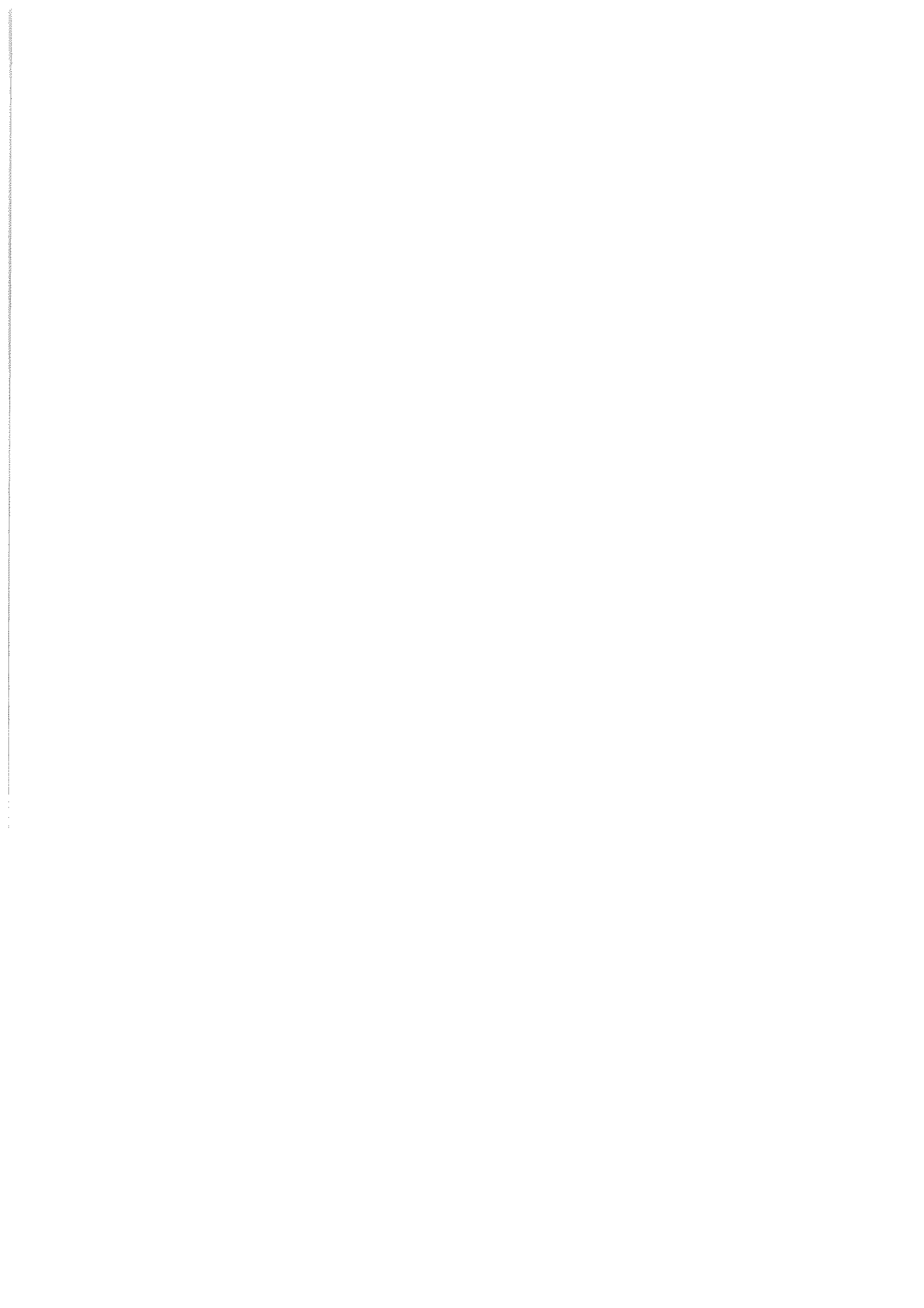
B SC Physics Hons (first class)

M SC (Operational Research)

Grad Dip Education

1

6





Fluoride

to:
askmedsafe
27/12/2014 08:19 a.m.
Hide Details
From:
To: askmedsafe@moh.govt.nz,

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

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

Name

Email:

Address:

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

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

Post to:

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



24 December 2014

Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection and Regulation
Ministry of Health
P O Box 5013
WELLINGTON

Dear Sir

SUBMISSION BY NEW HEALTH NEW ZEALAND INC

Summary

The proposal

1. The proposal is that a new regulation be made under s 105(1)(i) of the Medicines Act 1981 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.

2. Two questions are posed:

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

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?

Response to Question 1

3. New Health NZ Inc does not support the proposed amendment for the following reasons:

- 3.1. A regulation is premature and should await the outcome of the Court of Appeal decision in *New Health NZ Inc v Attorney-General*.

- 3.2. The regulation is an improper attempt to pre-empt the Court of Appeal's consideration of whether HFA and SSF are medicines.
- 3.3. The consultation document makes no reference to the appeal and is misleading as to the true rationale for the proposal. It should have referred to the appeal and expressly stated that a purpose of the exemption was to avoid the Court of Appeal determining that HFA and SSF are medicines.
- 3.4. The purpose of s 105(1)(i) of the Medicines Act 1981 is to declare substances that would otherwise be medicines not to be medicines. The power is exercised on the assumption that the substance is a medicine but that there is no need for the Medicines Act provisions to apply. The consultation document does not proceed on this basis and is flawed. On the assumption HFA and SSF are medicines, there is no rational or proper basis to exempt them from the Medicines Act. To the contrary, there are compelling reasons why they should be subject to the protections of the Act.
- 3.5. The consultation process is flawed. Insufficient information about the true reason for the proposal has been provided, the proposal fails to address the propriety of exempting these substances if they were medicines, and insufficient time has been provided to the public to respond.

Response to Question 2

4. No. The reference to treating water supplies is misleading. Water fluoridation is not a water treatment process. The only purpose of water fluoridation is therapeutic, ie to treat people, not water.

Summary of the High Court decision and grounds of appeal

5. In its decision dated 9 October 2014, the High Court held that HFA and SSF when added to domestic water supplies in NZ to produce fluoride concentrations up to 1.5 mg/l are not medicines within the meaning of the Medicines Act 1981 (*New Health NZ Inc v Attorney-General*).
6. Under the Medicines Act 1981 a medicine is defined as a substance that is manufactured, sold or supplied wholly or principally for administering to a human being for a therapeutic purpose and which achieves its intended action on the human body by pharmacological means.
7. The judge found that HFA and SSF satisfied all of the key elements of the definition of a medicine. He held that they were administered for a therapeutic purpose, namely the prevention of tooth decay, and that they achieved their intended action on human beings by a pharmacological process: paragraphs [14] to [39].
8. However, the judge found that the context, namely the Medicines Regulations 1984, required a different interpretation.
9. The judge reasoned:

- 6.1. the concentration threshold for substances to be medicines in Schedule 1 of the Medicines Regulations 1984 is 10 mg/l; and
- 6.2. the concentration of fluoride in domestic water supplies is no more than 1.5 mg /l; then
- 6.3. fluoride would only be a medicine under the Act if it was added to domestic water supplies in concentration of 10 mg/l or more.

(refer paragraphs [45] to [50] of the judgment)

- 10. The judgement is under appeal. A hearing is to be held on 12 March 2015.
- 11. New Health raises three grounds of appeal. First, the judge made a basic error of statutory interpretation when he used the Medicines Regulations to read down a definition in the parent Act.
- 12. Secondly, the judge misconstrued the Medicines Regulations and Schedule 1 in particular. Schedule 1 does not define what is or is not a medicine per se. What this Schedule does is classify the particular medicines listed as either prescription medicines, restricted medicines or pharmacy-only medicines: refer regulation 3.
- 13. Schedule 1 is not an exhaustive list of medicines.
- 14. The prefatory words in the Schedule 1 state:
 - Unless specific reference is made otherwise, every reference to a medicine in this schedule applies –
 -
 - If the medicine is not an injection or eye preparation, only if the concentration of the medicine is greater than 10 milligrams per litre or per kilogram.
- 15. This means that medicines listed in the Schedule that do not specify a concentration, are only prescription medicines, pharmacy-only medicines or restricted medicines if they are at a concentration of more than 10 milligrams per litre.
- 16. However, they are still medicines at concentrations less than 10 milligrams per litre.
- 17. The judge wrongly interpreted the Schedule to mean that the substance is not a medicine unless its concentration is more than 10 milligrams per litre. This interpretation is contrary to the plain words of the Medicines Regulations and Schedule 1.
- 18. Thirdly, as set out in the judgement at footnotes 20 to 22 of the judgment, fluoride is classified in various preparations as a prescription medicine, pharmacy only medicine and restricted medicine in Schedule 1. Contrary to the judge’s approach, the prefatory words in the Schedule do not apply to fluoride because “specific reference” has been made to define when fluoride is a prescription, pharmacy-only and restricted medicine. Put another way, the default concentration of more than 10 milligrams per litre does not apply to fluoride in order for it to be a pharmacy-only, prescription or restricted medicine.

19. The judge appears to have overlooked that fluoride is a general sale medicine at 15 milligrams or less per litre: refer footnote 23 of the judgment. That concentration captures the concentration of HFA and SSF in drinking water.

Scope of the exemption power

20. Section 105(1)(i) of the Medicines Act empowers the Governor-General to make a regulation “specifying, by name or description, substances or articles, or kinds or classes of substances or articles, that are, or are not medicines for the purposes of this Act”.
21. The definition of a “medicine” in s 3 excludes “any substance or article of a kind or belonging to a class that is declared by regulations not to be a medicine for the purposes of this Act”.
22. The purpose of s 105(1)(i) of the Medicines Act 1981 is to declare substances that would otherwise be medicines not to be medicines. The power is exercised on the assumption that the substance is a medicine but that it is not appropriate for the Medicines Act provisions to apply.
23. To date the power has been exercised in relation to dentifrice products, anti-dandruff hair products, anti-acne skin products, barrier creams and anti-bacterial skin products. Regulation 58A of the Medicines Regulations exempts these products from being medicines or related products provided they don’t contain medicines specified in Schedule 1 (ie pharmacy-only, prescription and restricted medicines) and only claim certain limited therapeutic purposes.
24. These products were exempt on the bases that they were relatively low risk products and that the Cosmetic Products Group Standard adequately protected consumers.

Improper exercise of exemption power

25. New Health raises the following concerns with the proposed exercise of the exemption power.
26. First, the regulation is premature.
27. Presently the Minister has the benefit of the High Court’s finding that HFA and SSF are not medicines. No regulation to exempt them from being medicines is required.
28. The proposed regulation is an improper attempt to pre-empt New Health’s appeal. Subordinate legislation should not be used in that way.
29. Unless New Health wins the appeal, there is no need for the regulation. If New Health succeeds on appeal, the Minister can then address whether HFA and SSF should not be medicines. By promoting a regulation now, the Minister is seeking to avoid exempting HFA and SSF on the basis that they are medicines.
30. The reference in the discussion document to the regulation providing “greater clarity about the issue by removing any possible ambiguity” is spurious as “clarity” was provided by the High Court. The true reason for the exemption is to pre-empt the appeal. The consultation document

is flawed by failing to refer to the existence of the appeal and the potential consequences of the High Court's decision being overturned.

31. Secondly, the Minister is proceeding on the basis that HFA and SSF are not medicines and that he is merely regularising the status quo. This is not the proper basis on which to exercise the power.
32. The correct approach is to assume that a substance is or is likely to be a medicine but that it not necessary that it is subject to the Medicines Act. The discussion document does not proceed on this basis or address considerations such as the relative risk of the substances or whether there are sufficient protections for the public if these substances are not regulated as medicines.
33. Thirdly, the proposal is an unusual exercise of the power. The proposal is to exempt HFA and SSF from being medicines "when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies".
34. Section 105(1)(f) permits substances to be specified by name or description or kinds or classes, not to be medicines.
35. The purpose of the provision is that particular substances or articles are either a medicine or not.
36. The proposal that HFA and SSF when put in the water supply are not medicines, but might otherwise be medicines if put in tablets for example appears contrary to that purpose.
37. It also raises the question why HFA and SSF should not be exempt in all applications and delivery mechanisms when used to prevent dental decay. Why limit the exemption to use in water fluoridation.
38. The proposal also implies that sodium fluoride tablets (which a pharmacy-only medicine) could suddenly be supplied exclusively for water fluoridation and in that form not be medicines. If that were seriously contemplated, the Ministry would need to carefully explain the rationale for such an approach.

Exemption cannot be justified if HFA and SSF medicines

39. To reiterate the regulation making power should proceed on the assumption that HFA and SSF are medicines. The question then is whether it is appropriate that they are not subject to regulation under the Medicines Act. This would include considering the risks of the substance and whether sufficient protections for consumers are available outside the Medicines Act.
40. For the reasons set out below there are compelling reasons why these substances as medicines should be subject to the controls of the Medicines Act.
41. It is incontrovertible that HFA and SSF are being used as an alternative to sodium fluoride tablets. One litre of water fluoridated at 1 ppm contains 1 mg of fluoride. That is the same amount of fluoride as two pharmacy-only sodium fluoride tablets.

A comparison of HFA/SSF and sodium fluoride tablets is set out in the table below.

	Sodium fluoride tablets (pharmaceutical grade)	HFA and SSF (industrial waste)
Claimed Purpose	Prevent tooth decay	Prevent tooth decay
Status	Medicine: Pharmacy-only medicine (ie illegal to be supplied by councils) subject to purity and other manufacturing standards set out in Medicines Act and Regulations	Hazardous substance: Toxic by-product of the superphosphate industry that may also contain arsenic, mercury and lead.
Concentration	Each tablet contains 0.5 mg of fluoride	Up to 1 mg of fluoride per litre of water
Recommended Maximum Dose of Fluoride	Not to be taken by children under 3 or during pregnancy. 3 to 5 years: half a tablet daily 6 to 8 years: 1 tablet daily Adults: Two tablets daily.	Dose is uncontrolled and depends on how much water is drunk by each individual. Many children and adults will exceed maximum daily recommended medicinal doses. Babies, toddlers, and pregnant women should not be drinking fluoridated water.
Informed consent	Yes	No

42. Sodium fluoride tablets and HFA and SSF are identical in terms of therapeutic purpose and effect. They are being used to prevent tooth decay and have the same pharmacological mechanism of action. Sodium fluoride tablets have been assessed to be of sufficiently high risk to be pharmacy-only medicines.
43. There is no justification for sodium fluoride tablets being regulated as medicines and subject to the quality, safety and efficacy requirements of the Medicines Act, but not HFA and SSF.
44. First, if sodium fluoride tablets are subject to the purity and manufacturing requirements of the Medicines Act, so too should HFA and SSF. HFA and SSF are heavy-metal contaminated toxic industrial waste products. These substances should not be permitted to be used on whole populations when there have been no reports of tests or clinical trials made to establish their safety and efficacy.
45. Secondly, there is the issue of dose. All medicines must be delivered in a dose form and have a specified maximum dose. Sodium fluoride tablets have a maximum stated dose for an adult of two tablets which is 1 mg of fluoride. Fluoride tablets should not be taken by babies, toddlers and pregnant women. There is no justification for the Ministry stipulating a maximum dose of fluoride for sodium fluoride tablets but permitting the same active ingredient to be delivered in uncontrolled doses through water fluoridation.

46. Many people will consume more fluoride through fluoridated water than is the recommended daily dose for an adult consuming sodium fluoride tablets. The potential risks of systemic over-exposure to fluoride are well documented. These risks include dental fluorosis, skeletal fluorosis, bone fracture, bone cancer, lowered IQ, kidney and thyroid dysfunction, and gastrointestinal problems. By failing to control the dosages of fluoride delivered through water fluoridation, the Ministry is potentially jeopardising the health of New Zealanders.
47. This is particularly so for babies and infants and toddlers who drink water or formula made with fluoridated water. With no or few teeth they derive no benefit from fluoridated water but depending on how much they drink, may be susceptible to fluoride poisoning in the form of dental fluorosis.
48. The Ministry doesn't permit any other medicine to be administered in uncontrolled doses, and HFA and SSF should not be treated any differently.
49. Thirdly, water fluoridation trespasses on personal rights and liberties. Contrary to ethical medicine delivery principles, HFA and SSF are administered to populations without informed consent.
50. The Ministry needs to explain why in respect of the provision of these medicines, informed consent can be overridden when that tenet is fundamental to the administration of all other medicines.
51. As a final but separate point it is noted that the prior use of the exemption power has been restricted to topical substances, such as hair and skin products and dentifrices.
52. The current proposal relates to medicines that are to be swallowed.
53. If a systemically ingested medicine is to be exempt, it should be on the basis of compelling evidence that the medicine worked systemically.
54. The scientific evidence, is clear that to the extent fluoride provides any benefit against tooth decay, its effect is primarily topical. The effect of ingested fluoride on dental decay is minimal and this point is not seriously contested. It is also not seriously in dispute that the concentration of fluoride in ductal saliva is too low to have any cariostatic effect.
55. It raises the question of why people should be required to swallow fluoride via water fluoridation when any benefit is provided topically. You don't drink sunscreen to provide protection for your skin.
56. Tellingly the Ministry in its discussion document acknowledges that "there is no universal acceptance of the positive health effects of the addition of fluoride to drinking water supplies": This is a welcome concession by the Ministry. It also demonstrates that the recent Gluckman/Skegg report which refused to consider the scientific evidence on efficacy on the grounds that there was "a clear consensus on the effectiveness of CWF", was wrong.

Second question

57. In its discussion document the Ministry refers to fluoride substances used to “treat drinking water”.
58. That phrase is inapt and spurious. Fluoride is not a water treatment agent. It is being put in the water solely to treat people.
59. HFA and SSF when used to prevent dental decay and when used in any manner, not just in water fluoridation, should not be exempt from the Medicines Act, and neither should any other so-called water fluoridation substance.

Consultation timeframe too short

60. New Health objects to the limited timeframe for making submissions and the fact that submissions are due so early in the New Year.
61. The timeframe is unreasonable and the submission period should have closed around early to mid February 2015. Under the Official Information Act the period 25 December to 15 January is excluded from the time within which officials are required to respond to requests for information. Submitters should not be expected to provide a response within this period either. Many people will still be on holiday.

Proper way for the Ministry to proceed

62. The proposal and process are flawed and open to challenge.
63. New Health says that the following should occur:
 - a. The Ministry withdraws the proposal.
 - b. Any new proposal proceeds on the following basis: that a regulation is only required if the Court of Appeal determines HFA and SSF are medicines; the Ministry fully explains in the consultation document why, if HFA and SSF are medicines, they should nonetheless be exempt from the Medicines Act.
 - c. The appeal is heard and determined.
64. For completeness New Health’s view is that the Minister could not responsibly promote an exemption on the basis that HFA and SSF are medicines. If the Ministry actually confronted the proposition that HFA and SSF were medicines it would not be able to explain why fluoride tablets must be pharmacy-only medicines but that HFA and SSF can be immune from the protections of the Medicines Act. A regulation must not be a mechanism to rubber stamp a flawed Ministry of Health policy, and some Councils’ practice of the past.

Request to be heard orally

65. New Health wishes to be heard in support of its submission. Counsel is away until 26 January 2015 but would be available from 27 January onwards.

Yours sincerely

v





Fluoride

o: askmedsafe@moh.govt.nz

25/12/2014 10:03 p.m.

I a pose this bill being passed for the effects that it will have on human beings living on this earth.

We are made up of 85% water, we require good healthy clean water to live healthily and as we are intended to be. Without this we deprive ourselves of one important source to sustain ourselves.

We are at a very crucial time where we need to make decisions and these decisions determine our -the human race existence.

Keep our resources pure and uncontaminated.

Fluoride has only one real outcome and it is not the one we need.

Ngati Ra, Ngati Ra, Ngati Ra.

Sent from my iPad



Floride

to:

askmedsafe

27/12/2014 12:46 p.m.

Hide Details

From

To: askmedsafe@moh.govt.nz,

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

I do not wish to speak to my submission.

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225

same as 208



flouride

F

to:

askmedsafe

29/12/2014 04:25 p.m.

Hide Details

F

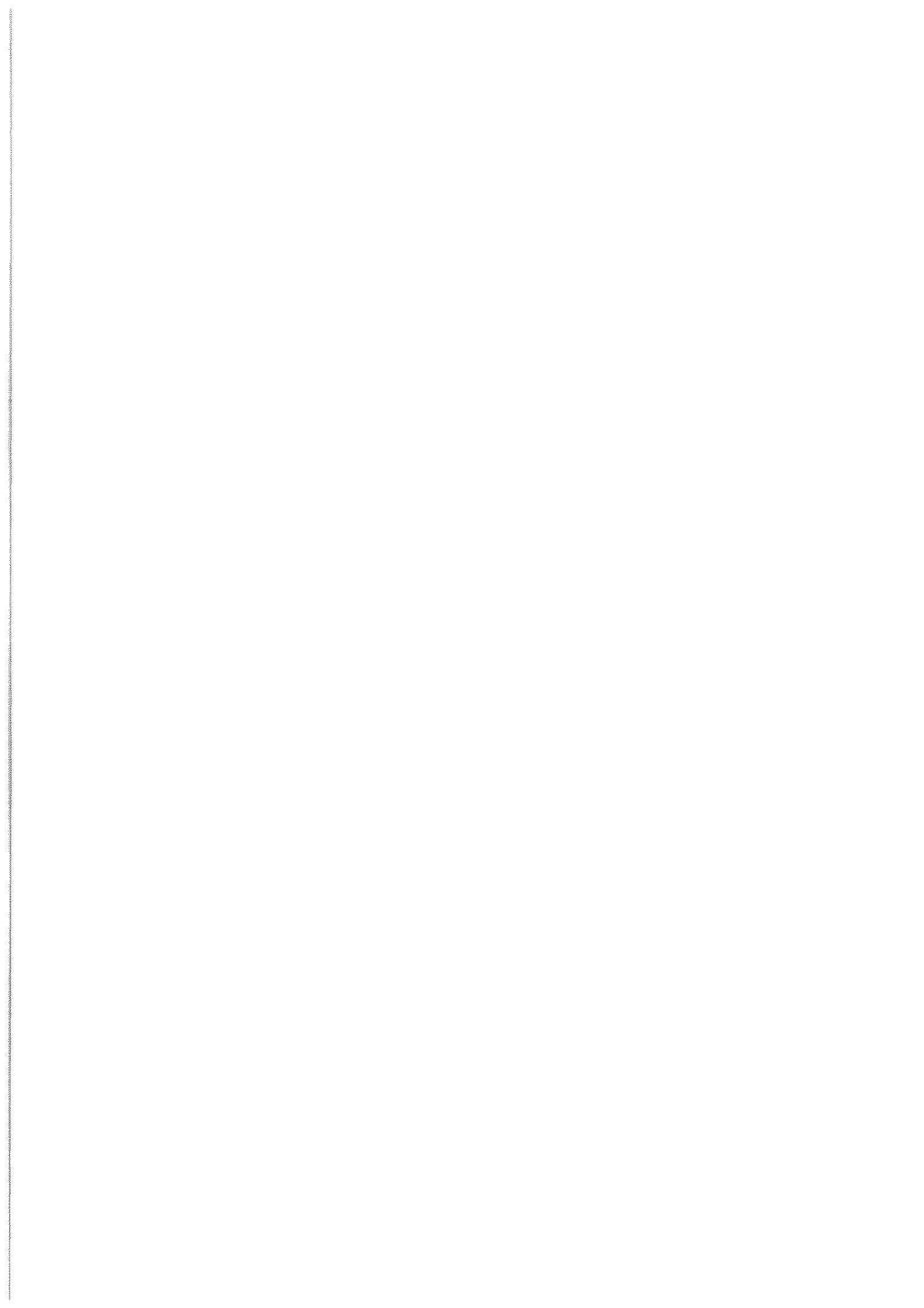
To: askmedsafe@moh.govt.nz,

Dear sir, madam,

I am referring to the proposed legislation that would remove the possibility of public opinion from decision making by government regarding the fluoridation of water. It is incomprehensible given the volume of exquisitely sound and peer reviewed science denouncing the use of fluoride in drinking water as ineffective, undesirable and potentially exquisitely dangerous. The late New Zealand dentist, Dr. John Calquhoun, whose research work revealed so long ago that fluoridation was a useless pursuit, showed the shortcomings of this pointless exercise without even touching on the pernicious dangers of the substance. Currently, one of the foremost, and irrefutably meticulously researched, experts in this field, Prof. Paul Connett, has warned repeatedly of the potentially wicked ramifications of water fluoridation and there is a great deal of other research available to boot:<https://www.youtube.com/watch?v=R6eedSasQ8>

Yet here is our government blandly trying to bully through legislation that will remove the citizenry's democratic right to object to being effectively poisoned and medicated without their consent. It is draconian in the extreme and I hereby express my disgust and outrage over the proposed legislation.

sent with love and blessings, and hope for your **SENSES** to be restored,



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):	Consumer
<p>Question 1</p> <p><i>Do you support the proposed amendment? If not, why not?</i></p>	<p>No .</p> <p>To make Flouride a non medical substance can have the potential to open up it's use in town water supplies that residents have fought to stop happening.</p> <p>Google Flouride alert.org (50 reasons to oppose flouridation) Dr Paul Connett</p>
<p>Question 2</p> <p><i>Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?</i></p>	I don't know.

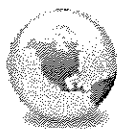
Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you consider should be properly withheld under this legislation, please make this clear in your submission, noting the reasons why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

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227



Fluoridation submission

to:
askmedsafe
27/12/2014 10:13 p.m.
Hide Details
From:
To: askmedsafe@moh.govt.nz,

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: , _ NatMed, DipHerbMed

Email:

Address:

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

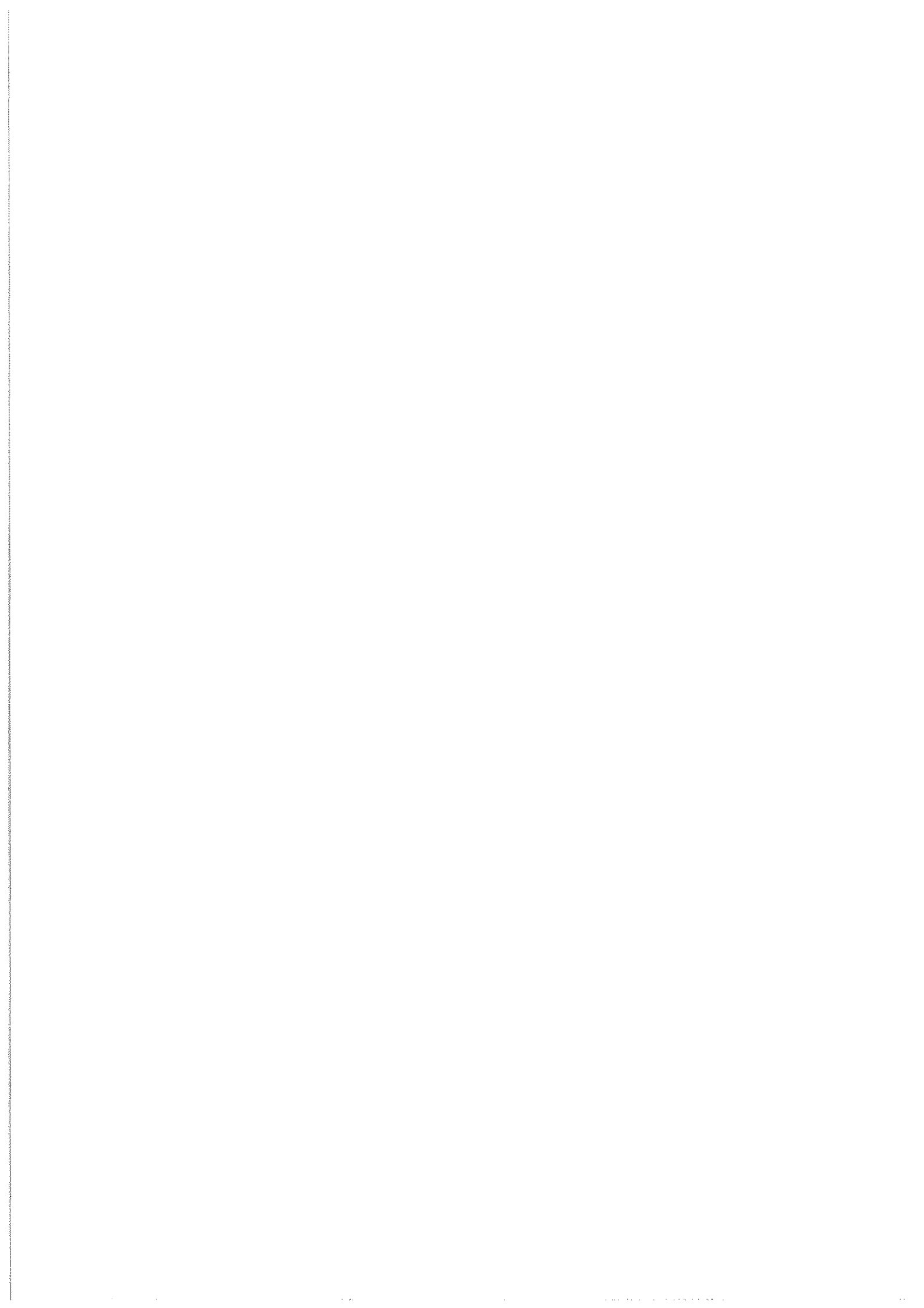
NO. I do not support the proposed amendment because:

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.





Fluoride

--

to:

askmedsafe

29/12/2014 10:48 p.m.

Hide Details

From:

To: askmedsafe@moh.govt.nz,

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:

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"
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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 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



Fluoride

to: askmedsafe

29/12/2014 01:11 a.m.

Subject:

Name:

Address:

Email: R

Your interest in this topic: Consumer. As a unicyclist, water is my main drink. This concerns me greatly that fluoride medicine might be added to the water I love without my consent. Water on tap is a great privilege in our country, please respect our choice not to be administered medicine while enjoying this privilege.

Question 1

Do you support the proposed amendment? If not why not?

No I do not support the proposed amendment.

HFA and SSF are mass medication, if fluoride is regulated as medicine for other applications then regulate it like other medicines for water treatment too.

People should given a choice if they want to take questionable medication with uncertain results. The dose should be administered with the consent of the patient not just added to the main supply and passed into waterways for unconsenting wildlife.

Fluoride is intended for topical use, if any use, not to be ingested.

It is relatively costly to set up a filter to remove HFA and SSF so it makes economic sense to not force the significant number of non-flouridated water drinkers to remove the medication from water if they choose not to be medicated. Fluoride tablets is an option for those who consent to taking the medicine.

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?

hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF)

I don't know of others currently but I suggest watching out for anything with fluoride in it being added to the water without a good reason. It could possibly rear it's head in new forms if regulated as it is currently used.

Thank you for valuing my submission, I really do not want this medicine back in my town water supply.

I do give permission for my personal details to be released to persons under the Official Information Act 1982, just don't give my email/mail to spammers please.

Regards



Fluoride

skmedsafe@moh.govt.nz

28/12/2014 03:39 p.m.

Question 1.

I support the envisaged change to section 105(1)(i) of the Medicines Regulations 1894 under the Medicines Act 1981. I understand this amendment was recommended for clarification in a recent court decision.

Question 2.

I know of no other source of fluoride in water treatment except of course water (the compound H₂O) which contains fluoride naturally.

I support the amendment because anti fluoride activists have exploited the medication point at needless expense to the community and to the well being of the public. This must be stopped. The frequently claimed assertion that individuals are the best judges of all things concerning their welfare is an out and out fallacy. Some things must be judged by our best scientific and medical evidence. Oral health is fundamental to human well being in general. This cannot be influenced by I'll informed political populism.

.. . . .

Sent from my iPhone



Fluoride

1

to:

askmedsafe

28/12/2014 02:40 p.m.

Hide Details

From ~

To: askmedsafe@moh.govt.nz,

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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Medsafe

Name:

Email:

Address:

th

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

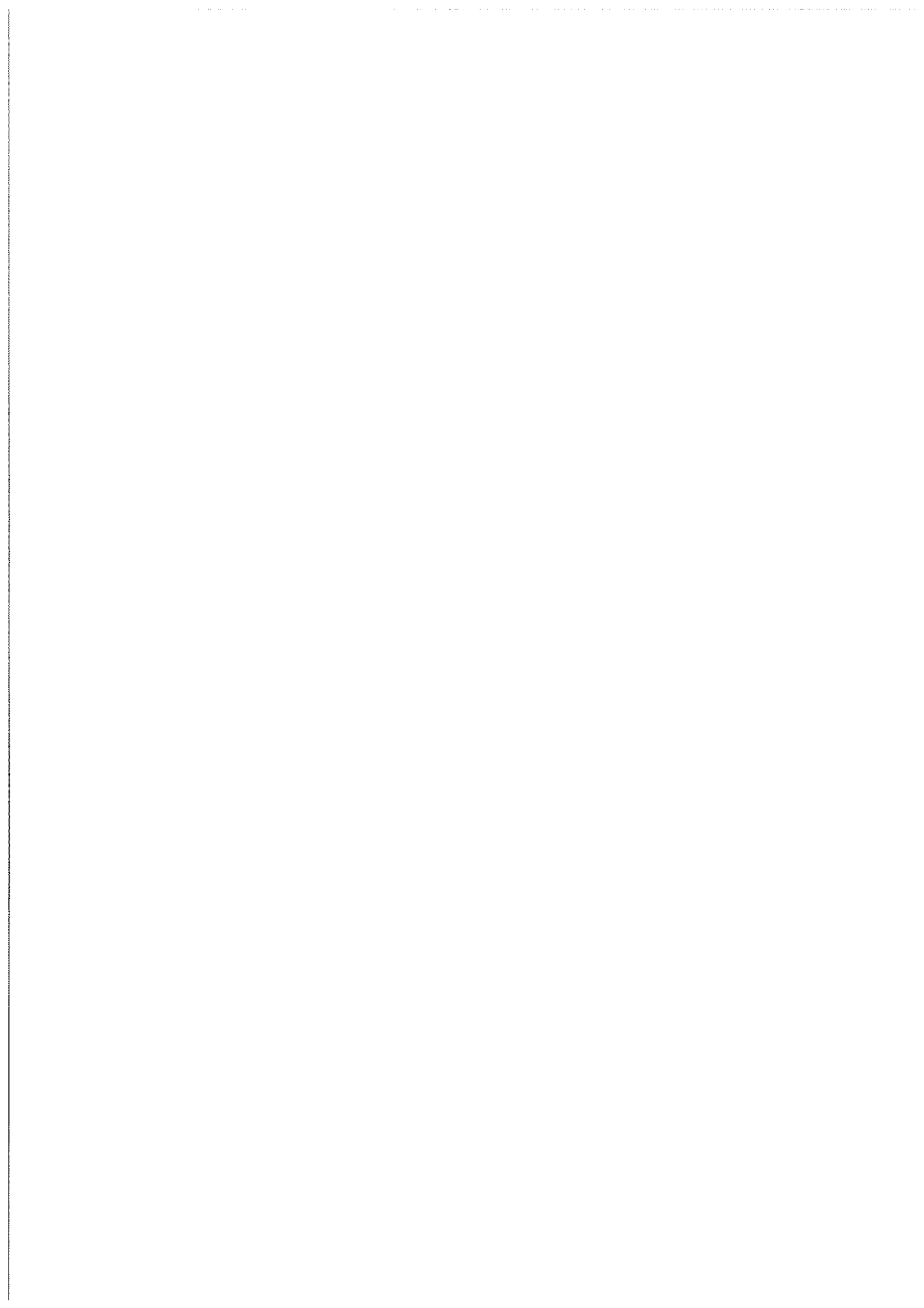
NO. I do not support the proposed amendment because:

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.





Fluoride

to:

askmedsafe

28/12/2014 02:34 p.m.

Hide Details

From: `

To: askmedsafe@moh.govt.nz,

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?*

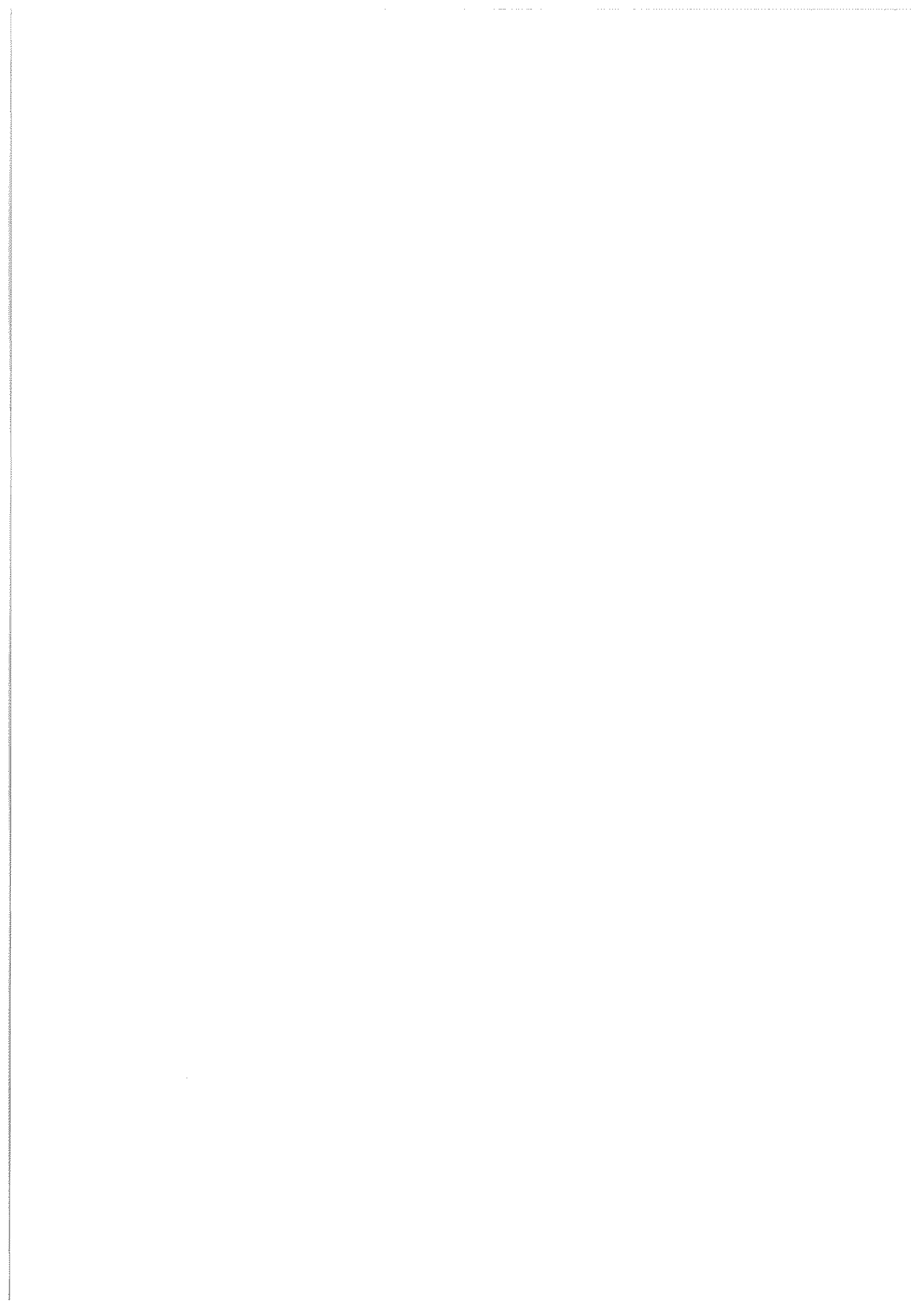
NO. I do not support the proposed amendment because:

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.



SUBMISSION FORM

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

Name:	Dr. BDS BSc
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 and health professional
<p>Question 1</p> <p><i>Do you support the proposed amendment? If not, why not?</i></p>	<p>I do not support the proposed amendment, because:</p> <ol style="list-style-type: none"> 1. The sole reason for adding fluoride to water is treatment of a disease in humans, tooth decay, it is not to treat the water like chlorine, therefore it should be controlled as a medicine. I do not agree with the cited rulings, and most countries do consider water fluoridation to be medication. Furthermore I believe it is procedurally inappropriate for Crown Law to be recommending this application for exemption to the health department. 2. Silicofluorides are different from naturally occurring fluorides. Their behaviour inside the body is unknown.

	<p>Therefore addition of industrial fluoride to the water supply is not an "adjustment", it is addition of a pollutant. (Sauerhuber, 2013)</p> <p>3. The dose of fluoride to any individual is unknown and unmonitored. Established chronic toxicity levels are exceeded by many citizens at 0.7 - 1ppm water fluoridation levels when added to other daily sources of fluoride such as toothpaste and food. (ESR 2009)</p> <p>4. Fluoride is a classified developmental neurotoxin (affects brain development) and an endocrine disruptor. It is linked to thyroid problems, SIDS, asthma, diabetes, depression, mental health disorders, bone and joint disease, cardiovascular disease, cancer, etc. CWF at 0.7-1ppm increases the risk of occurrence. (Grandjean, 2014) (NRC 2006)</p> <p>5. Fluoride crosses the placenta, it's effect on the unborn development is unknown (NRC 2006)</p> <p>6. There is already too much fluoride intake in many population groups, CWF increases the chance of overdose.</p> <p>7. CWF increases inequities in health with maori and Polynesians being more susceptible to fluoride toxicity. (ESR 2009)</p> <p>8. Benefits of CWF are minimal or zero: it is of no benefit to the majority of consumers. (York review, 2000) (SHER review 2011) (NZMOH data)</p> <p>9. Exempting fluoride from the control of the medicines act sets a precedent for using the water supply as a vehicle for other mass medication.</p> <p>NOTE THAT I WISH TO MAKE AN ORAL SUBMISSION</p>
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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-containing compounds are used to treat community water supplies, they are used to treat communities.

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:

CHECK 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

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:	n/a
Please provide a brief description of the organisation if applicable:	n/a
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Person of the general public.
<p>Question 1</p> <p><i>Do you support the proposed amendment? If not, why not?</i></p>	<p>No, I do not support the proposed amendment.</p> <p>I, like many others, see the addition of fluoride (in any form) to our water supplies for the purposes of combatting tooth decay (in any form) as being medicinal.</p> <p>I also fell, like many others, that individuals should have the freedom to choose whether or not to self-administer medicines (obviously including fluoride) is a basic right.</p> <p>I choose to use toothpaste brands that are not fluoride-based, so having doses in our water supply really quite defeats the option.</p>
Question 2	

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

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Fluoride submission

to:

askmedsafe

27/12/2014 07:05 p.m.

Hide Details

From:

To: askmedsafe@moh.govt.nz,

class="hmmmessage" >

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

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

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):	Consumer, health advocate
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	<p>of every New Zealander to be safe from the indiscriminate use of medicines.</p> <p>Further, I am appalled at this cynical attempt to remove the power to decide on fluoridation of water supplies from local communities via their council; and at the timing of this call for submissions!</p>
<p>Question 2</p> <p><i>Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?</i></p>	<p>NO. Fluoride 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</p>

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237



Fluoride Submission Form

to:
askmedsafe
29/12/2014 04:36 p.m.
Hide Details
From: J
To: askmedsafe@mon.govt.nz
Please

0.112

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

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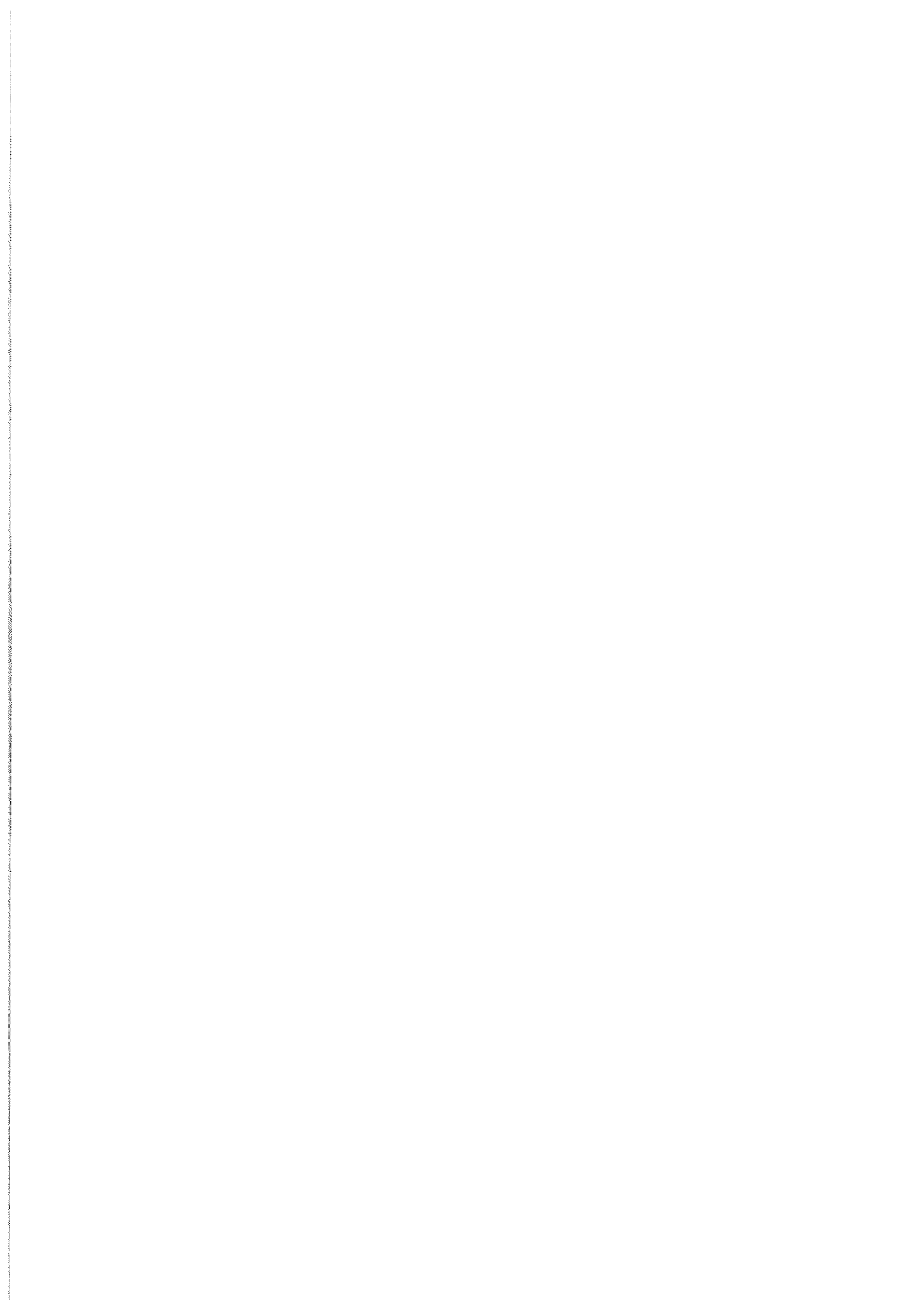
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I do not (delete whichever does not apply) wish to speak to my submission.



2-3 8



FW: Submission Fluoride Poison

to:

askmedsafe

28/12/2014 09:32 p.m.

Hide Details

From: "

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

vZ>

1 Attachment



image001.png

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"

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 (CUFF) the **purpose** of fluoride and its compounds is to **treat people**

I do not wish to speak to my submission.

Email to: askmedsafe@moh.govt.nz

Regulations under the Medicines Act 1981 Consultation

Medsafe

Clinical Leadership Protection & Regulation

Ministry of Health

PO Box 5013

Wellington 6145



This email is free from viruses and malware because avast! Antivirus protection is active.

New Zealand



public submissions on a pending application to exempt fluoride (HFA and SSF) from the New Zealand Medicine's Act

to:

askmedsafe@moh.govt.nz

27/12/2014 08:40 p.m.

Hide Details

From: F

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

To whom it may concern

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

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

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Further information:

Dr. Connett, who co-authored the book *The Case Against Fluoride*, is recognized worldwide as a leader in the movement to eliminate fluoride from municipal water supplies, and I'm pleased to be working with him to achieve this goal. He recently compiled a comprehensive and eye-opening list of reasons why water fluoridation must be challenged. Here are some of the highlights:3

Fluoride is not a nutrient; no biochemical process in the human body *needs* fluoride

The level of fluoride in a mother's milk is exceedingly low. Formula-fed infants receive up to 175-250 more fluoride than a breast-fed infant

Once fluoride is added to the water supply, there is no way of controlling the dose; it goes to everyone regardless of age, weight, health, need, or nutritional status

Fluoride accumulates in bone and other calcified tissues over a lifetime; early symptoms of fluoride poisoning of the bones are identical to arthritis, and fluoride accumulation may make bones brittle and

The addition of fluoride to the public water supply violates the individual's right to informed consent to medical or human treatment

Children in fluoridated countries are being over-exposed to fluoride as demonstrated by the very high prevalence of dental fluorosis; according to the CDC, 41 percent of American children aged 12-15 have some form of dental fluorosis

The evidence that fluoridation or swallowing fluoride reduces tooth decay is very weak

Most dental authorities now agree that the predominant benefit of fluoride is *topical*, not systemic

prone to fracture

Fluoride is known to have toxic properties at low doses

The effectiveness of swallowing fluoride to reduce tooth decay has never been demonstrated by a randomized control trial

Fluoridation is designed to treat a disease (dental caries) but has never been approved by the US Food and Drug Administration (FDA); the FDA classifies fluoride as an "unapproved drug"

The vast majority of countries neither fluoridate their water nor their salt, but according to the World Health Organization, tooth decay in 12-year-olds is coming down as fast, if not faster, in non-fluoridated countries as it is in fluoridated countries

Fluoride Added to List of Chemicals That Cause 'Brain Drain' (Along with Mercury and Lead)

In 2006, researchers from Harvard School of Public Health and Icahn School of Medicine at Mount Sinai did a systematic review and identified five industrial chemicals as developmental neurotoxicants. This included unquestionable poisons like lead, methylmercury, polychlorinated biphenyls, arsenic, and toluene. Since then, they've documented six *additional* developmental neurotoxicants and have added them to the list of what are now 11 known industrial chemicals that harm brain development in human fetuses and infants.⁴ One of the recently added neurotoxicants is fluoride, and one of the study's authors has previously said:⁵

"Fluoride seems to fit in with lead, mercury, and other poisons that cause chemical brain drain... The effect of each toxicant may seem small, but the combined damage on a population scale can be serious, especially because the brain power of the next generation is crucial to all of us."

The debate over the dangers of fluoride has been ongoing for more than six decades, despite the fact that study after study has confirmed that fluoride is a dangerous, toxic poison that bio-accumulates in your body while being ineffective at preventing dental decay. So what exactly does fluoride do to your brain?

There are 37 human studies linking fairly modest fluoride exposures with reduced intelligence (nine of these studies found lowered IQ at less than 3 ppm in the water) and 12 human studies linking fluoride with neurobehavioral deficits. There are also three human studies linking fluoride exposure with impaired fetal brain development,⁶ and approximately 100 animal studies linking it to brain damage. This includes such effects as:⁷

Reduction in nicotinic acetylcholine receptors	Damage to the hippocampus	Formation of beta-amyloid plaques (the classic brain abnormality in Alzheimer's disease)
Reduction in lipid content	Damage to the Purkinje cells	Exacerbation of lesions induced by iodine deficiency
Impaired antioxidant defense systems	Increased uptake of aluminum	Accumulation of fluoride in the pineal gland

Check Out the Truth: Drinking Fluoride Doesn't Prevent Cavities

Even if you were willing to overlook the proven fact that fluoride is a poison to the human body, would you *still* want to drink fluoride if it wouldn't protect your teeth? The truth is, it won't. Fluoride advocates often claim that the reduction in tooth decay that's occurred since the 1950s is a benefit of fluoridated water, but the facts just don't add up. For example, in 1999 the US Centers for Disease Control and Prevention (CDC) claimed that dental caries declined precipitously during the second half of the 20th Century.

But what they failed to mention is that tooth decay rates "precipitously declined" in ALL Western nations, regardless of whether or not fluoridation was used – and most of those countries did NOT fluoridate!⁸ According to World Health Organization (WHO) data, the US, which fluoridates about two-thirds of public water supplies, actually has *higher* rates of tooth decay than many countries that do not fluoridate their water, including Denmark, the Netherlands, Belgium, and Sweden.⁹ Furthermore, if fluoride were effective in preventing caries, you would expect to see an increase in tooth decay when fluoridation is stopped. Yet, this is not what we see! The following demographic studies and fluoridation trends make it clear that fluoridation has very little to do with whether or not you develop cavities.

- In Japan, fluoridation has been virtually nonexistent since the 1970s, yet rates of dental caries have declined since that time.¹⁰
- In the town of Tiel in the Netherlands, water fluoridation was discontinued in 1973, and by 1993, rates of dental caries had declined.¹¹
- In the town of Kuopio, Finland, water fluoridation was stopped after 1992. In 1995 and 1998, dental caries had either decreased or stayed the same.¹²
- In two towns in former East Germany, a significant fall in the prevalence of dental caries was seen in the 20 years following cessation of water fluoridation.¹³
- In Canada, "the prevalence of caries decreased over time in the fluoridation-ended

community while remaining unchanged in the fluoridated community."¹⁴

Fluoride Has Nothing to Do with the Underlying Causes of Tooth Decay

Dental caries are caused by demineralization of your teeth (enamel and dentin) by the acids formed during the bacterial fermentation of dietary sugars. Demineralization is countered by the deposit of minerals from your saliva, or remineralization, which is a slow process. Enthusiasts report that fluoride prevents dental caries by enhancing mineralization. However, dental caries are not caused by a lack of fluoride, just as depression is not caused by a lack of Prozac. Some of the true primary causes of tooth decay cited in the literature include:

- Consistent use of refined sugar, sugary soft drinks, and processed foods in general
- Children going to bed with a bottle of sweetened drink in their mouth, or sucking at will from such a bottle during the day
- Poor dental hygiene and poor access to and utilization of dental health services, usually related to socioeconomic status
- Mineral deficiencies, like magnesium, which can weaken bones and teeth¹⁵
- More than 600 medications promote tooth decay by inhibiting saliva

It's often said that fluoride helps to re-mineralize your teeth and make them stronger, but even this must be questioned. A groundbreaking study published in the journal *Langmuir* uncovered that the fluorapatite layer formed on your teeth from fluoride is a mere six nanometers thick¹⁶ -- you'd need *10,000* of these layers to get the width of a strand of your hair! Scientists now question whether this ultra-thin layer can actually protect your enamel and provide any discernible benefit, considering the fact that it is quickly eliminated by simple chewing. They wrote: "*...it has to be asked whether such narrow... layers really can act as protective layers for the enamel.*"

More Than 100 US Communities Have Ditched Water Fluoridation

Since 2009, about 130 communities have stopped water fluoridation. Canada has dropped from about 60 percent of the population drinking fluoridated water down to about 32-33 percent. Victories have also been logged in Australia, Israel, New Zealand, and across the US. The latest fluoride-free victories include:¹⁷

1. **Wellington, Florida:** After hours of debate and testimony from medical experts and residents, council members voted to end 14 years of fluoridation. A number of pro-fluoride dentists are unfortunately working to overturn the council's vote, but it's still a victory for now.
2. **Amherst County, Virginia:** The Service Authority Board voted to discontinue fluoridation because of conflicting opinions on what constitutes "optimal" levels of fluoride. According FAN, "Several board supervisors felt that the additive was unnecessary and a waste of resources."

3. **Wood Village, Oregon:** The Woodville City Council was considering adding fluoride to the city's drinking water, but after polling residents found that 100% of respondents were against it. They have since ended their fluoridation discussions.
4. **Sebastopol, California:** City Councilors voted unanimously against fluoridation in Sonoma County because of concerns the fluoride could leach into their groundwater from surrounding communities, putting residents at risk.
5. **Bantry, Ireland:** Town Councilors voted unanimously in favor of a resolution calling for an immediate end to fluoridation throughout Ireland. Two other towns--Skibbereen and Clonakitty--also passed similar resolutions in 2013. Support for this historic vote was provided by the local group West Cork Fluoride Free.
6. **Boyer City, Michigan:** In early May 2014, city commissioners voted 3-2 to end more than 40 years of fluoridation for the town's approximately 4,000 residents. Commissioner Gene Towne summed up the council's decision, saying: "It comes down to choice. I don't see how you can control the dosage (of fluoride that people ingest) if it's in everything. If there's a chance that it could cause any health problems... this should all come down to your choice."
7. **Buffalo and Union, Missouri:** In May 2014, Alderman voted to end a decade of fluoridation, saying the additive damaged equipment, city trucks, and was not economical. Also in May, councilors in **Union, Missouri** voted 7-1 to end fluoridation after the city's public service committee recommended the city not repair fluoride injection equipment destroyed by the corrosive additive. According to the city engineer, "It's an acid and it eats the pipes. Employees are handling it and they don't want to be."

Help End The Practice of Fluoridation

There's no doubt about it: *fluoride should not be ingested*. Even scientists from the EPA's National Health and Environmental Effects Research Laboratory have classified fluoride as a "chemical having substantial evidence of developmental neurotoxicity." Furthermore, according to the Centers for Disease Control and Prevention (CDC), 41 percent of American adolescents now have dental fluorosis—unattractive discoloration and mottling of the teeth that indicate overexposure to fluoride. Clearly, children are being overexposed, and their health and development put in jeopardy. *Why?*

The only real solution is to stop the archaic practice of water fluoridation in the first place. Fortunately, the Fluoride Action Network has a game plan to END water fluoridation worldwide. Clean pure water is a prerequisite to optimal health. Industrial chemicals, drugs, and other toxic additives really have no place in our water supplies. So, please, protect your drinking water and support the fluoride-free movement by making a tax-deductible donation to the Fluoride Action Network today.

Internet Resources Where You Can Learn More

I encourage you to visit the website of the Fluoride Action Network (FAN) and visit the links below:

- Like FAN on Facebook, follow on Twitter, and sign up for campaign alerts.
- 10 Facts About Fluoride: Attorney Michael Connett summarizes 10 basic facts about

fluoride that should be considered in any discussion about whether to fluoridate water. Also see 10 Facts Handout (PDF).

- 50 Reasons to Oppose Fluoridation: Learn why fluoridation is a bad medical practice that is unnecessary and ineffective. Download PDF.
- Health Effects Database: FAN's database sets forth the scientific basis for concerns regarding the safety and effectiveness of ingesting fluorides. They also have a Study Tracker with the most up-to-date and comprehensive source for studies on fluoride's effects on human health.
-

Sent from my iPad



submission

re:

to:

askmedsafe

28/12/2014 07:09 p.m.

Hide Details

From

To: <[redacted]@moh.govt.nz>

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

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

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

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Name

Email

Address

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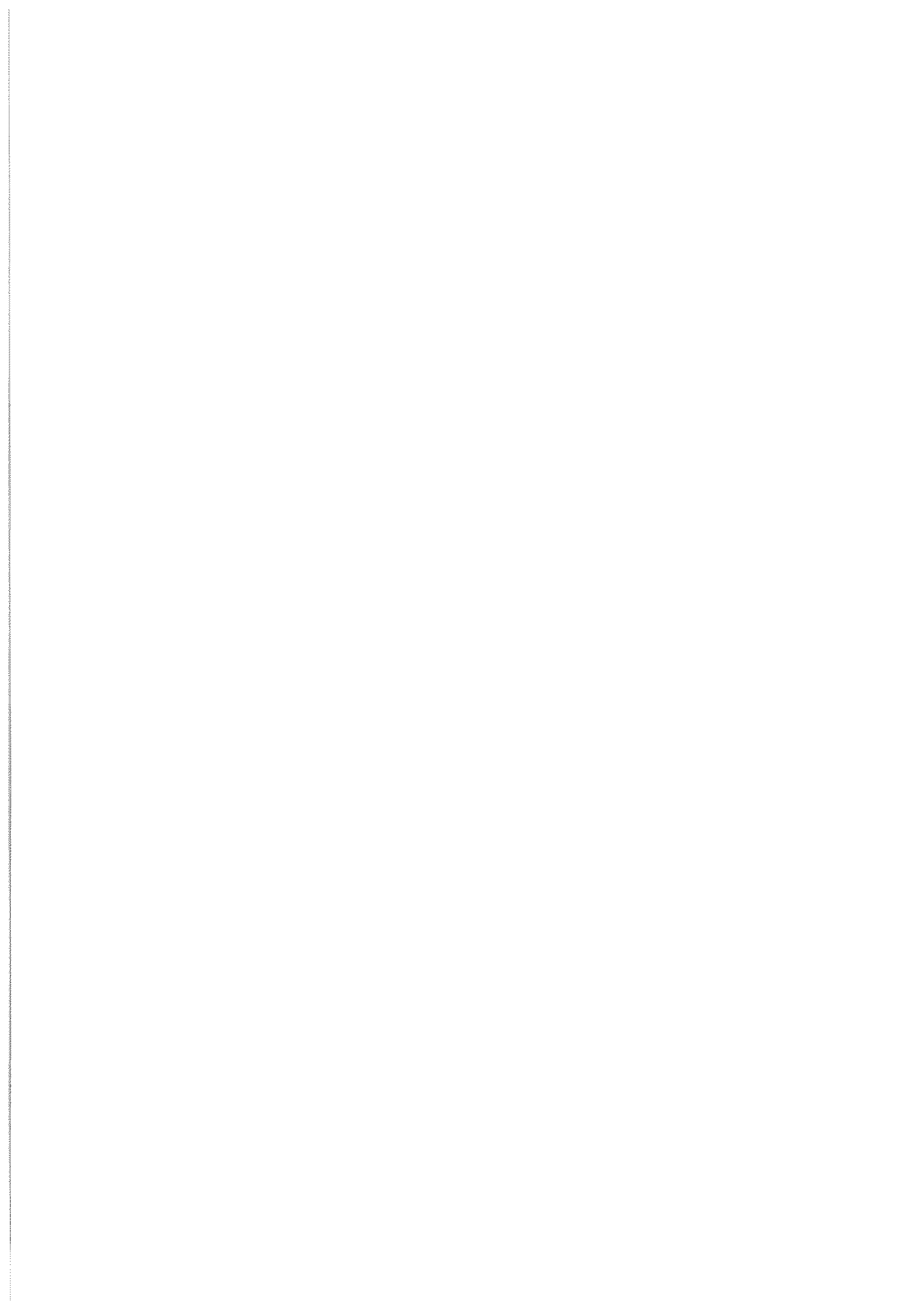
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4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right

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I do not wish to break my submission.





Submission

to:
askmedsafe
27/12/2014 06:06 p.m.
Hide Details
From:
To: askmedsafe@moh.govt.nz,

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

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Medsafe

Name:

Email

Address

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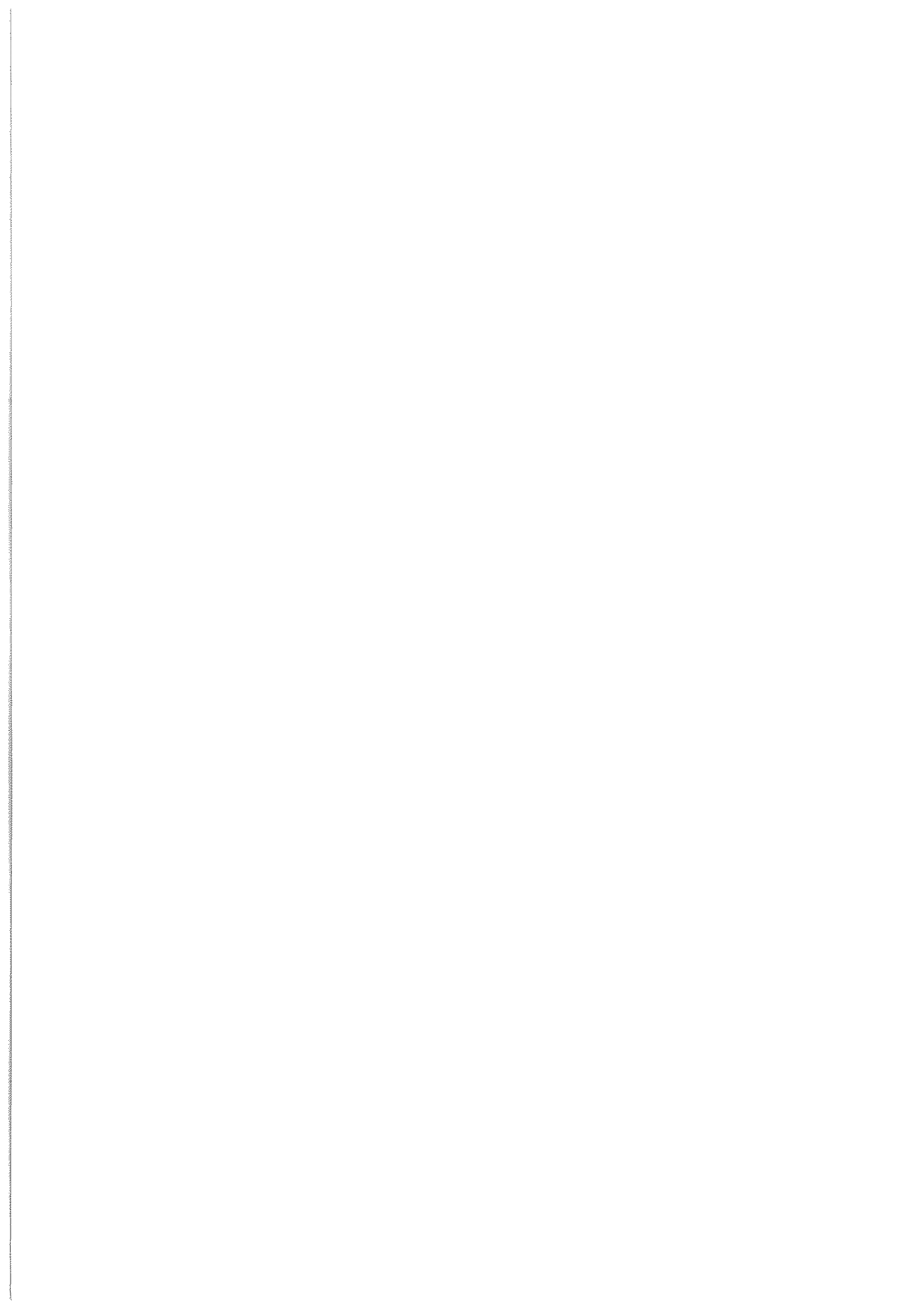
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I do not wish to speak to my submission.





Submission regarding flouridation

to:

askmedsafe

29/12/2014 11:05 p.m.

Hide Details

From:

To: askmedsafe@moh.govt.nz,



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

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Medsafe

Name

Email:

Address:

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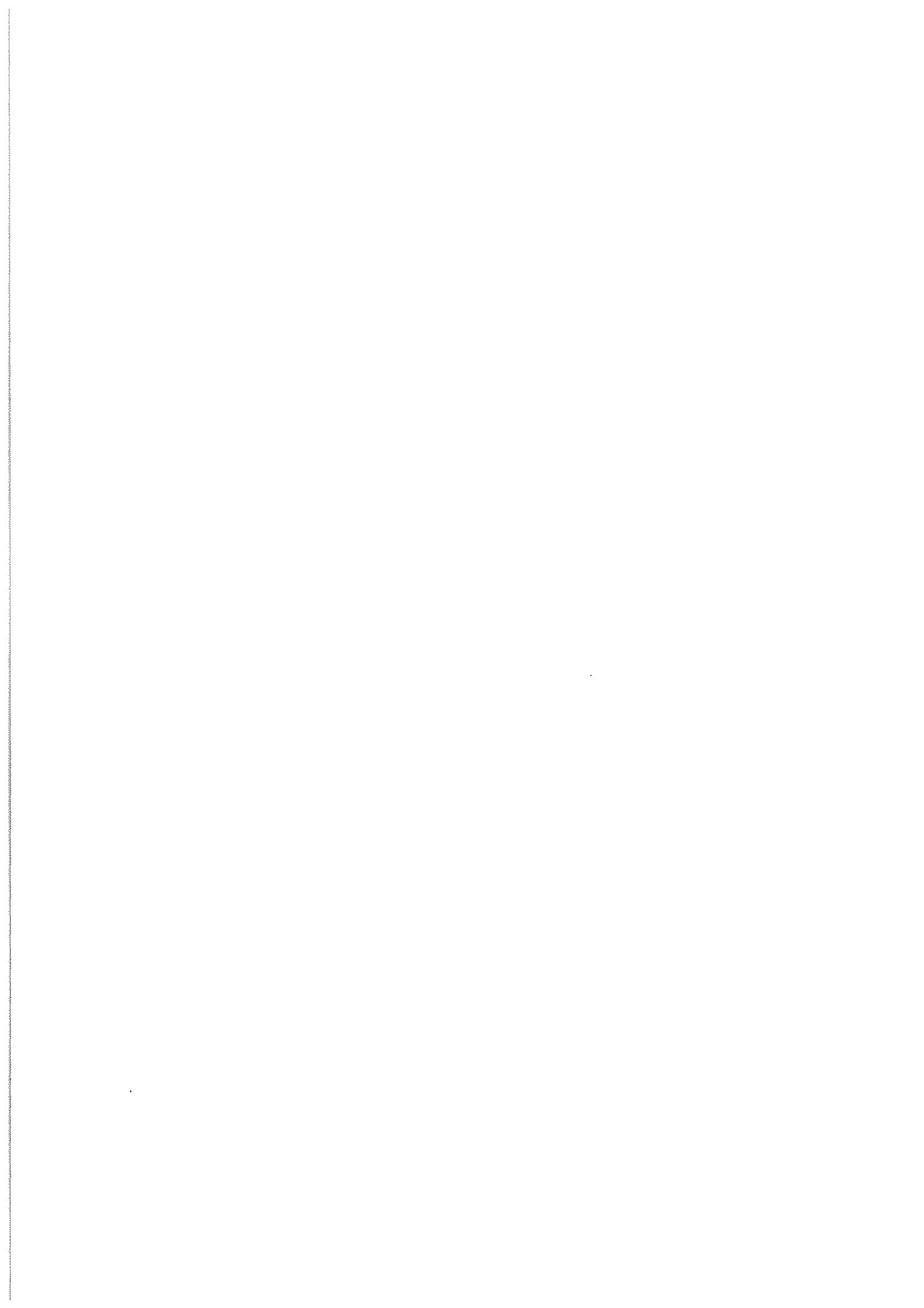
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I do not (delete whichever does not apply) wish to speak to my submission.

Regards,





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

to:

askmedsafe@moh.govt.nz

28/12/2014 08:47 a.m.

Hide Details

From:

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

Please respond to

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

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Email:

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NO.

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This is known to be true in every case - how it can be called anything other than 'treating people' is unlawful because it is a lie (a false statement with the deliberate intent to deceive).

I do not wish to speak to my submission.

Post to:

Regulations under the Medicines Act 1981 Consultation

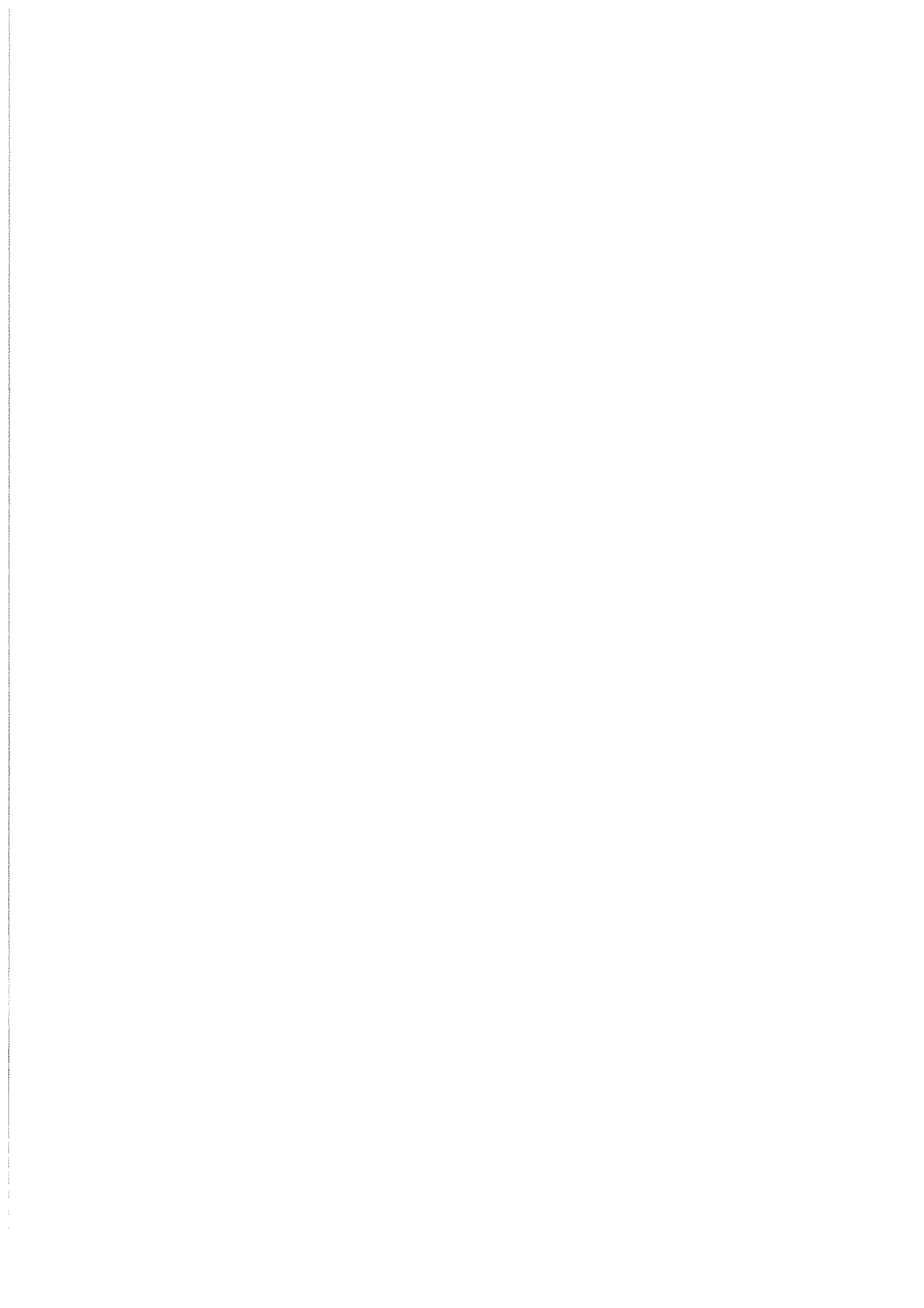
Medsafe

Clinical Leadership Protection & Regulation

Ministry of Health

PO Box 5013

Wellington 6145





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

to:
askmedsafe
27/12/2014 09:18 p.m.
Hide Details
From:
To: askmedsafe@moh.govt.nz,

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:
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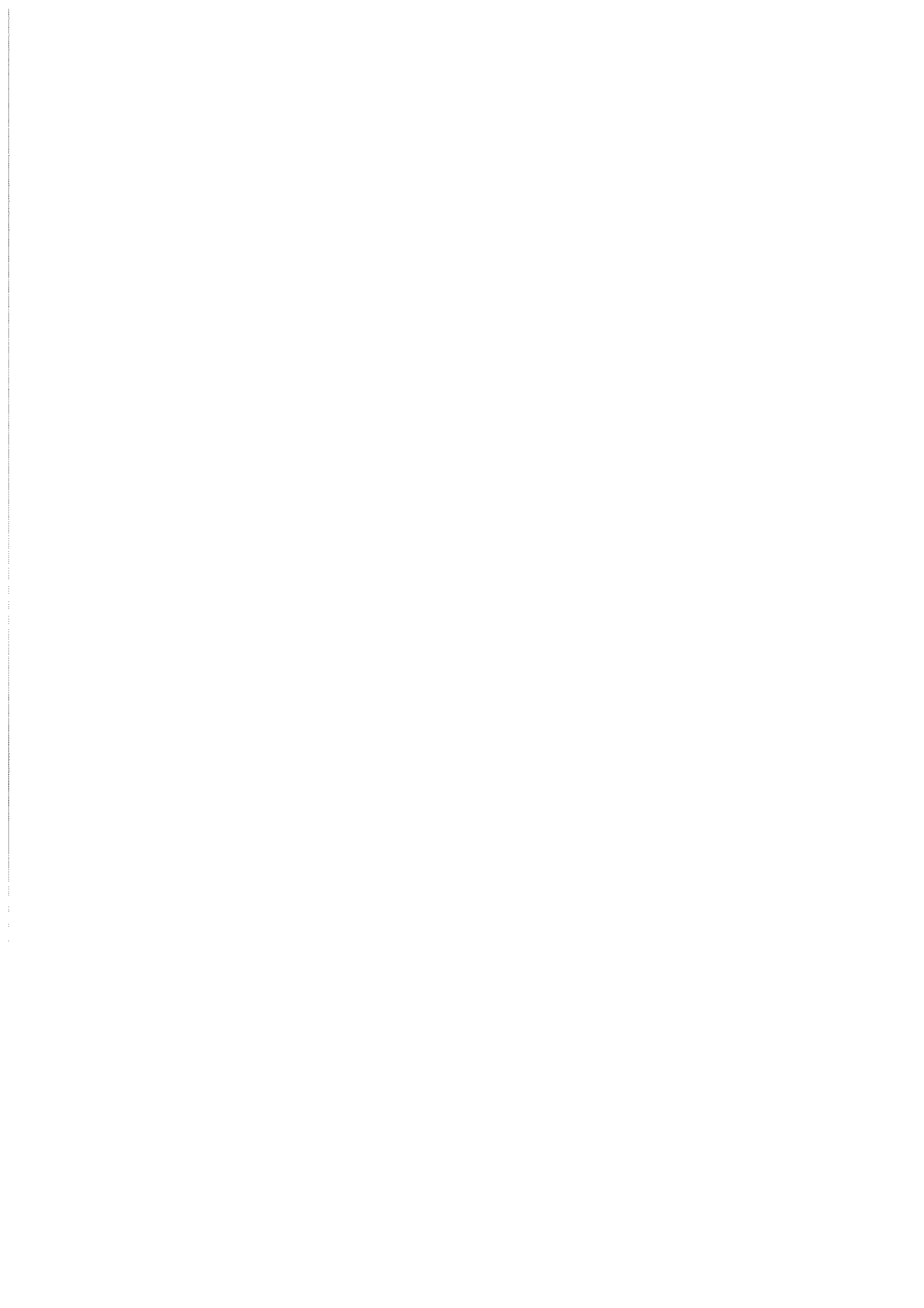
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I do not wish to speak to a representative about my submission





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to:
askmedsafe
27/12/2014 08:18 p.m.
Hide Details
From
To: askmedsafe@moh.govt.nz,

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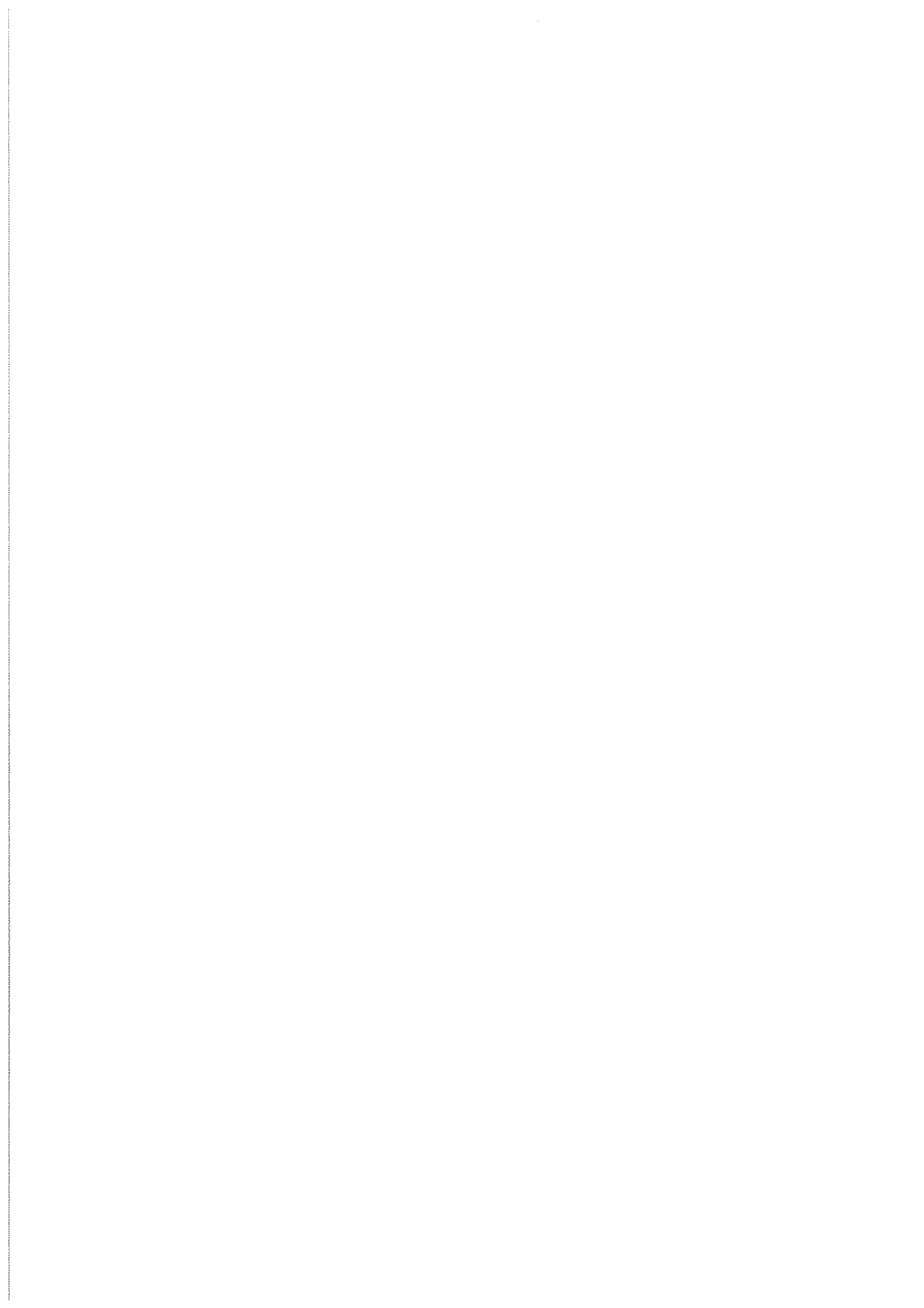
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Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

to:

askmedsafe

27/12/2014 05:59 p.m.

Hide Details

From: '

To: <askmedsafe@moh.govt.nz>

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

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5. There is not and never has been a reason to add fluoride to water as it is freely available in many common toothpastes which I believe some Dentists will proscribe if they deem fit.

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

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

to:

askmedsafe@moh.govt.nz

27/12/2014 01:05 p.m.

Hide Details

From

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

Please respond

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

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Post to:

Regulations under the Medicines Act 1981 Consultation

Medsafe

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PO Box 5013

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Time For You



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Name

Email

Address:

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

NO. I do not support the proposed amendment because:

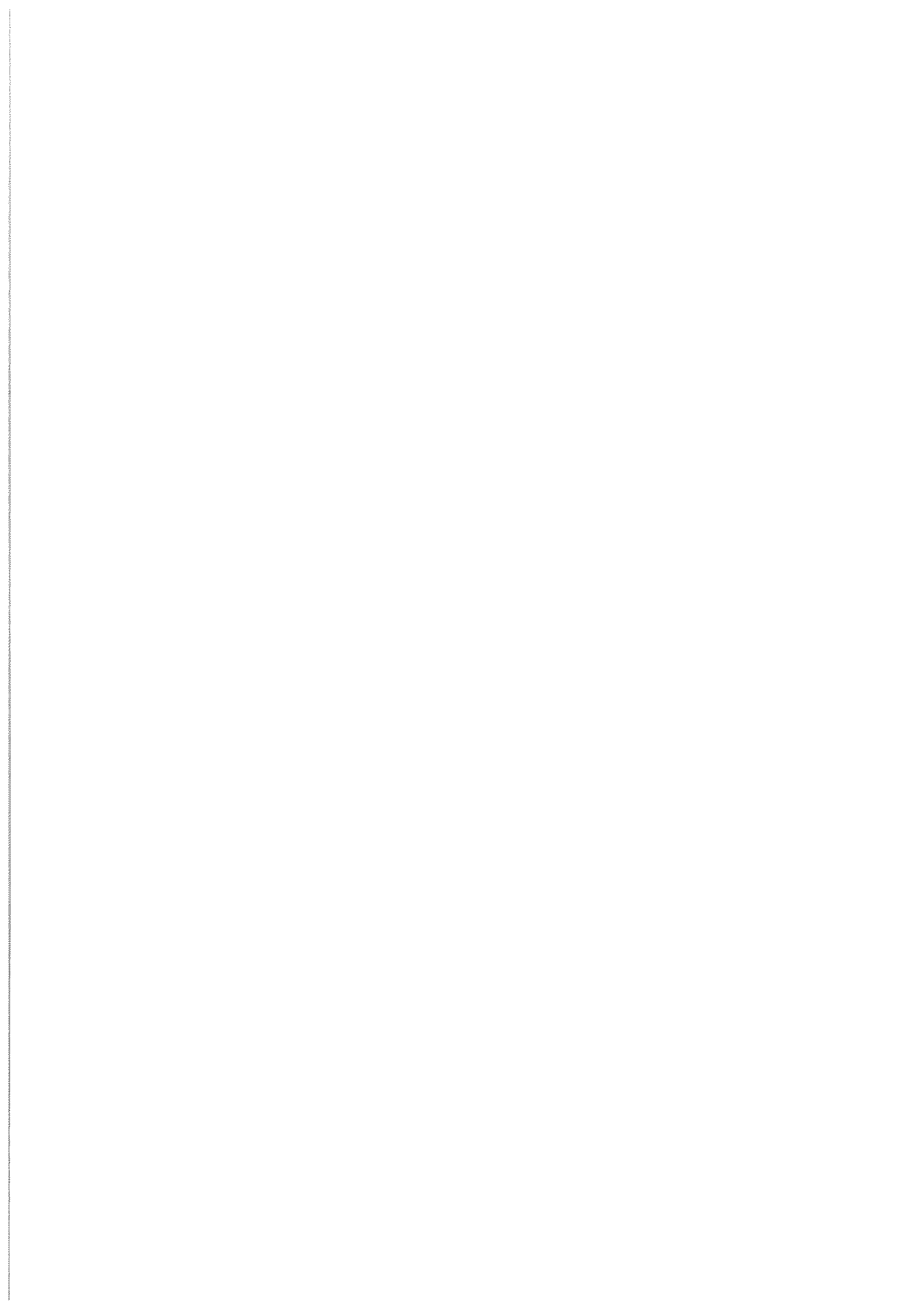
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals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

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

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

I do not wish to speak to my submission.

I also object to the timing and timeframe allowed for this submission as it is short notice of a short timeframe at a time when people are on holiday.





Submissions on an application to exempt fluoride (HFA and SSF) from the Medicines Act.

to:
askmedsafe
29/12/2014 12:09 p.m.
Hide Details
From: [redacted]
To: askmedsafe@moh.govt.nz,

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

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Email: [redacted]

Address: [redacted]

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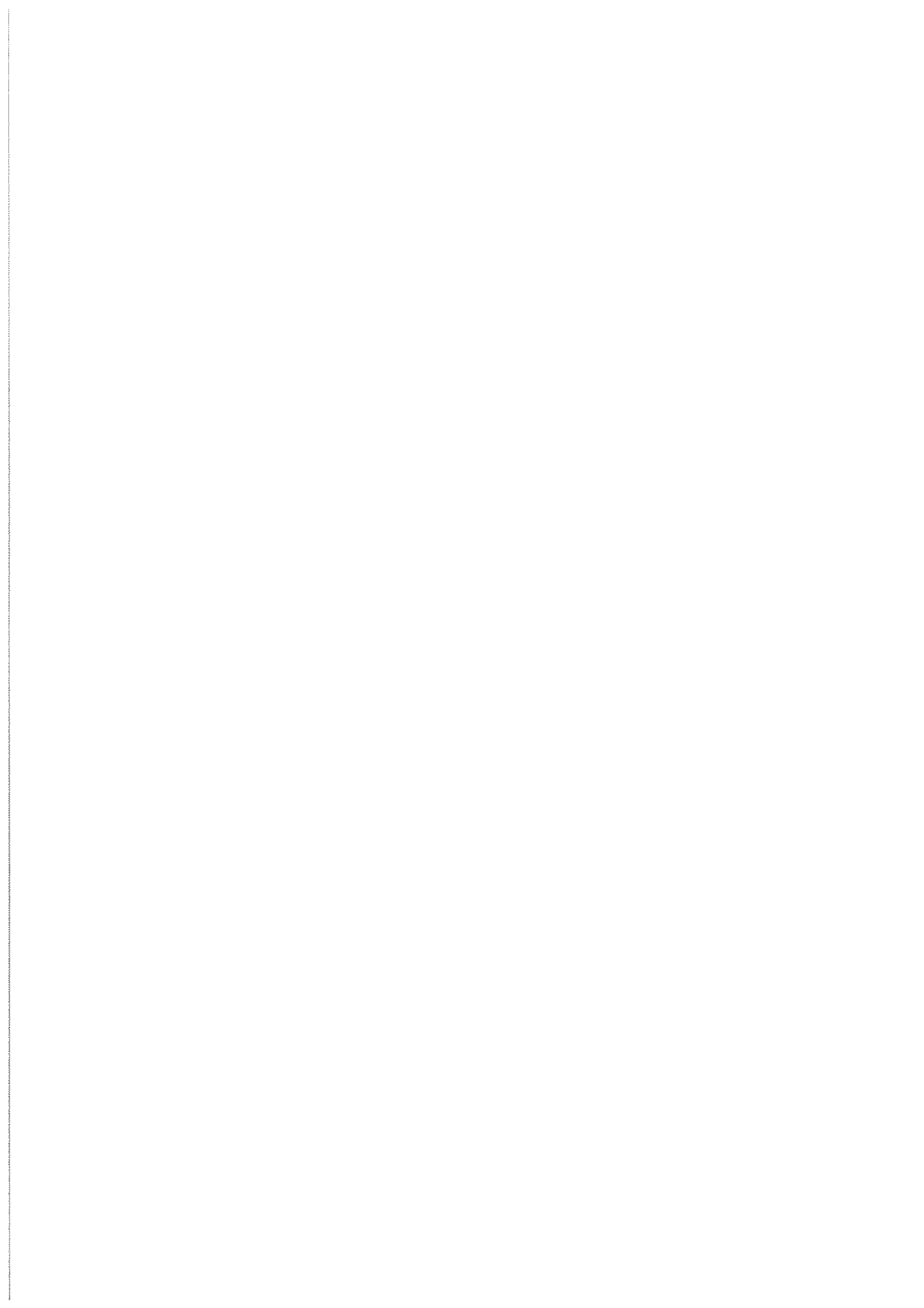
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I do wish to speak to my submission.

Signed





to:
askmedsafe@moh.govt.nz
27/12/2014 06:34 p.m.
Hide Details
From
To: "askmedsafe@moh.govt.nz" <askmedsafe@mon.govt.nz>,

SUBMISSION FORM

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

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Sent from Windows Mail

