



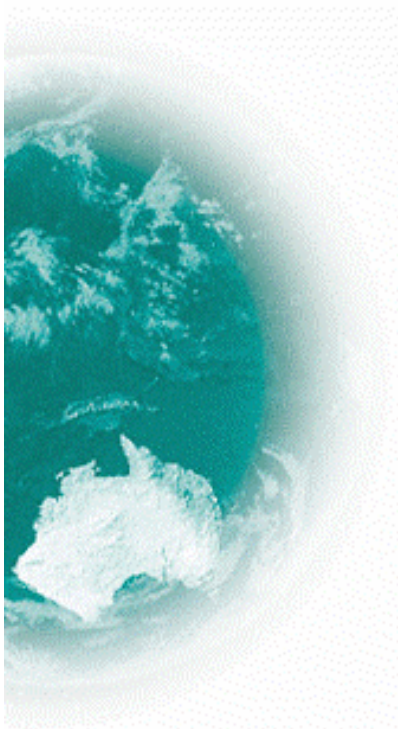
Australian Government

**Department of Health and Ageing
Therapeutic Goods Administration**

CONSULTATION PAPER:

**Proposed Section 7 Declaration:
that products in capsule, tablet or pill form
are therapeutic goods**

CALL FOR COMMENT



October 2009

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HOW TO COMMENT ON THIS CONSULTATION PAPER

Submissions may be sent by post and/or email and should, where possible, contain relevant evidence, and/or examples, to support the views expressed.

Content of submissions

It would be helpful if your submission included:

- your name and full contact details including: address, telephone number and, if applicable, facsimile and email address
- information and data concerning the impact of proposed changes on affected parties
- in the case of organisations; the level at which the submission was authorised.

In addition, submissions might:

- include any other relevant information eg. scientific and technical, economic, international obligations, business and consumer information
- identify and discuss any perceived omissions or alternative approaches, in addition to those already included in the consultation paper.

Confidentiality of submissions

If you wish any information contained in a submission to be treated as confidential, please clearly identify the information and outline the reasons why it is confidential, in the consultation submission cover sheet provided.

Address for submissions

Electronic submissions should be emailed to: Section7consultation@tga.gov.au

Hard copy submissions should be addressed to:

The Project Officer
Section 7 Consultation 2009
Regulatory Compliance Unit
Therapeutic Goods Administration
PO Box 100
WODEN ACT AUSTRALIA

Questions relating to submissions

Any questions relating to submissions should be directed to the Project Officer, by email at: Section7consultation@tga.gov.au

Deadline for submissions

The deadline for receipt of submissions is close of business, Monday 30th November 2009.

PROPOSED SECTION 7 DECLARATION

Background

In Australia, it has long been recognised that there is a legislative 'interface', or overlap, between foods and medicines for human oral consumption. As the food and complementary medicine sectors have evolved over recent years, a 'grey area' has unintentionally developed at this food-medicine interface. The confusion is due to certain areas of food legislation and therapeutic goods legislation overlapping in such a way that makes it difficult to determine which legislation should be applied in many cases.

Currently, some orally consumed products fall under the definition of both a food and a therapeutic good. This situation is creating uncertainty for many people and organisations, including importers, manufacturers, consumers, and government regulators. There is particular concern regarding the potential for this confusion to prevent the consumer from making an informed choice. There is also a potential public health and safety risk arising from this situation, particularly if the products in question have not been manufactured to an acceptable standard or are found to be contaminated and/or to include a prescription-only substance.

The Therapeutic Goods Administration (TGA) and Food Standards Australia and New Zealand (FSANZ) have recognised that the food-medicines interface confusion is heightened by the practice of presenting certain foods in capsule, tablet or pill form. This form of presentation, except in the case of unmedicated confectionary, gives the impression that the product is a medicine. The impression that a product is a medicine carries consumer expectations that the product has been assessed by the TGA and that the claims on the label have been approved.

The current proposal to declare (under Section 7 of the *Therapeutic Goods Act 1989*) that goods presented for oral consumption in tablet, capsule or pill form are therapeutic goods, aims to resolve many of these issues and clarify regulatory requirements for industry. Should this initial consultation indicate that the Section 7 Declaration is warranted, a full regulatory impact statement would be prepared.

When is a medicine not a medicine?

The principal distinction between therapeutic products and food products is based on the definitions of '*therapeutic goods*' and '*therapeutic use*' in the *Therapeutic Goods Act 1989* (the Act), which are as follows:

therapeutic goods means goods:

- (a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
 - (i) for therapeutic use; or
 - (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or
 - (iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or
- (b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);

and includes medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:

- (c) goods declared not to be therapeutic goods under an order in force under section 7; or
- (d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or
- (e) goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined in subsection 3(1) of the Australia New Zealand Food Authority Act 1991; or
- (f) goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

therapeutic use means use in or in connection with:

- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or
- (b) influencing, inhibiting or modifying a physiological process in persons or animals; or
- (c) testing the susceptibility of persons or animals to a disease or ailment; or
- (d) influencing, controlling or preventing conception in persons; or
- (e) testing for pregnancy in persons; or
- (f) the replacement or modification of parts of the anatomy in persons or animals.

These definitions state that goods, likely to be taken for the purpose of influencing, inhibiting or modifying a physiological process in persons, are therapeutic goods **unless** there is an existing **food standard** for these goods. This means that, unless there is a **Section 7 Declaration** in force, the existence of a food standard determines that the goods are a food and not therapeutic goods.

Objectives of the Section 7 Declaration

Food standards are in place for many substances that are often marketed as therapeutic goods, such as: edible oils (eg. Fish oil, evening primrose oil, flaxseed oil) and formulated supplementary sports foods.

Many of these substances are only marketed as therapeutic products when they are presented in capsule, tablet or pill form. Therefore, it has been proposed that a Section 7 Declaration, that these forms of presentation identify the goods as therapeutic goods, is a logical step towards resolving the problem.

The Section 7 Declaration aims to:

- 1) Provide more clarity for industry about whether their products should be marketed as foods or therapeutic goods;
- 2) facilitate more informed consumer choices; and
- 3) provide government regulators with improved means of distinguishing between foods and therapeutic goods.

What is a Section 7 Declaration?

Section 7 of the *Therapeutic Goods Act, 1989* (the Act), provides the power for the Secretary to declare that goods **are** or **are not** therapeutic goods. This section of the Act exists to address certain goods that have either unintentionally **not** been captured, **OR** have unintentionally **been** captured by the definition of 'therapeutic goods'. Section 7 of the Act is worded as follows:

7 Declaration that goods are/are not therapeutic goods

- (1) Where the Secretary is satisfied that particular goods or classes of goods:
 - (a) are or are not therapeutic goods; or
 - (b) when used, advertised, or presented for supply in a particular way, are or are not therapeutic goods;the Secretary may, 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 this Act, therapeutic goods.
- (2) The Secretary may exercise his or her powers under this section of his or her own motion or following an application made in writing to the Secretary.
- (3) A declaration under this section takes effect on the day on which the declaration is published in the *Gazette* or on such later day as is specified in the order.
- (4) If a declaration under this section:
 - (a) is a declaration that particular goods or classes of goods are not therapeutic goods; and
 - (b) applies wholly or partly to goods that, apart from this section, would be medical devices;the goods are not medical devices, or are not medical devices when used, advertised, or presented for supply in the way specified in the declaration.

Proposed wording of the Section 7 Declaration

It is proposed that the TGA gazette a declaration under Section 7 in the included goods orders with the following wording:

I, XXXX, delegate of the Secretary to the Department of Health and Ageing for the purposes of subsection 7(1) of the Therapeutic Goods Act 1989 (the Act), acting under that subsection and subject to the exclusion described below, DECLARE that goods when manufactured in tablet, capsule or pill form intended for oral consumption in that form, are for the purposes of the Act, therapeutic goods.

Unmedicated confectionery in a finished tablet, capsule or pill form is excluded from the scope of this declaration.

This Order commences on Gazettal.

Questions for consideration by stakeholders

1. Do you feel that the proposed Section 7 Declaration will provide more clarity for consumers in determining the difference between goods regulated as foods and goods regulated as therapeutic products?
2. Can you think of any ways in which this Declaration would negatively impact on consumer choices?
3. Would the proposed Section 7 Declaration have negative financial implications for your business? If yes, please indicate the approximate cost to your business (such information should be identified as confidential in the consultation submission cover sheet).
4. Are there any other negative implications for business?
5. Do you have any further comments?