



**THERAPEUTIC
GOODS
ADMINISTRATION**

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Minute

Mr Terry Slater
National Manager
TGA

AMENDMENT TO THERAPEUTIC GOODS EXCLUSION ORDER - COLLOIDAL SILVER PRODUCTS PROMOTED AS THERAPEUTIC GOODS

Purpose

To seek your approval to change the Therapeutic Goods Order 1 *Excluded Goods* in order that substances used to purify or treat drinking water, including colloidal silver, for which therapeutic claims are made will not be excluded from the *Therapeutic Goods Act 1989*.

Background

The Therapeutic Goods (*Excluded Goods*) Order (the Order) specifies that "equipment, or substances, for use in the purification or treatment of drinking water" are not therapeutic goods for the purposes of the *Therapeutic Goods Act 1989* (the Act). This exclusion applies regardless of whether or not therapeutic claims are made about such products.

Colloidal silver has a history of use as a water purification agent and is still used in remote areas in some instances and is therefore excluded from the scope of the Act.

High level therapeutic claims are being made about colloidal metal products, especially colloidal silver products, in the marketplace. The products include both substances and equipment used to generate the substances. In this context, the products are being presented inappropriately as medicines. However, as water treatment agents they are also excluded goods and the TGA is not able to take action against such products.

No application has been received for the approval of colloidal silver as a complementary medicine substance and there are no colloidal silver products approved for supply as medicines in Australia.

The Complementary Medicine Evaluation Committee (CMEC) considered the safety for use of colloidal silver and determined that there appeared to be little evidence to support therapeutic claims and that the risk to consumers of silver toxicity outweighed any benefit of unsubstantiated claims. The CMEC has also recommended that efforts should be made to curb the inappropriate presentation of colloidal silver products as unapproved therapeutic goods.

The issue was discussed at the TGA Policy & Planning Committee on 10 September 2002.

The committee recommended that any amendments to the Order should only capture water purification substances for which therapeutic claims are made. Water purification equipment would remain excluded goods and this issue would be assessed separately as part of the overall review of legislation pertaining to therapeutic devices.

An amendment to the Order is proposed so that substances used for the purification or treatment of water, for which therapeutic claims are made, will not be excluded from the Act. It is also proposed that the amended order be enacted immediately upon publication in the *Gazette* so that action can be taken against the water purification products that are being presented as medicines.

Consultation

The following organisations were consulted on the proposed amendment to the Order:

- Office of the NHMRC (NHMRC)
- National Registration Authority (NRA)
- Australian Competition and Consumer Commission (ACCC)
- CRC for Water Quality and Treatment (CRC)
- Association of Therapeutic Goods Consultants (ATGC)
- Complementary Healthcare Council of Australia (CHC)
- Water Services Association of Australia (WSAA)
- Australian Water Association (AWA)
- Australian Self-Medication Industry (ASMI)
- Direct Selling Association of Australia Inc. (DSAA)

There was broad support for the amendment of the Order so that water purification substances, including colloidal silver, for which therapeutic claims are made will be subject to therapeutic goods legislation.

Water industry organisations did not foresee any implications for their industry since only those substances for which therapeutic claims are made would be captured and legitimate water purification substances would not be affected.

The complementary medicine industry organisations strongly supported the amendment and cited equity issues for sponsors who supply approved medicines. The issue of advertising control was raised in particular. The ASMI requested that both substances and equipment should be captured under the change. There were no comments regarding the immediate commencement of the amended order upon gazettal.

The NRA supported the amendment but requested that only products intended for human use should be captured by our legislation.

The proposed change to the Order is in accord with the comments from the consultation process. As noted above, the supply of water purification equipment will be considered separately in conjunction with other changes to the legislation covering therapeutic devices. Veterinary use of water purification substances will not be affected, since the proposed change is specific to therapeutic goods as defined in our Act.

Regulatory basis for this request

Subsection 10(1) of the *Therapeutic Goods Act 1989* allows the Minister for Health & Ageing to publish an order in the *Gazette* specifying a standard for therapeutic goods or a class of therapeutic goods identified in the order.

The Parliamentary Secretary to the Minister has delegated authority, under this section of the Act, to the National Manager of the TGA. A gazette notice removing substances used for the purification or treatment of water for which therapeutic claims are made from excluded goods is attached for your signature.

A Minute has been prepared to advise the Hon Trish Worth, MP, Parliamentary Secretary to the Minister for Health and Ageing, of the change to the Order that is to be gazetted, and is attached for your signature.

Office of Regulatory Review

The Regulatory Impact Statement for the proposed amendment to the Order has been cleared by the Office of Regulatory Review (ORR number 3395).

Recommendation

That you sign the attached Amendment Order for gazettal (to be returned to the TGA Legal Unit) and Minute to the Hon Trish Worth, MP.

Pio Cesarin
Director
Chemicals and Non-Prescription Medicines Branch
December 2002

Attached for signature:

1. Notice for publication in the *Gazette*.
2. Minute to the Hon Trish Worth, MP, Parliamentary Secretary to the Minister for Health and Ageing.

MINUTE TO THE MINISTER / PARLIAMENTARY SECRETARY INFORMATION ONLY



MS WORTH

cc: SENATOR PATTERSON

CHANGE TO EXCLUDED GOODS ORDER: COLLOIDAL SILVER PRODUCTS

PURPOSE

To advise you of a change to the Therapeutic Goods Order 1 (*Excluded Goods*) (the Order) such that substances used to purify or treat water, which carry therapeutic claims, will no longer be excluded under the *Therapeutic Goods Act 1989*. The change to the Order will be implemented *via* a gazettal notice to this effect, which will be published in the *Commonwealth Government Notices Gazette* by the end of 2002 or very early in January 2003 and will commence from the date of publication.

BACKGROUND

1. There are no colloidal silver products approved for supply as medicines in Australia. However, colloidal silver products are being widely marketed in Australia as medicines, many with high level therapeutic claims.
2. The TGA has been unable to take action against these products because colloidal silver substances are excluded from the scope of the *Therapeutic Goods Act 1989* (the Act).
3. Colloidal silver substances and the equipment used to make colloidal silver are included in the Therapeutic Goods (Excluded Goods) Order number 1 (the Order) and are thus excluded from the scope of the Act. The basis for the exclusion is that colloidal silver has a history of use as a water purification agent and is still used for this purpose in remote areas and for animal use.
3. Although the TGA has not assessed an application for a colloidal silver product, the Complementary Medicine Evaluation Committee (CMEC) was asked to consider the safe use of colloidal silver as a medicine. The CMEC and the TGA determined that the risk to consumers of silver toxicity outweighs any purported value of the unsubstantiated therapeutic claims. The CMEC recommended that efforts should be made to stop the supply of colloidal silver products as therapeutic goods.
4. The TGA agreed with the CMEC recommendation and proposed to change the Order so that silver products that are marketed with therapeutic claims are not excluded from the Act.
5. The TGA proposal to change the Order was consulted with the complementary medicine industry bodies, water quality industry and relevant government agencies. There is broad support for the TGA proposal, with the proviso that the genuine use of colloidal silver for water purification purposes does not become captured under the Act. A list of the organisations that were consulted is included in Attachment 1.
4. A notice will be published in the *Gazette* either before the end of 2002 or very early in January 2003 that will remove water purification substances, including colloidal silver, for which therapeutic claims are made from being excluded goods (Attachment 1). Given the

increased promotion of these products and the associated risk to public health, the change to the Order will come into force on the day of publication of the gazettal notice.

ISSUES

- Following publication of the change to the Therapeutic Goods Order (Excluded Goods) in the *Gazette*, colloidal silver products making therapeutic claims will become therapeutic goods under the *Therapeutic Goods Act, 1989*.
- The TGA has not approved any colloidal silver medicines and most of the products currently being marketed will become illegal therapeutic goods. The TGA will take action to stop the supply of these illegal therapeutic goods.
- While there is support for this action from the peak industry bodies, there is likely to be considerable protest from those who are currently supplying colloidal silver products as medicines. Many of these suppliers are passionate about the claimed benefits of using colloidal silver as a medicine.
- Those wishing to market colloidal silver products as therapeutic goods may submit an application with the relevant information to the TGA to have their product placed on the Australian Register of Therapeutic Goods (ARTG) and it will be considered in due course, as for any other therapeutic good.

CONSULTATION

- The change to the Excluded Goods Order was consulted with the water purification industry, complementary medicine industry, and government agencies that might be affected by the proposed change.
- There was broad support for the proposed change to make water purification substances, including colloidal silver, for which therapeutic claims are made subject to the *Therapeutic Goods Act, 1989*.
- The complementary medicine industry organisations strongly supported the amendment and cited equity issues for sponsors who supply approved medicines. The issue of equity in advertising controls was raised in particular. Water industry organisations did not foresee any implications for their industry.

RECOMMENDATION

R1. That you NOTE

The Therapeutic Goods Order 1 (*Excluded Goods*) will be changed such that substances used to purify or treat water that carry therapeutic claims will no longer be excluded from the *Therapeutic Goods Act 1989*. The change to the Order will be implemented via a gazettal notice to this effect, which will be published in the *Commonwealth Government Notices Gazette* before the end of 2002 or very early in January 2003 and will be in force from the date of publication.

Terry Slater
National Manager
Therapeutic Goods Administration
date

Action Officer
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OUTCOME: 1: Population Health and Safety

MINISTER'S COMMENTS:

MINISTER'S ACTION

Trish Worth

- NOTED
- PLEASE DISCUSS
- PROVIDE FURTHER UPDATE

COMMONWEALTH OF AUSTRALIA

Therapeutic Goods Act 1989

Therapeutic Goods (Excluded Goods) Order No.1 of 2002

TG1/2002

I, ~~TERRENCE~~ SLATER, a delegate of the Secretary of the Department of Health and Ageing for the purposes of section 7 of the *Therapeutic Goods Act 1989* (the Act), and acting under subsection 7(1) of that Act, make the following Order.

Dated December 2002

Delegate of the Secretary of the Department of Health and Ageing

Citation

1. This Order may be cited as the Therapeutic Goods (Excluded Goods) Order No 1 of 2002.

Commencement

2. This Order commences on Gazettal.

Amendment

3. Therapeutic Goods (Excluded Goods) Order No.1 of 1998 * ("the 1998 Order") is amended as set out in this Order.
4. Delete paragraph 3(i) and replace with the following new paragraph: "3(i) equipment for use in the purification or treatment of drinking water;"
5. After item 12 in the Table insert:

(i) in column 1 –

"13"

(ii) in column 2 –

"substances for use in the purification or treatment of drinking water"

(iii) in column 3 –

"if no therapeutic claims are made"

* TG1/98 published in Commonwealth of Australia Gazette No. S 79 of 25 February 1998