Colleen Spence
18/12/2002 16:06

To: "O'Donohue, Jane" <JODONOHU@pc.gov.au>
cc:
bcc:

Subject: RE: FW: Amended RIS

Dear Jane,

thanks very much for your timely help

RIS 3395 TGA Excluded Goods 18Dec02.

Colleen
OCM/TGA

# REGULATORY IMPACT STATEMENT

**Amendment of the Therapeutic Goods (Excluded Goods) Order in relation to Water Purification or Treatment Substances promoted as Therapeutic Goods**

## PROBLEM

- **Some Australian suppliers are promoting colloidal metal products as medicines that may be used to treat serious diseases, such as cancer, malaria and HIV/AIDS.**
- **Colloidal metal products have a use in the purification or treatment of drinking water and for this reason are Excluded Goods from the *Therapeutic Goods Act 1989*. There is a strong potential that other substances used to purify or treat water will also be promoted as therapeutic goods.**
- **The TGA holds serious concerns about the risks to public health and safety that are presented by the promotion of these products as medicines, both because of the claims to treat serious diseases and also because of the potential toxicity of the products.**
- **The TGA is aware of businesses supplying such products in all States and Territories of Australia.**

### Presentation of water purification substances as medicines

Since the late 1990s, there has been an increasing incidence of the presentation of colloidal metal products as medicines. The most prominent substance is colloidal silver, which is also used in water treatment and purification processes, however colloidal gold is also being promoted as a medicine.

Although much of the present problem involves colloidal silver products, there is a strong potential for other water purification substances to be presented as therapeutic goods. Under the current legislation, any water purification substance can be advertised and supplied as a medicine to treat any disease without being reviewed for safety and effectiveness. This is contrary to the intention of the *Therapeutic Goods Act, 1989*, which aims to ensure the supply of safe, quality and efficacious medicines in Australia.

The claims that are being made are for serious diseases. As an example, the following are two cases of promotion of colloidal silver products [by companies based in Victoria and New South Wales].

| | | |
|---|---|---|
| Aids | Acne | Arthritis |
| Athlete's foot | Cancer | Conjunctivitis |
| Dermatitis | Diabetes | Dysentery |
| Eczema | Gastritis | Gonorrhoea |
| Impetigo | Leprosy | Malaria |
| Meningitis | Pleurisy | Pneumonia |
| Prostrate | Psoriasis | Scarlet fever |
| Septicaemia | Shingles | Stomach ulcers |
| Syphilis | Toxaemia | Trachoma |
| Tuberculosis | Whooping cough | |

| | | |
|---|---|---|
| Burns | Eye ear nose throat infections | |
| Treatment of allergies | Parasites | Boils |
| Chronic fatigue | Candida | Cystitis |
| Diabetes | Herpes | Hepatitis |
| Lupus | Ringworm | Cold/flu |
| Warts | Sleepwalking | Skin cancer |
| Tonsillitis | Staph infections | Cuts and wounds |

**Public Health & Safety Concerns**

There is a strong risk to public health and safety associated with the promotion of any substance as a medicine without proven safety and effectiveness. Concerns are based on the following:

- Consumers may self diagnose and treat potentially serious illnesses without seeking appropriate medical advice;
- Patients may be mislead by advertisements for substances claimed to treat serious disease and take those products in place of approved medicines that have been prescribed by their doctor and are known to be effective;
- The substance and the recommended dosage are not regulated and may result in toxicity to the patient.

*Unsubstantiated therapeutic claims*

To assist in assessing the risk to public health associated with the promotion of colloidal metal products for serious disease, the expert committee advising on the regulation of complementary medicines, the Complementary Medicine Evaluation Committee (CMEC), was asked to review the toxicity and efficacy of colloidal silver based on the medical and scientific evidence. The CMEC advised that there was inadequate evidence to support therapeutic claims for this product type.

*Appropriate and Timely Medical Care*

For the treatment of serious diseases, such as cancer, malaria or meningitis, there is a strong risk associated with the patient not seeking timely professional medical advice. The *Therapeutic Goods Act, 1989* (the Act) includes measures that are intended to protect people who may be vulnerable because of serious or chronic disease and encourage appropriate medical care.

Medicines indicated for the prevention, cure, treatment or diagnosis of serious disease usually require a prescription from a medical doctor to ensure that the patient receives appropriate and individual medical advice. Prescription medicines and some medicines available from pharmacies may not be advertised directly to the consumer for the same reason and also to protect those who may be vulnerable because of their own fears for their health.

*Potential toxicity*

The usual content of silver in water purification products promoted as medicines is 100 times higher than the NHMRC guideline for content of silver in drinking water. There is scientific evidence that long-term ingestion of colloidal silver can cause damage to the kidneys, liver and central nervous system and there are many validated cases of agyria (a permanent discolouration of the skin caused by the deposit of silver in the skin). The advice from the CMEC was that the risk to consumers of silver toxicity outweighs any

purported value of the unsubstantiated therapeutic claims and efforts should be made to curb the availability of colloidal silver products, which is a significant public health issue.

## Magnitude of the Problem

It is difficult for the TGA to estimate the number of companies that are manufacturing or supplying water purification substances and presenting these as medicines with therapeutic claims. The water purification industry and complementary medicine industry organisations are not able to provide this information because the companies involved do not in general form part of their membership.

*Referrals to TGA*

The TGA's Surveillance Unit receives many referrals from other areas of TGA about colloidal metal products being presented as medicines. Most of the referrals are complaints from the public or other business about specific products or about misleading advertising. It is estimated that 10 to 15 referrals are received per year over the last few years. Complaints have been received about companies operating in every State and Territory.

*Reported Adverse Reactions*

Adverse reactions for colloidal metal products have been reported.

For the period January 2000 to June 2002, there were five reports of adverse reactions associated with the ingestion of colloidal silver products. The patients were aged from 6 years to 80 years and the adverse reactions ranged from nausea and headache to collapse due to hypotension, skin discolouration and altered liver function. There were no deaths and four patients recovered, with no further report on the fifth patient.

In general, adverse reactions are under-reported and this is even more pronounced for complementary medicines and other self-selected medicines where a healthcare professional may not be involved.

## Current Legislative Controls

All medicines supplied in Australia must be entered in the Australian Register of Therapeutic Goods (ARTG) before they may be supplied, unless they are exempt. Before a medicine is entered in the ARTG, the TGA assesses the medicine for safety, quality and efficacy.

Substances used to purify or treat drinking water are specifically excluded from coverage by the *Therapeutic Goods Act, 1989* through the Therapeutic Goods (Excluded Goods) Order number 1 (the Order). The intention of the Order was to exclude products that are not medicines from the scope of the *Therapeutic Goods Act, 1989*. At the time of the enforcement of the Order, the presentation of water purification products as medicines was not an issue. This exclusion applies regardless of whether or not therapeutic claims are made about such products.

Colloidal metals and colloidal silver in particular have a history of use as water treatment and purification substances and are still used for this purpose in remote areas. Therefore, these products are Excluded Goods from the *Therapeutic Goods Act, 1989* and the TGA cannot take action to protect public health and safety with regard to this issue.

*Advertising Controls*

Sponsors of approved medicines, which are on the ARTG, may advertise their products within the legislative restrictions and co-regulatory guidelines. The goal of advertising regulation for medicines is that advertisements be truthful and not misleading and do not target vulnerable groups.

As Excluded Goods, the advertising of water purification substances is unregulated other than under the *Trade Practices Act 1974*. The Australian Competition and Consumer Commission (ACCC) has taken action against companies under the *Trade Practices Act 1974* for promoting colloidal silver products as medicines. The Federal Court granted an injunction against at least one company, preventing any further supply and advertising of equipment used to make colloidal silver. The company had been advertising colloidal silver made with their machines as a treatment for AIDS, cholera, diabetes, leprosy, leukaemia, lupus, skin cancer syphilis and whooping cough.

**Equity Issues for Australian Complementary Medicine Industry**

There are equity issues for sponsors of medicines that have in good faith complied with therapeutic goods legislation. The peak industry bodies in the area of complementary medicines have strongly expressed their views that colloidal metal products should not be Excluded Goods and should be subject to the same regulation as their complementary medicine products.

## OBJECTIVE

The objectives of the Government are:

- Protect public health and safety;
- Ensure that medicines supplied in Australia are safe, of a high quality and are effective;
- Ensure that advertisements about medicines are truthful and not misleading;
- Ensure that the regulation of medicines is equitable for industry.

## OPTIONS

### 1. Do Nothing

*Status quo* remains.

### 2. Regulate all water purification substances as medicines when therapeutic claims are made

Under this option, therapeutic goods regulation would only apply to those water purification substances for which therapeutic claims are made. Substances used to genuinely treat and purify water would not be affected. This would address public health and safety concerns and substances promoted as medicines would be regulated as medicines.

The companies making therapeutic claims about colloidal metal products are not, in general, members of the water purification or the complementary medicine industry bodies. Self-regulation by the sponsors is not feasible given their own lack of organisation.

# IMPACT ANALYSIS

## Option 1

*Consumers*

Consumers will continue to be placed at risk of inappropriate treatment with potentially ineffectual and toxic medicines. Their only recourse will continue to be through the ACCC and the *Trade Practices Act 1974*.

*Companies making therapeutic claims*

No impact - status quo maintained.

*Companies not making therapeutic claims*

No impact - status quo maintained.

*Other Complementary Medicine Companies*

Sponsors of complementary medicines that are within the scope of the *Therapeutic Goods Act, 1989* will face inequalities in the regulation of their products. Since sponsors of colloidal silver products making therapeutic claims align themselves with the complementary medicine industry, the industry as a whole will suffer damage to its credibility as a result of the unsubstantiated claims being made for water purification substances.

*Commonwealth Government*

There are potential costs associated with the inappropriate treatment of people with serious disease with water purification substances that are not efficacious. There are also potential medical costs for the medical treatment of people who may experience adverse reactions to water purification substances promoted as medicines.

## Option 2

*Consumers*

This option would empower the TGA to regulate the advertising and supply of water purification substances that are presented as medicines with therapeutic claims. This would fully address the public health and safety concerns in relation to the Order.

*Companies making therapeutic claims*

Sponsors making therapeutic claims for their colloidal silver products will be required to cease supply of their products upon publication of the Order amendment in the *Gazette*. Advertising for any colloidal silver products that include therapeutic claims will also be required to cease.

Sponsors may choose to supply their products as water treatment or purification agents without any therapeutic claims on the labels or in other advertising material. This may require repackaging before supply can legally recommence.

Sponsors may choose to apply to the TGA for approval to supply their products as medicines. The typical cost to Register a new complementary medicine is $10,000 to

$20,000 depending on the application and would take between 6 to 12 months. If the application were approved, supply could not recommence until the medicine was entered in the ARTG at the end of the process.

Alternatively, a sponsor or a group of sponsors may jointly apply to have colloidal silver made a Listable substance. This means that colloidal silver, as defined in the applicants, could be used by any sponsor in a Listed medicine. The typical cost to apply for a new Listable substance is $5000 to $7000 depending on the application and would take between 3 to 12 months for assessment. If the application to make colloidal silver a Listable substance were approved, each sponsor would need to List their product on the ARTG. The cost to List a medicine in the ARTG is $460 and takes about 10 days and there is an annual fee of $390.

There may be additional costs involved in the application and approval processes, such as the cost of preparing an application or the cost of a consultant to assist in the preparation of an application.

If the medicine meets the standards for safety, quality and efficacy and is entered on the ARTG, then sponsors can advertise their product and therapeutic claims within the advertising regulations and guidelines.

*Companies not making therapeutic claims*

No impact. Since no therapeutic claims are being made, these products will remain Excluded Goods and there will be no impact on this business sector.

*Other Complementary Medicine Companies*

This option would ensure that sponsors of all complementary medicines are regulated equitably and would safeguard the creditability that the Australian complementary medicine industry has built.

*Commonwealth Government*

The TGA has in place regulatory processes to assess new medicines, to enter medicines that are deemed to be safe and effective into the ARTG, to monitor medicines after inclusion in the ARTG, and to take action against the illegal supply of unapproved medicines. There is also a co-regulatory scheme with industry for the regulation of advertising of medicines. There is a potential savings to the Commonwealth through consumers receiving timely and appropriate medical treatment for serious disease and not being exposed to potentially toxic substances.

## CONSULTATION

### TGA Communication with Public and Industry

The recommendations of the CMEC to bring colloidal silver products that are promoted as medicines within the scope of the *Therapeutic Goods Act, 1989* are published on the TGA web site.

There has been substantial media interest in colloidal silver products that are presented as medicines and the high level therapeutic claims being made about them. In conjunction with this media interest, the director of the TGA's Office of Complementary Medicines has been interviewed and quoted extensively in the media that action was in process to bring colloidal silver products under regulation as medicines.

A change in the regulation of colloidal silver products for which therapeutic claims are made was foreshadowed in the July 2002 issue of the TGA News. The TGA News is a publication used to communicate with industry as a whole on regulatory issues. The TGA News is distributed to industry and is on the TGA web site.

**Formal Consultation**

The TGA formally sought comments on the proposed amendment to the Excluded Goods Order from the following organisations:

- Office of the NHMRC (NHMRC)
- 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)

All respondents considered that the presentation of water purification substances as medicines is inappropriate and they expressed concerns about the resulting risk to public health and safety.

The water purification industry and the NRA additionally requested that water purification substances not making therapeutic claims should remain Excluded Goods and that the change to the Order should not impact on veterinary use of such substances.

The CHC and the ASMI expressed concerns that the significant and unsubstantiated therapeutic claims being made for colloidal metal products would seriously damage the credibility of the entire Australian complementary medicine industry.

All organisations supported amendment to the Order such that all water purification substances for which therapeutic claims are made will no longer be excluded from the *Therapeutic Goods Act, 1989* (Option 2).

Additional comments were received from FulHealth Industries Pty Ltd as a result of information released through the media and the complementary medicine industry organisations. FulHealth Industries proposed that colloidal silver remain Excluded Goods as long as no therapeutic claims are made on the product label, the concentration and dosage of silver is within a given guideline, and all products presented as medicines be manufactured and tested by accredited companies.

This proposal would allow the presentation of colloidal silver products as medicines through advertising and does not address the public health and safety issues related to unsubstantiated therapeutic claims, safety in use or quality of the products. For these reasons, this option is not considered feasible.

## CONCLUSION & RECOMMENDATION

The TGA recommends Option 2 to amend the Order so that all water purification or treatment substances that are presented as human medicines with therapeutic claims will not be excluded from the *Therapeutic Goods Act, 1989*.

This Option is consistent with the comments received during the consultation process and is consistent with the intention of the Order and the intention of the *Therapeutic Goods Act, 1989*. Substances promoted as medicines would be regulated as medicines and substances promoted as water purification agents would be excluded from therapeutic goods regulation.

The recommended amendment to the order would:

- Protect public health and safety;
- Ensure that products being presented as medicines with therapeutic claims, including substances that may also be used for water purification purposes, are safe, of high quality and are effective;
- Ensure that advertising for products presented as medicines, including substances that may also be used for water purification, is truthful and not misleading;
- Have no impact on the promotion or supply of substances for the purpose of water purification or treatment where no therapeutic claims are made;
- Create a level playing field for the Australian complementary medicine industry as a whole.

## IMPLEMENTATION & REVIEW

TGA proposes to amend the Order such that it will come into force upon gazettal because:

- There are public health and safety concerns about the promotion and supply of water purification substances as medicines with therapeutic claims and concerns about the safety of use of such products;
- The industry has been consulted both formally through the consultation process and informally through media interviews, the TGA News and the TGA web site and is aware of the proposed change in regulation;
- Amending the Order would allow immediate action to be taken against water purification substances that are being presented as medicines;
- The amendment to the Order will not affect products that are promoted and supplied as water purification or treatment substances and for which no therapeutic claims are made.

Upon gazettal of the amendment to the Order, the Surveillance Unit of the TGA would be responsible for implementing and reviewing its utility.

The Office of Complementary Medicines would be responsible for the assessment of any applications for a colloidal metal medicine and would be available to provide information on that process.