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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

THE SENATE

THERAPEUTIC GOODS LEGISLATION AMENDMENT BILL 1999

EXPLANATORY MEMORANDUM

(Circulated by authority of the Parliamentary Secretary to the Minister for Health and Aged Care, Senator the Hon Grant Tambling, MP)

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THERAPEUTIC GOODS LEGISLATION AMENDMENT BILL 1999

OUTLINE

This Bill amends the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Amendment Act 1997*.

The Bill encompasses the first component of a package of reforms designed to provide a new and appropriate framework for the regulation and management of complementary medicines. The new framework for complementary medicines addresses key issues related to market access, the regulatory environment as well as allowing for greater expert and industry participation in the regulation of complementary healthcare products.

This Bill also makes a number of more general amendments to improve the overall efficiency and effectiveness of the *Therapeutic Goods Act 1989*.

In summary, the Bill:

- amends key definitions in the *Therapeutic Goods Act 1989* (the Act) to provide a better delineation between foods, complementary medicines and other medicines such as over the counter and prescription medicines;
- includes a new part in the Act which establishes the existing Complementary Medicines Evaluation Committee as a statutory committee;
- includes amendments to the Act which shift the focus from premarket clearance to post market vigilance for listable goods by:
 - providing a more streamlined and efficient process for the listing of goods on the Register, enabling sponsors of relatively low-risk products to market such products without undue delay; and
 - reinforcing the existing requirement that all sponsors of listable goods must hold evidence to substantiate therapeutic claims made in the market place.
- describes offences and penalties in relation to the publication of certain advertisements in mainstream print media; and
- establishes a statutory body, the National Drugs and Poisons Schedule Committee and describes the functions and powers of the Committee.

FINANCIAL IMPACT STATEMENT

The Therapeutic Goods Legislation Amendment Bill 1999 will not have any significant financial impact for the Commonwealth.

THERAPEUTIC GOODS LEGISLATION AMENDMENT BILL 1999

REGULATION IMPACT STATEMENT

The Therapeutic Goods Legislation Amendment Bill 1999 (the Bill) amends the *Therapeutic Goods Act 1989* (the Act) and the *Therapeutic Goods Amendment Act*. The Bill encompasses the first component of a package of reforms designed to provide a new and appropriate framework for the regulation and management of complementary medicines. This Bill also makes a number of more general amendments to improve the overall efficiency and effectiveness of the Act.

Key stakeholders/Consultation

On 2 December 1998, the Parliamentary Secretary to the Minister for Health and Aged Care, the Hon Grant Tambling, announced the formation of a Working Party to develop reforms in the regulation of the complementary medicines.

Both the Working Party and the Therapeutic Goods Administration consulted widely regarding problems with the current regulation of complementary medicines and areas for reform. Over 30 peak organisations were consulted including the Proprietary Medicines Association of Australia, the Complementary Health Care Council of Australia, the Consumers Health Forum of Australia, the National Herbalists Association, the Australian Medical Association and the Royal College of General Practitioners. All of the amendments to the legislation, described below have been endorsed by key stakeholders.

The Changes and Their Impact

1. AMENDMENTS TO KEY DEFINITIONS

Background

- a) **The Food-Therapeutic Good Interface** - The definition of 'foods' in the Act has created some confusion particularly with respect to when the Therapeutic Goods Act has application and when the Australia New Zealand Food Act applies.
- b) **Use of the word "drug"** - The word 'drug' has sometimes been associated with particular classes of therapeutic goods, such as prescription drugs or drugs of dependence and is considered by many to be an inappropriate term for use in association with complementary medicines

Objective of reform

To clarify terminology used in the regulatory environment so those therapeutic goods can be recognised, evaluated and regulated appropriately.

Regulatory approach

- a) Remove the definition of 'foods' from the Act and amend the definition of 'therapeutic goods'.

- b) Replace the reference to ‘drugs’ in the interpretation section of Part 1 of the Regulations with the term ‘medicines’. Other references to ‘drugs’ in both the Act and the Regulations would be removed and replaced with the term ‘medicines’ to provide a more inclusive, positive and publicly acceptable term.

Impact analysis-statement of costs/disadvantages and benefits/advantages

For Government - Greater clarity in administration of legislation; ensuring public health and safety through correct identification, evaluation, labelling and regulation of approved products. No disadvantages identified at this stage.

For Industry - Greater certainty; fewer resources expended sorting out definitional problems; prompt marketing of products. No disadvantages identified at this stage

For Consumers - No disadvantages identified at this stage.

2. SHIFTING THE FOCUS FROM PRE-MARKET CLEARANCE TO POST MARKET VIGILANCE FOR LISTABLE GOODS

Background/Objective of reform

Once the TGA is satisfied that a substance is sufficiently low risk for its intended purpose, goods that incorporate the substance may be eligible for ‘listing’ in the Australian Register of Therapeutic Goods (ARTG). At present, changes to the list of goods that qualify as ‘listable’ goods require an amendment to the Regulations. This is a cumbersome process that often fails to accommodate the commercial realities involved in enabling low-risk products to become publicly available. It is also important that quicker market access does not mean marketing of less safe products or misleading marketing claims. The Bill confirms the existing condition that requires the sponsor to hold evidence supporting any claims.

Regulatory change

- a. Amendment to section 17 of the Act to allow the Minister to gazette new substances that may be included in ‘listable’ therapeutic goods. This is in lieu of an amendment to regulations and provides for a quicker, more responsive process.
- b. Reinforcing through legislative change, the existing requirement that all sponsors of listable goods must hold evidence to substantiate therapeutic claims made in the market place. This supporting evidence will not be required as a matter of routine but will be called upon in cases where there is a clear public health or safety matter at issue or where there has been deliberately or recklessly misleading information provided to the public about a product.

Impact analysis-statement of costs/disadvantages and benefits/advantages

For Government – Can approve low risk products in a less resource intensive manner without compromising parliamentary processes, Ministerial accountability or public health and safety.

For Industry - Low risk products are granted swifter market access. No disadvantages

identified at this stage.

For Consumers- Quicker access to new products. No disadvantages identified.

3. ESTABLISHMENT OF THE COMPLEMENTARY MEDICINES EVALUATION COMMITTEE (CMEC) AS A STATUTORY COMMITTEE.

Background

In order to reflect the increasing role of complementary medicines within the TGA, it has been proposed that the role of the CMEC be enhanced by establishing it as a statutory committee. This is an acknowledgment of the growing significance of this industry and the need to improve the government's access to expertise in this area. This will provide an opportunity for expert, experienced and appropriate input into the evaluation of medicines.

Objective of reform

To improve administration and management of issues pertaining to complementary medicine and to increase the expert participation of industry.

Regulatory approach

The measures require a change to the legislation to include a new Part which establishes the CMEC as a statutory committee. Detailed information about the functions and constitution of the Committee will be included in the Regulations

Impact analysis-statement of costs/disadvantages and benefits/advantages

For Government - By improving the advice the TGA receive regarding the evaluation of complementary medicines, public health and safety is optimised. No disadvantages identified at this stage.

For Industry- Increased industry input into policy decisions regarding its products and a greater opportunity to discuss issues with professional peers within the public sector. No disadvantages identified at this stage

For Consumers - Clearer information that might result from enhancements to CMEC. No disadvantages identified at this stage

4. OFFENCES AND PENALTIES IN RELATION TO THE PUBLICATION OF CERTAIN ADVERTISEMENTS IN MAINSTREAM MEDIA

Background

Under the Regulations, advertisements for medicines placed in mainstream print media are required to be cleared by the Secretary before they may be published. The Secretary has delegated this function to the PMAA and the CHC. It is proposed that a new Part be included in Act which describes the offences and accompanying penalties where an advertisement in mainstream media without pre-clearance. The offence provisions are identical to those that are currently in the Regulations. The move of the provisions and the increase in penalties is important because it: lends greater support to industry decisions and consumer confidence, through the CHC and PMAA clearance; reflects the importance of preclearance of

advertisements for publication in mainstream media; and ensures consistency with similar provisions in the *Broadcasting Services Act 1996*.

Regulatory approach

The inclusion of a new Part in the Act which sets out the offences and penalties for advertising in the mainstream media without prior approval or in breach of the conditions of approval.

Impact analysis-statement of costs/disadvantages and benefits/advantages

For Government - Ensures that advertisements which have a wide audience have been appropriately cleared. No disadvantages identified at this stage.

For industry- No disadvantages identified at this stage.

For consumers- Greater assurances that the material that is placed in mainstream media has been appropriately cleared and is not misleading to the consumer.

5. ESTABLISHMENT OF THE NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE (NDPSC) AS A STATUTORY COMMITTEE

Background/Object of reform

It is proposed that a new Part be added to the Act to establish the existing NDPSC as a statutory committee. Decisions of the Committee relate to the publication of successive editions of the Poisons Standard. This Part of the Bill does not relate to the reforms in respect of complementary medicines.

Regulatory approach

The inclusion of a new Part in the Act which establishes the NDPSC and describes its functions and role in relation to the Poisons Standard.

Impact analysis-statement of costs/disadvantages and benefits/advantages

For C'w Government - Encourages uniform approach to the classification of substances throughout Australia for regulatory purposes. No disadvantages identified at this stage.

For State/Territory Governments - Assured representation on the Committee that makes decisions re the classification of substances; increased impetus for a more uniform approach throughout Australia. No disadvantages identified at this stage.

For industry - Potentially less confusion and discrepancy in the way substances are dealt with throughout Australia. No disadvantages identified at this stage.

For consumers- No disadvantages identified at this stage.

THERAPEUTIC GOODS LEGISLATION AMENDMENT BILL 1999

NOTES ON CLAUSES

CLAUSE 1 - SHORT TITLE

This is a formal provision that specifies the short title of the Act as the *Therapeutic Goods Legislation Amendment Act 1999*.

CLAUSE 2 - COMMENCEMENT

This clause provides that the Act will commence on the day on which it is Proclaimed or, if the Act (other than Schedule 2) is not Proclaimed within 6 months from the day it receives Royal Assent, it will commence on the day following the end of that period.

Subclause 2(3) provides that Schedule 2 is taken to have commenced immediately after the commencement of Part 2 of Schedule 1 to the *Therapeutic Goods Amendment Act 1997*.

CLAUSE 3 – SCHEDULE(S)

This clause provides that every Act specified in the Schedule to this Act is either amended or repealed as set out in that Schedule, and any other item included in the Schedule is to have effect according to its terms.

SCHEDULE 1 – AMENDMENT OF THE THERAPEUTIC GOODS ACT 1989

SUMMARY

ITEMS 1, 2, 4, 5, 7

These items include in subsection 3(1) of the *Therapeutic Goods Act 1989* (“the Act”), definitions of the following words:

current Poisons Standard This expression has the meaning given by section 52A. Section 52A is a new definitions section included in this Bill which accompanies a new Part relating to the National Drugs and Poisons Schedule Committee.

first Poisons Standard This expression has the meaning given by section 52A

medicine ‘Medicine’ is defined as:

- (a) therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of an human or an animal; and
- (b) any other therapeutic goods declared by the Secretary, for the purpose of the definition of therapeutic device, not to be therapeutic devices.

poison ‘Poison’ means a substance or preparation which, or the use of which, may cause death, illness or injury and includes any substance or preparation referred to in a schedule to the current Poisons Standard

Scheduling ***Scheduling*** has the meaning given by section 52A (a new provision inserted as part of these amendments). Section 52A defines scheduling for the purposes of the new Part 5B. Scheduling, in relation to a drug or poison, means determining the schedule or schedules to the Poisons Standard in which the name or a description of the medicine or poison is to be included.

ITEM 3

This Item repeals the definition of ***foods*** in subsection 3(1) of the Act.

ITEM 6

This Item omits from the definition of ‘restricted goods’ (contained in subsection 3(1)), the words “drugs within regulation 2 of the Therapeutic Goods Regulations” and replaces that terms with the word “medicines”. This reflects the addition of “medicines” in the interpretation section of the Act as a replacement for the word “drugs”, defined in the

Regulations. The definition of “drugs” in the Regulations will be repealed before this Bill is proclaimed.

ITEM 8

This Item repeals paragraph (e) of the definition of therapeutic goods (contained in section 3(1) of the Act) and replaces it with:

- (e) either
 - (i) goods for which a standard is prescribed in the Australian and New Zealand Food Standards Code as defined in subsection 3(1) of the *Australia New Zealand Food Authority Act 1991*; or
 - (ii) goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

A good which has a tradition of use in Australia or New Zealand is one which has a history of significant human consumption in the broad community in Australia or New Zealand, and for which there exists adequate knowledge in the broad community such that there is a reasonable certainty that no harm will result from the intended use of the food.

ITEM 9

This Item repeals section 4 of the Act and replaces it with a new clause which describes the object of the Act. The change extends the object to include providing a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling, of poisons in Australia. All States and Territories have agreed to the extension of the objects section of the Act.

ITEM 10

This Item adds to section 17 of the Act a provision which enables the Minister to declare by notice published in the Gazette any therapeutic goods that must be included in the part of the Register for listed goods. If regulations are subsequently made, with the effect of requiring the same goods to be included in the part of the Register for either listed goods or registered goods, then the Gazette notice ceases to have effect as it will become obsolete. The amendment has been necessary to reduce delays in the marketing of low-risk products by allowing these to be included in the Register as listed goods, rather than registered goods.

ITEM 11

This Item adds a subsection to section 28 to require an applicant making a claim in relation to an application for the listing of therapeutic goods, to comply with certain conditions where the claim is included in the Register. The conditions, which have been applied to sponsors seeking to list goods, require the sponsor to hold information or evidence to support the claim and, if requested, provide such information or evidence to the Secretary. Any information or evidence must also comply with the regulations where the regulations prescribe the amount, standards or type of information required. The addition of this provision safeguards

consumers by ensuring that therapeutic claims made in the marketplace can be substantiated by evidence.

This supporting evidence will not be required as a matter of routine but will be called upon in cases where there is a clear public health or safety matter at issue or where there has been deliberately misleading information provided to the public about a product. The level of evidence that will be required will be directly related to the risk associated with the product and the nature of the claim made about the product. However, testimonials, 'advertorials' or 'infomercials' will not be acceptable as proof of efficacy.

ITEM 12

This Item inserts a new part in the Act relating to advertising.

Part 4A - Advertising

Clause 42A – Application

This clause explains that this new Part only applies to advertisements to which Division 2 of Part 2 of the Therapeutic Goods Regulations applies. Division 2 of Part 2 only applies to advertisements for designated therapeutic goods published or inserted, or intended to be published or inserted, for valuable consideration, in mainstream media. The Division does not, however, apply to certain types of advertisements such as advertisements for goods not for human use, nor does it apply to advertisements for therapeutic goods that have been exported or are intended solely for export.

Clause 42B - Definitions

This clause defines terms used throughout the new Part 4A such as *approved advertisements*, *approval number*, *mainstream media* and *publisher*.

Clause 42C – Offences relating to publication of advertisements

This clause describes the offences, and accompanying penalties, relating to publishing or inserting in mainstream media an advertisement that:

- is not an approved advertisement (100 penalty units);
- differs from an advertisement that was approved (except to the extent that the differences only relate to the price of the goods, a photographic or other reproduction of the goods, the locations or times at which the goods are offered for sale or information reasonably necessary to identify the person offering the goods for sale) (100 penalty units);
- is an approved advertisement but is not accompanied by its approval number or has a number purporting to be its approval number but which is not its approval number or with an expired approval number (50 penalty units);
- is an approved advertisement in contravention of a condition of its approval (100 penalty

units).

The offences described in the clause are offences of strict liability. They do not, however, apply to publishers in respect of an advertisement received by the publisher for publication or insertion in the ordinary course of business (section 42D deals specifically with publishers).

Clause 42D – Offences relating to publishers

This clause provides that a publisher must not knowingly or recklessly, publish or insert in mainstream media an advertisement that is not an approved advertisement. To do so attracts a penalty of 100 penalty units.

ITEM 13

This Item inserts two new parts in the Act: Part 5B, relating to the National Drugs and Poisons Schedule Committee; and Part 5C which establishes the Complementary Medicines Evaluation Committee.

Part 5B – National Drugs and Poisons Schedule Committee

Clause 52A – Definitions

This Clause defines a number of additional words and phrases, for the purposes of this part. The words and phrases defined are: *Committee*; *current Poisons Standard*; *substances*; *poisons*; *first Poisons Standard*; and *scheduling*.

Clause 52B – Establishment and constitution of Committee

This Clause establishes the National Drugs and Poisons Schedule Committee and provides that the Committee is to be constituted and to hold meetings and take decisions in accordance with the regulations.

The clause also provides that the Commonwealth, each State, the Northern Territory and the Australian Capital Territory are each entitled to nominate a representative on the Committee.

Clause 52C – Functions of Committee

This Clause describes the functions of the National Drugs and Poisons Schedule Committee. The Committee will be one which makes decisions in relation to the classification and scheduling of substances, maintains the Poisons Standard and facilitates harmonization between Australian and New Zealand in relation to the classification and scheduling of substances. The Committee may consider matters referred to it by the Minister, the Secretary or the National Co-ordinating Committee of Therapeutic Goods (NCCTG). Consistent with this, the Committee must report to the Minister, the Secretary or the NCCTG.

The Committee may also undertake other functions prescribed by the regulations.

Clause 52D – Poisons Standard

This Clause describes the powers of the Committee in relation to the *Standard for the Uniform Scheduling of Drugs and Poisons*, published by the Australian Health Ministers Advisory Council (the current Poisons Standard). The Committee may amend the existing Poisons Standard, prepare a new Poisons Standard and amend any new Poisons Standard.

The Clause also provides that any new Poisons Standard, or any amendments to either the current Poisons Standard or any new Poisons Standard, must be published in the Gazette as soon as possible after the Standard or amendment has been prepared.

Clause 52E – Matters to be taken into account in exercising powers

This clause describes the matters the Committee is to take into account when considering the classification or scheduling of a drug or poison as follows;

- (a) its toxicity and safety;
- (b) the risks and benefits associated with its use;
- (c) the potential hazards associated with its use;
- (d) the extent and patterns of its use;
- (e) its dosage and formulation;
- (f) the need for access to the drug or poison taking into account its toxicity compared with other substance available for a similar purpose;
- (g) the potential for its abuse;
- (h) the purposes for which it is to be used; and
- (i) any other matters the committee considers necessary to protect public health, including the risks of death, illness or injury resulting from its use.

The Committee may also take into account the labeling and presentation of the substance.

The clause also provides that in taking into account the matters described in the clause, the Committee must comply with any guidelines of the Australia Health Ministers Advisory Council or the NCCTG.

Part 5C – Complementary Medicines

Clause 52F – Definitions

This clause provides definitions for words and phrases used in this Part. Definitions are provided for the following words/phrases: active ingredient; complementary medicines; designated active ingredient; and traditional use.

Clause 52G - Establishment and constitution of Committee

This Clause establishes the Complementary Medicines Evaluation Committee. Regulations will prescribe the functions of the Committee in relation to complementary medicines and how the Committee is to be constituted, hold meetings and take decisions.

ITEM 14

In April 1998 amendments were made to the *Therapeutic Goods Act 1989* to transfer, from the *Customs (Prohibited Imports) Regulations* and the *Customs (Prohibited Exports) Regulations* into the *Therapeutic Goods Regulations*, administrative powers relating to the issue of permits and licences for the import of prohibited imports and prohibited exports for which the TGA has responsibility. The accompanying offences and penalties in the Customs Act were not transferred across to the *Therapeutic Goods Act 1989* at the same time because Attorney-General's Department sought changes to the level of penalties. This issue has since been resolved and this item inserts a new clause, 54AA, into the Act which describes the offences relating to breaches of conditions imposed in association with the issue of licences and permits for the importation and exportation of prohibited imports and export.

If the holder of a licence (or permission to import or export) in relation to therapeutic goods contravenes a condition or requirement of the licence (or permission) under the regulations, he/she will be guilty of an offence punishable, on conviction, by a fine. The clause describes the different circumstances under which different penalties will be imposed in relation to contravention of conditions imposed under the regulations.

SCHEDULE 2 – AMENDMENT OF THE THERAPEUTIC GOODS AMENDMENT ACT 1997

Item 1

The effect of this Item is to renumber section 25A (Registration of therapeutic device to which conformity assessment certificate applies) as section 25B.