

EATH, Joy

Sent: Tony Gill
To: Thursday, 28 November 2013 12:59 PM
Subject: Bill Turner
Fw: TGA response re fluoridation 23 Aug 13 [SEC=UNCLASSIFIED]

Bill

Are we happy?

Tony

Dr Tony Gill MBBS MPH FAFPHM
Senior Medical Adviser
Office of Scientific Evaluation
Phone: 02 6232 8395 Fax: 02 6232 8329
Mobile: 0432 758 162
Email: anthony.gill@tga.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

----- Forwarded by Anthony Gill/TGA/Health on 28/11/2013 12:58 PM -----

From: [REDACTED]
To: Anthony.Gill@tga.gov.au
Cc: [REDACTED]
Date: 28/11/2013 12:42 PM
Subject: Re: Fwd: RE: TGA response re fluoridation 23 Aug 13 [SEC=UNCLASSIFIED]

Good Morning Tony

Thank you very much for your assistance with this issue, it is much appreciated. Such that we do not have to refer further correspondence of this nature to the TGA please could you advise if the TGA is able to give approval for the use of the paragraph below (or wording of a similar nature) to address allegations of breaches of TGA legislation in correspondence sent to state or territory governments:

In November 2013 the Therapeutic Goods Administration confirmed that it has always been their position that fluoride used for the fluoridation of water and fluoridated water are not therapeutic goods. As such, claims made about the health benefits of fluoridated water by state or territory governments or water suppliers can not be considered to be in non-compliance with the Therapeutic Goods Act 1989.

If you wish to discuss this request further please don't hesitate to give me a call,

Kind regards

Department of Health
15 Butterfield Street
Herston Qld 4006

PO Box 2368
Fortitude Valley BC 4006
[REDACTED]

Out of hours number for Environmental Health: 1800 128 962

Visit us on the web at:

<http://www.health.qld.gov.au/ph/ehu/eh-science-regulation.asp>

>>> <Anthony.Gill@tga.gov.au> 19/11/2013 2:43 pm >>>
[REDACTED]

We have just responded to a letter writer on fluoridation and what we have said is:

"In your most recent letter and previous correspondence, you have shared a view that there has been a non-compliance with the *Therapeutic Goods Act 1989* in the act of fluoridating water supplies in Australia.

With respect to whether state water authorities are in breach of the therapeutic goods legislation, I can advise you that it has always been the TGA's position that fluoride used for the fluoridation of water and fluoridated water are not therapeutic goods, regardless of the claims that might be made about the fluoridated water by state and territory governments or water authorities. It has also always been the TGA's position that the regulation of fluoride in drinking water is a matter for the states and territories, as it was at the time the Act was enacted.

This remains the TGA's position. As such, there is no non-compliance on which the TGA could or would take action.

However, I recognise that we have provided conflicting information to you in the past, which may have led you to form an incorrect view that the Act covers fluoride used in drinking water and the resulting fluoridated water and I apologise for this confusion. It is clear from the historical record that it was the intent of the legislative drafters to ensure it was understood that fluoride used to fluoridate drinking water and the drinking water itself were not covered by the Act (for example, I would refer you to documents 10 and 15 in FOI 156-1213-19, which discuss how the Excluded Goods Order of the time was to handle this matter).

I note that you have also asked some unanswered questions about risk assessments of fluoride. As fluoride for use in drinking water does not, in our opinion, come within the operation of the Act, the TGA has no role in carrying out such risk assessments. I would refer you to two documents (one of which I know you have previously been referred to) published by the National Health and Medical Research Council (NHMRC):

- The Australian Drinking Water Guidelines 2011 (http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/eh52_aust_drinking_water_guidelines_update_120710_0.pdf), which state that 'based on **health considerations** [my emphasis], the concentrations of fluoride in drinking water should not exceed 1.5mg/L'.
- Nutrient Reference Values for Australian and New Zealand (http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/n35.pdf), which states that 'because of its role in the prevention of dental caries, fluoride has been classified as essential to human health' and sets 'adequate intake' levels for fluoride."

This correspondence also covers a response to a letter forwarded to us by the QLD Minister of Health for answering.

Regards

Tony

Dr Tony Gill MBBS MPH FAFPHM

Senior Medical Adviser

Office of Scientific Evaluation

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Email: anthony.gill@tga.gov.au

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au

From: [REDACTED]

To: <anthony.gill@tga.gov.au>

Date: 19/11/2013 01:50 PM

Subject: Fwd: RE: TGA response re fluoridation 23 Aug 13 [SEC=UNCLASSIFIED]

Good Afternoon Tony

Please could you provide an update on the matter below.

Kind regards

[REDACTED]

Environmental Health Regulation and Standards

Health Protection Unit

Department of Health

15 Butterfield Street

Herston Qld 4006

PO Box 2368

Fortitude Valley BC 4006

[REDACTED]

Out of hours number for Environmental Health: 1800 128 962

Visit us on the web at:

<http://www.health.qld.gov.au/ph/ehu/eh-science-regulation.asp>

>>> [REDACTED] 9/10/2013 1:23 pm >>>

Good Afternoon Tony

Thank you for returning my phone call earlier today. As discussed we are coming under increasing pressure to provide response to ministerial correspondence relating to drinking water fluoridation with respect to the *Therapeutic Goods Act 1989* and the Therapeutic Goods Advertising Code. As much of the correspondence alleges that agencies across the country have made claims that breach these standards we are unable to make a response without TGA evaluation of the issue.

We also assist local governments with their fluoride correspondence upon request and can advise that we have at least one Local Government also requesting a response on this matter as they also have correspondence awaiting response.

Please could you advise on any update on this matter and if correspondence of this nature should be redirected to the TGA?

Kind regards

[REDACTED]

[REDACTED]

Environmental Health Regulation and Standards

Health Protection Unit

Department of Health

15 Butterfield Street

Herston Qld 4006

PO Box 2368

Fortitude Valley BC 4006

[REDACTED]

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>>> <Anthony.Gill@tga.gov.au> 18/09/2013 4:20 pm >>>

[REDACTED] et al

At the current time the TGA does not have an update on this issue. The TGA will inform you all if there are any further developments.

The TGA's long term view that reticulated fluoridated water is not a therapeutic good remains extant.

Regards

Tony

From: [REDACTED]

To: "Anthony.Gill@tga.gov.au" <Anthony.Gill@tga.gov.au>

Cc: [REDACTED]
[REDACTED]

Date: 18/09/2013 10:46 AM

Subject: RE: TGA response re fluoridation 23 Aug 13 [SEC=UNCLASSIFIED]

Hi Tony

I don't think I've received an update from the TGA since your last email.

Have there been any developments?

Thanks,

Population Health | Department of Health and Human Services

3/25 Argyle St Hobart GPO Box 125 Hobart Tas 7001

A fair and healthy Tasmania

From: Anthony.Gill@tga.gov.au [<mailto:Anthony.Gill@tga.gov.au>]

Sent: Friday, 23 August 2013 2:23 PM

To: [REDACTED]

Subject: TGA response re fluoridation 23 Aug 13 [SEC=UNCLASSIFIED]

Dear all

In response to your emails relating to correspondence from [REDACTED]

The Therapeutic Goods Administration (TGA) is aware of the issues raised with state and territory health authorities about potential issues with the fluoridation of water with respect to the *Therapeutic Goods Act 1989* and the Therapeutic Goods Advertising Code. Due to the complexity of the issues the TGA is further investigating the issues raised. The TGA is meeting early next week on these issues and will update the states and territories when further information is available.

Regards

Tony

Dr Tony Gill | MBBS MPH FAFPHM AFACHSM | Senior Medical Adviser | Office of Scientific Evaluation | Therapeutic Goods Administration | PO Box 100, WODEN ACT 2606 | Ph: 02 6232 8395 | Fax: 02 6232 8239| Mob: 0432 758 162 | Email: anthony.gill@tga.gov.au

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