[redacted]

Fw: Letter of Request for Information: Apparent contradictions requiring clarification [SEC=UNCLASSIFIED]

Gary Lacey to: Anthony Gill 17/01/2013 10:18 AM

Tony

The full story and my response

Dr Gary Lacey
Office of Parliamentary & Strategic Support
Therapeutic Goods Administration

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[redacted]

----- Forwarded by Gary Lacey/TGA/Health on 17/01/2013 10:17 AM -----

From: Gary Lacey/TGA/Health
To: info@TTRA
Date: 16/06/2011 10:19 AM
Subject: Fw: Letter of Request for Information: Apparent contradictions requiring clarification [SEC=UNCLASSIFIED]

Shannon

As discussed, the holding response that was sent to [redacted] on 7 March is attached below. The following text should now be sent as the final response:

Dr Gary Lacey
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[redacted]

Dear [redacted]

I refer to your email of 6 March 2011. You have asked the Therapeutic Goods Administration (TGA) to clarify, in terms of its own guidelines, whether or not chemicals involved in the fluoridation of drinking water (particularly fluorosilicic acid and sodium fluorosilicate) should

be classified as medicines. I apologise for the delay in responding, however I felt it would be useful to wait until the current version of the Excluded Goods Order was "*Gazetted* ". This occurred on 31 May 2011.

The TGA's primary consideration in considering the nature of a particular product is a consideration of whether or not it should be subject to regulation as a therapeutic good under the provisions of the *Therapeutic Goods Act 1989* (the Act). Under the Act, the Commonwealth Minister for Health and Ageing (the Minister) and the Secretary of the Commonwealth Department of Health and Ageing (the Secretary) are given certain powers in relation to the regulation of therapeutic goods.

The Act provides for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia, whether produced in Australia or elsewhere, or exported from Australia. The definitions provided in section 3 of the Act are used to determine whether or not a particular product is a therapeutic good for the purposes of regulation under the Act and, if so, what type of therapeutic good it should be regulated as. The definitions provided in section 3 of the Act are solely for the purposes of determining if and how a particular product should, or should not, be regulated under the Act. The definitions provided under section 3 of the Act cannot, and should not, be used in more general terms to determine whether or not a particular product should be considered to be a medicine for purposes beyond the scope of the Act.

If the Secretary is satisfied that particular goods or classes of goods are, or are not, therapeutic goods; or when used, advertised, or presented for supply in a particular way, are or are not therapeutic goods; the Secretary may (under section 7 of the Act), by order published in the *Gazette* , declare that the goods, or the goods when used, advertised, or presented for supply in that way, are or are not, for the purposes of the Act, therapeutic goods. In accordance with this provision of the Act, the Secretary has declared that certain products are not therapeutic goods for the purposes of the Act (Therapeutic Goods (Excluded Goods) Order No. 1 of 2011, available at www.tga.gov.au/industry/legislation-excluded-goods-order-1101.htm). This declaration relevantly declares that oral hygiene products for care of the teeth are not therapeutic goods if:

- any benefits claimed to result from use are directly related to improvements to oral hygiene, including for the prevention of tooth decay or the use of fluoride for the prevention of tooth decay; and
- other benefits in relation to diseases or ailments, e.g. gum or other oral disease or periodontal conditions are not claimed to result from use.

Fluoridated water satisfies this requirement and is therefore not a therapeutic good for the purposes of the therapeutic goods regulatory scheme. The Act defines medicines as " *therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human* "; as fluoridated water is not a therapeutic good, it cannot be a medicine for the purposes of the regulatory scheme.

The TGA has no role in considering whether or not a particular product should be defined as a medicine for any purpose other than regulation under the Act. The role of the TGA is to protect public safety by maintaining a system that ensures therapeutic goods available in Australia meet appropriate standards of quality, safety and efficacy, the TGA has no role in

determining whether or not therapeutic goods are used in accordance with principles such as informed consent, this is a matter for professional medical practice.

In order for material to be an "advertisement" under therapeutic goods legislation, the material must be in relation to goods that are regulated under the Act. The TGA makes no comments on material that promotes goods that are excluded from the regulatory scheme.

The TGA does not classify ingredients as suitable, or otherwise, for human consumption. Under section 52D of the Act, the Secretary can amend the poisons standard to include particular substances in any schedule of the standard. In deciding which schedule a particular substance should be included the Secretary must take the following matters into account:

- risks and benefits of the use of the substance;
- the purposes for which the substance is to be used and the extent of use of the substance;
- the toxicity of the substance;
- the dosage, formulation, labelling, packaging and presentation of the substance; and
- the potential for abuse of the substance;

Therefore, it is possible to include the same substance in different schedules of the poisons standard based on intended use, formulation, presentation etc. When considering the scheduling of substances the Secretary must have regard to any recommendations or advice of the Advisory Committee on Medicines Scheduling or the Advisory Committee on Chemicals Scheduling. Further details on this process can be found on the TGA website at http://www.tga.gov.au/committee/acmcs.htm

Substances included in Schedule 7 are substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.

For further information regarding the regulation of substances that are classified in Schedule 7 of the Poisons Standard, you may wish to contact the National Industrial Chemicals Notification and Assessment Scheme. (www.nicnas.gov.au)

Thank you for your enquiry and I hope this information has been of assistance to you.

----- Forwarded by Gary Lacey/TGA/Health on 16/06/2011 10:08 AM -----

From: Info
To: [redacted]
Date: 07/03/2011 03:59 PM
Subject: Re: Letter of Request for Information: Apparent contradictions requiring clarification [SEC=UNCLASSIFIED]
Sent by: Cindy Chan

Dear [redacted]

Thank you for your query regarding the definition of a therapeutic good and fluoride compounds.

Given the complexity of the issues that you have raised, in accordance with the TGA customer service charter, the TGA may not be able to provide you with a full response within 5 working days.

This enquiry is being considered by the relevant areas of the TGA and a response will be provided as soon as possible.

Kind regards,

Information Officer
Parliamentary and External Relations Unit
Office of Parliamentary and Strategic Support
Therapeutic Goods Administration

[redacted] 06/03/2011 12:58:11 AM

[redacted]

Sent by: [redacted]

06/03/2011
12:57 AM

To info@tga.gov.au

cc

Subject Letter of Request for Information: Apparent contradictions requiring clarification

RE: http://www.tga.gov.au/docs/html/medregs.htm#artg

ATTN:

- **TGA National Manager, Dr Rohan Hammett**
- **Principal Medical Adviser, Dr Megan Keaney**
- **Principal Legal Adviser, Ms Philippa Horner**
- **Chief Regulatory Officer, Ms Jenny Hefford**
- **Chief Operating Officer, Ms Kim Loveday**
- **Acting Principal Adviser Regulatory Reform, Stephen Dellar**

SUBJECT: Letter of Request for Information: Apparent contradictions requiring clarification

1. OVERVIEW

I refer you to the following document **http://www.health.vic.gov.au/environment/fluoridation/fluoriqa.htm** – page 29 of which states:

The compounds recommended by the National Health and Medical Research Council (NHMRC) and used by water authorities throughout Australia are sodium fluoride (NaF), sodium fluorosilicate (Na2SiF6) and fluorosilicic acid (H2SiF6). In Australia, the Therapeutic Goods Administration (TGA) is responsible for regulating therapeutic goods to ensure their quality, safety and efficacy. The TGA does not require fluoride compounds (such as standard fluoride toothpaste and fluoride that is added to community drinking water supplies) to be registered as medicines if they:

• are used for the prevention of dental decay; and

• *are also not scheduled as a drug or poison in the Standard for the Uniform Scheduling of Drugs and Poisons."*

In 2006, the NHMRC, Australian Government Department of Health and Ageing and New Zealand Ministry of Health included fluoride as a 'nutrient' in Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes. This document states: "Because of its role in the prevention of dental caries [decay], fluoride has been classified as essential to human health."

However, upon reading specific TGA classification regulations in more detail (**http://www.tga.gov.au/docs/html/medregs.htm#artg**), the above – from the Department of Health – seems odd. For instance, the TGA says that:

A product's principal use is of primary consideration when determining whether it is a food or a medicine... One of the main factors in determining whether a product is a cosmetic or a medicine is the claims made about the product... or if therapeutic claims are made on its label, or in advertising... For the purposes of evaluation and assessment, a therapeutic good is a product for use in humans that is used in, or in connection with:

- *preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; or*
- *influencing inhibiting or modifying a physiological process; or...*

... Listed medicines may only contain well known established ingredients, usually with a long history of use, such as vitamin and mineral products or sunscreens. They do NOT contain substances that are scheduled in the SUSDP... Listed medicines are assessed by the TGA for quality and safety but not efficacy. This means that the TGA has not evaluated them individually to see if they work.

2. POINTS OF INTEREST

a. Product claims

The Department of Health (DH) (formerly the Department of Human Services - DHS) actively promotes/advertises preventing the "prevention/alleviation" of the DISEASE of tooth decay via the addition of fluoride compounds to the drinking water; however, the DH claims EXEMPTION from TGA medicinal clarification for fluoridating compounds if they "are used for the prevention of dental decay" (http://www.health.vic.gov.au/environment/downloads/fluori_qa07.pdf).

This is an unusual argument, since the TGA apparently says the opposite, i.e. that a substance must be classified as a "medicine" or a "therapeutic good" if its manufacturer(s) and/or promoter(s) claim its use in prevention or alleviation of a disease. In this case, tooth decay. The TGA even provides examples, such as:

i. One of the main factors in determining whether a product is a cosmetic or a medicine is the claims made about the product. For example, moisturisers which contain a sunscreening agent as a secondary component and have a stated therapeutic purpose (e.g. 'helps protect skin from the damaging effects of UV radiation') are medicines.

ii. The presentation of a product can help to determine whether it will be treated as a food or a medicine. For example, a clove of garlic is a food. However, if it is concentrated and marketed in capsule form with claims that it can be used to relieve cold and 'flu symptoms it will be treated as a medicine.
http://www.tga.gov.au/docs/html/medregs.htm#artg

Here is a claim made by [redacted] "Tooth decay is a disease... Water fluoridation (i.e. the addition of fluoridation chemicals - my emphasis) helps protect teeth against decay." http://www.health.vic.gov.au/environment/fluoridation/index.htm Under TGA classification guidelines, this claim falls under the category of the alleviation or prevention of a disease, and thus a medicine classification is required for the compounds in question.

Orica Chemicals and Incitec Pivot also make claims as to the efficacy of their products. For example, Orica says:

Australia has been fluoridating potable water for more than 40 years to reduce tooth decay... Fluoride strengthens tooth enamel and dentine by:

- *Inhibiting acid formation by bacteria.*
- *Interfering with the growth of harmful bacteria.*
- *Reducing the effect of acid on the tooth.*
- *Enhancing minor repair of enamel.*
- *Fluoride is incorporated into enamel while the tooth is developing.*

http://www.orica-chloralkali.com/?page=54
http://www.orica-chloralkali.com/index.asp?page=19
http://www.orica-chloralkali.com/?page=55

Incitec Pivot says:

"Low concentrations are good for teeth." http://data.rmt.com.au/msds/3082468.pdf

The DH and the manufacturers are, without a doubt, claiming their products to be – or at least implying their products to be – aimed at treating and/or preventing disease. Furthermore, consider the following claims:

There are three main modes of action in which fluoride acts to reduce dental decay. Each is described below...

The first mode of action occurs when teeth are developing in the jaws before they come into the mouth (the 'pre-eruptive phase'). When fluoride-containing foods/drinks are ingested, fluoride is absorbed from the gastrointestinal tract and redistributed into developing tooth structure. Such tooth structure is more resistant to acid attack, so when the tooth erupts into the mouth, it is better able to withstand the demineralisation that can occur when sugar-containing foods/drinks are ingested.

The second mode of action occurs when fluoride-containing foods/drinks are ingested and fluoride is absorbed from the gastrointestinal tract and redistributed into salivary glands and then into saliva. This fluoride-containing saliva then bathes the teeth over extended periods of time, again remineralising tooth structure which has commenced demineralisation. This benefit also occurs topically, but does so after the fluoride has been ingested.

The third mode of action occurs when fluoride-containing foods/drinks wash over teeth during eating and drinking.10 The fluoride provides an instant benefit as it remineralises tooth structure which has commenced demineralisation. This is done topically.

The second and third modes of action occur after the teeth have erupted into the mouth (the 'post-eruptive phase').

http://www.health.vic.gov.au/environment/fluoridation/fluoriqa.htm

This clearly describes a systemic mechanism of action, whereby physiological changes in the body occur as a direct result – an INTENDED one – of the product's administration. According to the TGA: "For the purposes of evaluation and assessment, a therapeutic good is a product for use in humans that is used in, or in connection with... influencing inhibiting or modifying a physiological process." http://www.tga.gov.au/docs/html/medregs.htm#artg

Fluoride compounds as used in drinking water are added for the purpose of making physiological changes in the human body.

b. Fluoridation chemicals

The fluoride compounds that are recommended by the NHMRC for water fluoridation in Australia are either sodium fluoride (NaF), sodium fluorosilicate (Na2SiF6) or fluorosilicic acid (H2SiF6); although, the relevant legislation takes a broader approach: "fluoride includes any compound of fluorine" (http://www.austlii.edu.au/au/legis/vic/consol_act/ha1973201/s2.html). One manufacturer of H2SiF6 clarifies, "Fluorosilicic Acid is the most widely used fluoridation agent in Australia" (http://www.incitecpivot.com.au/products_1.cfm).

The DH claims exemption from TGA medicinal classification, guidelines and regulations for the NHMRC specified chemicals in the following manner:

The TGA does not require fluoride compounds (such as standard fluoride toothpaste and fluoride that is added to community drinking water supplies) to be registered as medicines if they... are also not scheduled as a drug or poison in the Standard for the Uniform Scheduling of Drugs and Poisons."
http://www.health.vic.gov.au/environment/fluoridation/fluoriqa.htm

I draw the TGA's attention to, "are also not scheduled as a drug or poison in the Standard for the Uniform Scheduling of Drugs and Poisons."

In the case, for instance, of Incitec Pivot's fluorosilicic acid product, the product's MSDS states: "Classified as a Schedule 7 (S7) Poison using the criteria in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)." http://data.rmt.com.au/msds/3082468.pdf

3. SUMMARY & KEY QUESTIONS

Based upon the above points deriving from the TGA's classification documents, the Department of Health's fluoridation documents, and the industrial chemical manufacturers documents, I hereby ask the TGA to clarify – in terms of its own guidelines – whether or not the above mentioned fluoridation chemicals (particularly fluorosilicic acid and sodium fluorosilicate) should be classified as medicines.

And, if classified as medicines, does the TGA believe they should be subject to the universal medical principle of individual "informed consent to medication" (as outlined here by the AMA:
http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/patient-physician-relationship-topics/informed-consent.shtml)?

Do the claims made by fluoridation promoters and manufacturers, about their products,

constitute a promotion/advertisement of their product's intention to prevent or allieviate disease via mechanisms which prompt physiological changes in the human body?

Are industrial-grade Schedule 7 poisons exempt from classification for human consumption by the TGA? If so, which body is able to verify their classification in terms of human administration -- and also, their safety for all members of the population?

Thank you for you time.

Sincerely,

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[redacted]