

# Regulation of colloidal silver and related products

- [Summary](#)
- [Background](#)
- [Current situation](#)

## Summary

In December 2002, an amendment was made to the Therapeutic Goods (Excluded Goods) Order such that products containing substances like colloidal silver, which make therapeutic claims, are no longer goods excluded from therapeutic goods legislation and must meet the requirements of other therapeutic goods. Colloidal silver products that are used in the purification or treatment of drinking water, and which do not make therapeutic claims, will remain excluded from therapeutic goods legislation.

## Background

In 1998, the Complementary Medicines Evaluation Committee (CMEC) was requested to provide advice to the National Drug and Poisons Scheduling Committee (NDPSC) on the efficacy of colloidal silver as a complementary medicine, to assist them in considering the use of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) in providing safeguards in the use of this substance.

Following an investigation by the Therapeutic Goods Administration (TGA), the CMEC recommended that the NDPSC be advised that there are no current legitimate uses of colloidal silver and that the Surveillance Section of the TGA be requested to investigate the illegal availability of colloidal silver products because of concerns about their significant toxicity. The reasons for the recommendation were that:

- there is little evidence to support therapeutic claims made for colloidal silver products;
- the risk to consumers of silver toxicity outweighs the value of trying an unsubstantiated treatment, and bacterial resistance to silver can occur; and
- efforts should be made to curb the illegal availability of colloidal silver products, which is a significant public health issue.

Ongoing concerns over the safety of colloidal silver led the CMEC to recommend that action be taken by the TGA in regard to the safety risk posed by illegal or potentially illegal products containing colloidal silver. The Surveillance Section of the TGA subsequently advised that it was not able to take any action against colloidal silver products regardless of whether such products make therapeutic claims or not. This is because colloidal silver may be used in the purification or treatment of drinking water and such goods were excluded, by virtue of the Therapeutic Goods (Excluded Goods) Order (the Order), from the requirements of the Therapeutic Goods Act 1989 (the Act).

The TGA undertook action to change the Order so that all products which may have a use in the purification or treatment of drinking water but which are marketed with therapeutic claims are not excluded from the requirements of the Act.

The TGA consulted with the peak complementary medicine industry bodies, the water quality industry and relevant government agencies that might be affected by the proposed change. There was broad support for the TGA's proposal, with the proviso that the genuine use of colloidal silver for water purification purposes should not become captured under the Act.

A notice was published in the Gazette on 20 December 2002 which removed water purification substances, including colloidal silver, for which therapeutic claims are made from being excluded goods. Given the increased promotion of these products and the associated risk to public health, the change to the Order came into force on the date of gazettal.

The TGA contacted current and potential suppliers of products based on colloidal minerals for which therapeutic claims are made to alert them to the revised regulatory status of such products.

## **Current situation**

As of 20 December 2002, colloidal products which make therapeutic claims are classified as therapeutic goods under the Act. To date, the TGA has not approved any colloidal silver products for use as therapeutic goods in Australia. The TGA will take action to stop the supply of any unapproved colloidal silver products which make therapeutic claims.

Sponsors wishing to market colloidal silver products as therapeutic goods in Australia will need to submit an application, with relevant supporting data, to the TGA. This could be in the form of an application to have colloidal silver approved as a new Listable substance (on the basis of demonstrated safety and quality) or an application to have products containing colloidal silver included on the Australian Register of Therapeutic Goods (on the basis of demonstrated safety, quality and efficacy). As for all such applications, sponsors are encouraged to seek the assistance of a consultant familiar with TGA application processes and requirements.

For further information on this topic please contact the TGA Information Officer by telephone on 1800 020 653 or email to [info@tga.gov.au](mailto:info@tga.gov.au).

- 11 June 2008 update: [Therapeutic Goods \(Excluded Goods\) Order No. 1 of 2008](http://www.tga.gov.au/legis/tgeg0801.htm) <<http://www.tga.gov.au/legis/tgeg0801.htm>> revoked and replaced Therapeutic Goods (Excluded Goods) Order No. 1 of 2005.
- 9 November 2005 update: Therapeutic Goods (Excluded Goods) Order No. 1 of 2005 revoked and replaced Therapeutic Goods (Excluded Goods) Order No. 1 of 2004.