

## WELLS, Rachel

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**From:** HORNER PSM , Philippa  
**Sent:** Wednesday, 13 January 2016 9:27 AM  
**To:** TURNER, Bill  
**Subject:** FW: Ea corro 440076 - Declaration under subsection 7(1) of the Therapeutic Goods Act 1989 [DLM=Sensitive:Legal]  
**Attachments:** 440076 - Declaration under subsection 7(1) of the Therapeutic Goods Act 1989.pdf

FYI

**Philippa Horner PSM**  
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Regulatory Services Group

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**Therapeutic Goods Administration**  
Department of Health  
PO Box 100  
Woden ACT 2606 Australia  
[www.tga.gov.au](http://www.tga.gov.au)

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**From:** SELL, Kirstie [<mailto:Kirstie.Sell@health.gov.au>]  
**Sent:** Wednesday, 13 January 2016 9:05 AM  
**To:** HORNER PSM , Philippa  
**Cc:** SKERRITT, John; SADOW, Andrea; TUCK, Damian; MCCLUSKEY, Sharon  
**Subject:** Ea corro 440076 - Declaration under subsection 7(1) of the Therapeutic Goods Act 1989 [DLM=Sensitive:Legal]

Good morning,  
Liz Cosson (A/g Secretary) has signed the above minute & letter – see attached.  
I will post the original letter to [REDACTED]  
The remaining paperwork will be sent back via the RSG courier.  
Kind regards,

**Kirstie Sell** | Administrative Assistant | Office of the Secretary | Department of Health | ☎ (02) 6289 8412 | ✉ [kirstie.sell@health.gov.au](mailto:kirstie.sell@health.gov.au)



**Australian Government**  
**Department of Health**

RECEIVED  
12 JAN 2016  
SECRETARY'S OFFICE

**MINUTE TO THE ACTING SECRETARY**

To:	Liz Cosson AM CSC	Deadline:	22 January 2016
Through Dep Sec:	John Skerrett	Contact officer:	Philippa Horner PSM
Date	11 January 2016	Phone:	6232 8881
		EA Corro Ref:	440076

**SUBJECT**

**Purpose**

To respond to a request from [REDACTED] that you make a declaration under subsection 7(1) of the *Therapeutic Goods Act 1989* that substances for use in the treatment of drinking water are therapeutic goods if they are used, advertised or presented for supply in association with claims for therapeutic use.

**Timing**

There is no particular timing.

**Background**

As you are no doubt aware, the addition of fluoride to water is a matter for the states and territories and there has been concerted action by a number of groups in Australia to stop the addition of fluoride to reticulated drinking water. Over recent years, the TGA has dealt with representations, requests under FOI, inquiries from state and territory departments and agencies, and from members of the public about the status of fluoridated water, and asking the TGA to take action on the basis that fluoridated water is therapeutic goods and fluoridation is a risk to public health. The TGA has responded that it does not regulate fluoridated drinking water.

An FOI request in January 2013 sought all information about the decision "the TGA has apparently made that both fluoridated water and water containing water fluoridation chemicals are to be excluded from being therapeutic goods" and the justification for such a decision. It also sought information about who made that decision and when. The assertion that such a decision had been made was based on the inclusion in the 2011 Excluded Goods Order of the following item.

Substances for use in the purification or treatment of drinking water if no claims are made for therapeutic use

The documents that were provided in response to the FOI request (which can now be found <http://www.tga.gov.au/documents-released-under-section-11c-freedom-information-act-1982-jul-2012-jun-2013>) indicated that it was clear that it had not been intended to exclude fluoridated water from the coverage of the Act by means of this item. This, and a later inquiry from the Ombudsman about the information provided by the TGA to an individual in response to a number of inquiries about



the regulatory status of fluoridated drinking water, prompted the TGA to get legal advice from the AGS.



On 11 April 2014, the TGA published in "Behind the news" on its website information about fluoride in drinking water which contained the statement:

Fluoridated drinking water is not therapeutic goods within the definition of the term in the *Therapeutic Goods Act 1989*. The Therapeutic Goods Administration thus has no role in regulating fluoridated drinking water.

The page can be found at <http://www.tga.gov.au/behind-news/fluoride-drinking-water>.

#### Issues

[REDACTED] is asking that item 10 be revoked and that a new determination be made by the Secretary under subsection 7(1) declaring fluoridated water to be therapeutic goods. I understand his argument to be that:

- the reason why the TGA states that fluoridated water is not therapeutic goods is because of item 10;
- that item is only effective to exclude goods from the coverage of the Act if no claims of therapeutic use are made; and
- the Commonwealth, states and territories are making such claims in relation to fluoridated water which means that item 10 cannot be relied on to exclude fluoridated water and that such claims have the effect of bringing the goods within the definition in the Act.

The draft response makes the point that the statement on the website is not based on item 10 of the EGO and that it is not possible for the Secretary to make a declaration that goods are not therapeutic goods unless the Secretary is satisfied that they are not. As you will appreciate, it would not be appropriate to disclose to [REDACTED] more about the reasoning behind the website statement.

#### Consultation

None.

#### Recommendation

That you sign the attached response to [REDACTED]

Approved / Not Approved / Please Discuss / Noted

Liz Cosson AM CSC

12/01/16

Copy to:





**Australian Government**  
**Department of Health**

**ACTING SECRETARY**

12 January 2016

[REDACTED]  
Switzerland

Dear [REDACTED]

**Request pursuant to Section 7(2) of the *Therapeutic Goods Act 1989***

Thank you for your letter dated 18 December 2015 in which you requested that I exercise my powers under subsection 7(1) of the *Therapeutic Goods Act 1989* (the Act) to declare that substances for use in the treatment of drinking water are therapeutic goods, in the public interest.

I appreciate that the issue of water fluoridation is a sensitive one in Australia and I am aware that the Therapeutic Goods Administration has been asked on a number of occasions about the status of fluoridated water and whether it is regulated under the Act.

In response to your suggestion that the statement in the 'Behind the news' article on the TGA website dated 11 April 2014, that 'Fluoridated drinking water is not therapeutic goods within the definition of that term in the *Therapeutic Goods Act 1989*', is based on one of the items in the 2011 Therapeutic Goods (Excluded Goods) Order No. 1 of 2011 (the EGO), I would make the following points:

- the relevant item (item 10 of the paragraph 5 table of the EGO) excludes from the operation of the Act substances for use in the purification or treatment of drinking water (provided no claims for therapeutic use are made), not purified or treated water itself.
- the statement on the website you refer to is not based on item 10 of the paragraph 5 table, so making any change to that item would not make any difference to the conclusion set out in the statement.

If goods are not as a matter of law therapeutic goods, then it is not possible under subsection 7(1) for a declaration to be made that they are so. This is because the subsection requires the Secretary to be satisfied that the goods that are the object of the order are 'therapeutic goods'. This was confirmed in a case decided by the Administrative Appeals Tribunal in 1992 (Re

Johnson and Johnson Australia Pty Ltd and the Minister of Aged, Family and Health Services), which can be found at <http://www.austlii.edu.au/au/cases/cth/AATA/1992/297.html>.

Thus the declaration you are seeking could not be made unless I was satisfied that fluoridated water is 'therapeutic goods'. As the statement on the website remains the position as to the status of fluoridated water (irrespective of item 10), I could not make such a declaration.

You may be interested in material published on the TGA website in April 2013 as a result of a Freedom of Information request made to the Department about the history of the exclusion in item 10 in the paragraph 5 table of the EGO. The documents can be found at <http://www.tga.gov.au/documents-released-under-section-11c-freedom-information-act-1982-jul-2012-jun-2013> with the date 18 April 2013.

Yours sincerely



Liz Cosson AM CSC

