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Therapeutic Goods Amendment Bill (No. 2) 2002

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Therapeutic Goods Amendment Bill (No. 2) 2002

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Contents

Therapeutic Goods Amendment Bill (No. 2) 2002

Date Introduced: 27 June 2002

House: House of Representatives

Portfolio: Health and Ageing

Commencement: The main provisions of the Act commence on proclamation

Purpose

The purpose of the *Therapeutic Goods Amendment Bill (No. 2) 2002* is to clarify the definition of "therapeutic good" and consolidate and amend the laws that regulate advertisements about therapeutic goods.

Background

Therapeutic goods

The *Therapeutic Goods Act 1989* (TG Act) creates a framework for the regulation of therapeutic goods that are used in and exported from Australia.[1] The Act imposes a number of controls on the advertising, manufacturing and distribution of therapeutic goods. These controls relate to the quality, safety, efficacy and timely availability of the goods.

"Therapeutic good" is defined in section 3 of the TG Act 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 for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined in subsection 3(1) of the *Food Standards Australia New Zealand 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.

Under this definition, 'therapeutic goods' includes medicines, complementary medicines and therapeutic devices.

Complementary medicines

Complementary medicines[2] include products such as vitamins, minerals, aromatherapy and homeopathic products. There is a growing trend for the increased use of complementary medicines in Australia.[3] Whilst statistics vary, research carried out by Adelaide University suggests that income spent on alternative medicines and therapies in 2000 was $2.3 billion.[4]

The supply and sale of complementary medicines in Australia is regulated by both the TG Act and the Australia New Zealand Food Standards Code (Food Standards Code). In December 1998, the then Parliamentary Secretary to the Minister for Health and Aged Care, Senator Grant Tambling, announced the establishment of a working party to oversee regulatory reform of the complementary healthcare industry.[5] This was in response to suggestions that there were inadequate mechanisms in place to adequately regulate the complementary healthcare industry.

Included in the Working Party's terms of reference was an examination of;

> the [Therapeutic Goods Advertising] Code and associated guidelines in respect of all medicines which may be advertised and recommend any changes to:
>
> - The Therapeutic Goods Act 1989 and legislation; and/or
> - The Code and related guidelines.[6]

As a consequence of the review, a range of changes have been made to the regulation of complementary medicines and therapeutic goods more broadly, including the establishment of the Office of Complementary Medicines within the TGA and the development of the revised Advertising Code of Practice which was released in April 2000. Some of the legislative proposals contained within the Therapeutic Goods Amendment Bill (No 2) 2002 were also suggested as a result of the working parties findings.

Definition of 'therapeutic goods'

Currently under the TG Act, section 3 provides that a good is classified as a therapeutic good if it has the characteristics that are set out in that section or if the Secretary of the Department of Health and Ageing declares that it is a 'therapeutic good' under section 7 of the TG Act. Under this current definition, if a good falls within one of the Food Standards contained within the Food Standards Code, it cannot be classified as a therapeutic good nor can the Secretary to the Department declare it to be a 'therapeutic good'.

This current arrangement has the following consequences:

- where the good falls within one of the Standards in the Food Standards Code and hence cannot be declared a therapeutic good, the manufacturer will be prevented from claiming any therapeutic properties even where the product has such properties.[7]
  - this poses a problem for industry, particularly the complementary medicines industry. On occasions, a complementary medicine may fall within one of the food standards under the Food Standards Code such as the Formulated Supplementary Sports Foods Standard. These medicines will have therapeutic properties but the manufacturer will be unable to claim that the good has those properties. This creates a marketing disadvantage for the industry;
- Goods that fall within a Food Standard and are prevented from being regulated as therapeutic goods will not be subject to pre-market assessment and post market regulatory surveillance even though this level of regulatory intervention is needed in order to avoid a threat to public health and safety.[8]

Legislative amendments are needed to rectify this problem.

Pan Pharmaceuticals

Awareness of the regulatory issues regarding the complementary medicines industry have recently been heightened with the recall of products manufactured by Pan Pharmaceuticals Limited (Pan). Pan reportedly manufactures and supplies 70 per cent of complementary medicines in Australia.[9] Pan also manufactures some 'over the counter' medicines such as pain relievers and cold and flu preparations. On 28 April 2003, the TGA suspended Pan's manufacturing licence for six months due to serious quality and safety breaches in the manufacture of therapeutic goods. The TGA also ordered an urgent recall of 219 products

manufactured and supplied in Australia by Pan. By 6 May 2003, the number of products subject to the recall had increased to 1546, the vast majority of these product lines being complementary medicines.

The Parliamentary Secretary to the Minister for Health and Ageing, the Hon Trish Worth has announced that the *Therapeutic Goods Act 1989* will be amended to change some of the regulatory arrangements for therapeutic goods in Australia. In particular the following changes have been mooted in the media;

- owners and executives of pharmaceutical companies will be required to comply with fit and proper person laws before being eligible for a manufacturer's licence,[10]
- existing maximum penalties for breaches of the Act will be increased to $220,000,[11] and
- companies will be required to list on packets the name of the manufacturer and where the product ingredients have been sourced from.[12]

This **bill** was introduced into Parliament on 27 June 2002. At this stage it does not contain any of the amendments that have been subsequently flagged by the Parliamentary Secretary.

Advertising requirements for 'therapeutic goods'

Regulatory requirements

Advertisements to consumers[13] for therapeutic goods albeit medicines, complementary medicines or therapeutic devices are subject to a number of regulatory requirements including those contained within the TG Act, Therapeutic Goods Regulations (TG Regulations) and the *Broadcasting Services Act 1992.* In summary, the advertising requirements in these pieces of legislation state that:

- advertisements to consumers for therapeutic goods (other than devices and goods listed in Schedule 4 and 8 of the Poisons Schedule and most goods listed in Schedule 3 of the Poisons Schedule - that is, prescription medicines) that:
  - appear in newspapers and magazines, cinematographic films and displays such as billboards (otherwise known as 'specified media'), must be approved by the Secretary of the Department of Health and Ageing[14]
  - that are broadcast through the television or radio, must be approved by the Secretary of the Department of Health and Ageing under the arrangements in the *Broadcasting Services Act 1992,*[15] and

- appear in any other media, such as over the internet or in catalogues must comply with the general advertising provisions set out in the TG regulations but do not need the approval of the Secretary of the Department of Health and Ageing.[16]

- advertisements relating to Schedule 4 and 8 of the Poisons Schedule and most goods listed in Schedule 3 of the Poisons Schedule (ie prescription medicines) are prohibited[17], and

- advertisements for therapeutic devices must comply with the general advertising provision set out in the TG regulations.[18]

Arrangement of regulatory requirements

Where advertisements for therapeutic goods are permitted they fall into two categories, namely those requiring a formal approval and those that do not require and approval but which have to comply with the rules set out in the regulations. The abovementioned regulatory arrangements for approved and non-approved advertisements are divided in a somewhat ad hoc manner between the TG Act, the *Broadcasting Services Act 1992* and the TG Regulations. In particular:

- the offence provisions for advertisements that are published and which do require an approval are contained within the TG Act whereas relevant definitions, the approval process, revocation of approval and right of appeal provisions are contained within the TG Regulations

- requirements relating to advertisements that are broadcast through mediums such as commercial television, commercial radio or subscription television and hence which require approval are contained within the *Broadcasting Services Act 1992*, and

- the offence provisions and related provisions for advertisements that are published and which do not need to be approved are contained within the TG Regulations.

Therapeutic Goods Advertising Code

The regulatory arrangements for therapeutic goods includes compliance with the Therapeutic Goods Advertising Code (TGAC). TGAC is a set of principles and guidelines that ensures socially responsible marketing and advertising of therapeutic goods.[19] TGAC forms the basis for determining whether advertisements for therapeutic goods directed to consumers are acceptable.

All advertisements for therapeutic goods that are directed to consumers (other than those distributed through the broadcast media) must comply with the TGAC.

In relation to advertisements requiring approval, the TG Regulations specify a list of requirements that an advertisement must meet before it is approved by the Secretary. Included in this list is the requirement that the advertisement complies with the TGAC.

If the advertisement does not meet the requirements in the TGAC and is published, the person who publishes the advertisement commits an offence under section 42C of publishing an advertisement that is not an approved advertisement.

In relation to non-approved advertisements, the TG regulations contains a specific provision that requires that all 'non-approved' advertisement subject to Part 2 of the regulations be in compliance with the TG Advertising Code. Where an advertisement is published and it does not meet the requirements of the TG Advertising Code the maximum penalty currently imposed for a breach of the requirement is 10 penalty units.

Main Provisions

Summary of the changes in the Therapeutic Goods Amendment Bill (No. 2) 2002

The Bill amends the definition of 'therapeutic good' so that products that fall within a Food Standard under the Food Standards Code can be declared 'therapeutic goods'.

The Bill also contains significant amendments to the advertising provisions contained within the Act. The primary affect of the amendments are threefold;

- the definition of TGAC is moved from the TG regulations to the TG Act and provision is made so that changes to the advertising Code will be notified in the Gazette,
- regulation of advertisements for therapeutic goods in the broadcast media is moved from the *Broadcasting Services Act 1992* into the TG Act,
- the regulatory obligations for non-approved advertisements is transferred from the TG regulations across to the TG Act and the penalties imposed for breaches of the general advertising offences is increased.

Amendment to the definition of 'Therapeutic Good'

Item 1 of Schedule 1 amends paragraph 3(1)(e) of the definition of 'therapeutic good' in the TG Act. The Explanatory Memorandum to the Bill states that;

> 'once a good has been or is declared to be, a therapeutic good, no matter when this occurs, it will be regarded as a therapeutic good, despite the fact that it is a good for which there is also a prescribed food standard'.

Therefore, this amendment intends to amend the definition of therapeutic good so that the Secretary to the Department of Health and Ageing may declare the food to be a 'therapeutic good' under section 7 of the TG Act. Whilst it is likely that the proposed amendment will achieves this end, it would appear that the provision could have been

more clearly drafted to clearly state that the Secretary can declare foods under the Food Standards Code to be therapeutic goods.

Definition of Therapeutic Goods Advertising Code

As noted above, all advertisements for therapeutic goods that are directed to consumers, other than those distributed through the broadcast media, must comply with the TGAC. TGAC is currently defined in the TG Regulations. From time to time the TGAC is amended. **Item 2** inserts a definition for the TGAC into the TG Act making it clear that amendments to the Code will be notified in the Gazette.

Approved and non-approved advertisements

The regulatory arrangements for approved and non-approved advertisements are divided between the TG Act, the *Broadcasting Services Act 1992* and the TG regulations. The amendments contained within the Bill consolidate the current regulatory arrangements for therapeutic goods advertising.

Scope of the regulatory arrangements

Currently regulations 4, 5 and 5A state that the following advertisements are not captured by the regulations;

- Advertisements directed to health professionals such as medical practitioners, psychologists, dentists, pharmacists, homeopathic practitioners, nutritionists, and persons who engage in the wholesale selling of therapeutic goods
- Advertisements in respect of goods that are not for use in humans, and
- Advertisements for therapeutic goods that have been exported or are intended exclusively for export.

The effect of regulations 4, 5 and 5A is to provide that the advertising requirements within the regulations only apply to advertisements directed to consumers. Currently the TG Act refers to regulations 4, 5 and 5A to limit the scope of the advertising provisions in the Act to advertisements directed to consumers.

Proposed **item 4** of the bill replicates regulations 4, 5 and 5A in the TG Act therefore making it clear on the face of the TG Act that the advertising provisions in the Act apply to advertisements directed at consumers.

Offences for publishing and broadcasting approved advertisements

The Bill makes amendments to the requirements for approved advertisements.

Item 3 and 5 are consequential amendments that give effect to the changes to the advertising provisions listed below.

As discussed above, regulation of therapeutic goods advertisements in the broadcast media currently falls within the requirements in the *Broadcasting Services Act 1992*. The Bill, in proposed **item 17,** amends section 42C of the TG Act to expand its application to advertisements that are published or broadcast. **Item 17** therefore makes it an offence to publish or broadcast an advertisement if an approval is needed and has not been obtained. The maximum penalty is set at 60 penalty units (reduced from the current level of 100 penalty units). **Item 17** also lists other offences related to publishing or broadcasting advertisements that require approval.

Items 6, 7 and 15 are consequential to this amendment and define the terms 'broadcaster', 'broadcast media' and 'visual broadcast media'. The bill redefines 'publisher' and inserts a definition of 'publishing' into the Act in proposed **items 10 and 11.** The inclusion of a definition of 'publishing' makes it clear that the process of 'publishing' includes inserting material within the pages of an item of mainstream media. **Item 14** inserts a definition of 'specified media' into the TG Act. Specified media is currently defined in the TG Regulations. The definition is amended to include 'broadcast media'.

Item 16 creates a separate Division for that part of the Act dealing with approved advertisements. **Item 16** also inserts a new **section 42BA** into the Act which limits the application of the Division to advertisements to which Part 2 of the TG Regulations applies. It would seem that the inclusion of this proposed section in the Act is unnecessary. As discussed above, **item 4** of the Bill replicates the provisions in Part 2 of the TG Regulations that set out the types of advertisements that are captured by the regulatory arrangement. Referring to Part 2 of the TG Regulations **section 42BA** therefore only duplicates what is achieved by **item 4** of the Bill.

Schedule 2 of the Bill makes consequential amendments to the *Broadcasting Services Act 1992* to provide that approvals for therapeutic goods advertisements that are broadcast need to be approved in accordance with the provisions of the TG Act rather than under the *Broadcasting Services Act 1992.*

Non-approved advertisements

The offences for a breach of the therapeutic goods advertising requirements that apply to advertisements that do not require an approval are currently contained within the therapeutic goods regulations.

The Explanatory Memorandum to the Bill states that;

> Some of the offences relating to advertising [that is advertisements that do not require an approval] still remain in the Therapeutics Goods Regulations, where the penalty for breaches of the advertising requirements is set at 10 penalty units. Other comparable advertising offences have been included in the Act, where the penalty for breaches of advertising offences is 50-100 penalty points.

It has been suggested that the penalties imposed for a breach of the advertising provisions for non-approved advertisements (currently set at 10 penalty units) should be increased so that they are on a par with penalties for a breach of provisions that relate to advertisements that require an approval. To achieve this, the offence provisions must be transferred across to the TG Act due to the requirements which are set out in the Legislation Handbook.

The Legislation Handbook sets out the matters that should be included within legislation rather than regulations.

The Legislation Handbook states that

> Matters of the following kind should be implemented only through Acts of Parliament….
>
> (f) provisions creating offences which impose significant criminal penalties (imprisonment or fines equal to more than 10 penalty units for individuals or more than 50 penalty units for corporations).[20]

The Bill, in **item 18**, gives effect to the proposal to increase the penalties for a breach of the therapeutic goods advertising provisions by replicating all of the advertising requirements for non-approved advertisements that are currently contained within the TG Regulations in the TG Act. **Item 18** increases the maximum penalty for a contravention of the non-approved advertising provisions (as set out in **proposed section** 42DL) from 10 to 60 penalty units. To give effect to this change, **items 9, 12 and 13** make consequential amendments to the Act.

The Bill also contains a provision (**proposed section 42DM**) increasing the maximum penalty, where a non-approved advertisement breaches the TAGC, from 10 penalty units to 60 penalty units.

Generic information about ingredients or components of therapeutic goods

Materials used in the formulation or construction of therapeutic goods also need to comply with the requirements of the TG Code. Currently this requirement is contained within the regulations. It was also considered appropriate to increase the penalty levels for failure to comply with the TG Code in relation to generic information. Therefore this Bill through **item 8 and item 18 (proposed sections 42DN, DO and DP)** includes the generic information requirements as they relate to the TG Code in the TG Act and increases the penalties for contravening the sections to 60 penalty units.

Concluding Comments

This Bill contains a number of uncontroversial measures in regard to advertising requirements for therapeutic goods and regulation of products that fall at the food/drug interface. In particular the Bill;

- amends the definition of "therapeutic good" so that products that fall within a Food Standard under the Food Standards Code can be declared "therapeutic goods" by the Secretary to the Department for Health and Ageing,
- Moves the definition of TGAC from the TG regulations to the TG Act so that changes to the TGAC will be notified in the Gazette,
- Includes regulation of therapeutic goods advertising in the broadcast media in the TG Act, and
- Transfers the regulatory obligations for non-approved advertisements from the TG regulations across to the TG Act and increases the penalties that may be imposed for breaches of the general advertising offences.

Many of the amendments simply replicate provisions that are currently contained within the TG Regulations. As a result, the TG Act as amended will contain provisions that are drafted in 'regulation' language rather than language that is entirely consistent with other provisions in the TG Act. It is hoped that this drafting style will not create interpretational difficulties.

Endnotes

1 *Therapeutic Goods Act 1989*, section 4.

2 Complementary medicine is defined in section 52F *Therapeutic Goods Act 1989.*

3 *AMA Position Paper: Complementary Medicine*, 2002, p. 1.

4 Alastair H MacLennan MD et al, 'The Escalating Cost and Prevalence of Alternative Medicine', *Preventive Medicine*, No 35, 2002, p. 166–173.

5 'Senator Tambling Foreshadows Revised Approach to Complementary Medicines Regulation', *Media Release*, Senator Grant Tambling, Parliamentary Secretary to the Minister for Health and Aged Care, 2 December 1998, [http://www.health.gov.au/archive/mediarel/1998/gt198.htm], (12 May 2003).

6 Review of the Advertising of Therapeutic Goods: Report of the Therapeutic Goods Advertising Code Council, 4 November 1999, p. 2.

7 *Australia New Zealand Food Standards Code* (the Code) Standard 1.1A.2, paragraph 3(a).

8 *Explanatory Memorandum, Therapeutic Goods Amendment Bill* (No.2) 2002, p. 1.

9 'Largest Ever Drug Recall', Daily Telegraph, 29 April 2003.

10 'Promise Of Tough New Laws On Labels', Australian, 30 April 2003.

11 ibid

12 'Promise Of Tough New Laws On Labels', Australian, 30 April 2003; List Debacle Prompts A Change To Medicine Labelling Laws', The Age, 1 May 2003.

13 Advertisements may also be directed to health care professions. These advertisements are subject to different regulatory requirements.

14 *Therapeutic Goods Act 1989,* section 42C and 42D, Therapeutic Goods Regulations Part 2 Division 2.

15 *Broadcasting Services Act 1992*, Schedule 2, section 6.

16 Therapeutic Goods Regulations 1990, Part 2 Division 3 and Division 4.

17 Therapeutic Goods Regulations 1990, Part 2 Division 3 and Division 4. Advertisements for Schedule 3 products that are listed in Appendix H of the Poisons Standard are not prohibited. They must however comply with the general requirements set out in the TG Act, TG Regulations and the *Broadcasting Services Act 1992.*

18 Therapeutic Goods Regulations 1990, Part 2 Division 3 and Division 4.

19 A copy of the *Therapeutic Goods Advertising Code* may be obtained at: [http://www.tgacc.com.au/code_gloss_files/ACF897F.pdf], (12 May 2003).

20 Department of the Prime Minister and Cabinet, *Legislation Handbook*, 1999, Canberra, 1999, p. 3, at: [http://www.pmc.gov.au/pdfs/LegislationHandbookMay00.pdf], 12 May 2003.