



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

The Secretariat
Product Safety Review
Competition and Consumer Policy Division
Department of the Treasury
Langton Crescent
CANBERRA ACT 2600

Dear Sir/Madam

I refer to the review of Australian consumer product safety currently being undertaken by the Ministerial Council on Consumer Affairs (MCCA).

I am pleased to provide a submission on behalf of the Therapeutic Goods Administration (TGA) that sets out the details of the existing arrangement under which the safety of therapeutic products manufactured in, supplied in, imported into or exported from Australia is assured. It is important the outcomes of the MCCA review take account of and do not duplicate these arrangements.

Thank you for the opportunity to make this submission.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Terry Slater', written in a cursive style.

Terry Slater
National Manager

10 November 2004

**Response to the
Discussion Paper on the Review of the
Australian Consumer Product Safety
System, August 2004**

Therapeutic Goods Administration

NOVEMBER 2004

1. INTRODUCTION

This paper provides an outline of the product safety system that applies to therapeutic products in Australia.

The Australian community expects that medicines and medical devices available in the marketplace are safe and of high quality, to a standard at least equal to that of comparable countries. The objective of the *Therapeutic Goods Act 1989* (the Act), which came into effect on 15 February 1991, is to provide a national framework for the regulation of therapeutic products in Australia and ensure their quality, safety and efficacy.

The regulatory framework is based on a risk management approach designed to ensure public health and safety, while at the same time freeing industry from any unnecessary regulatory burden. Essentially, any product for which therapeutic claims are made must be entered in the Australian Register of Therapeutic Goods (ARTG) before the product can be supplied in Australia. The ARTG is a computer database of information about therapeutic products for human use approved for supply in, or exported from, Australia.

The Act, Regulations and Orders set out the requirements for inclusion of therapeutic products in the ARTG, including advertising, labelling, product appearance and appeal guidelines. Some provisions such as the scheduling of substances and the safe storage of therapeutic products are covered by the relevant State/Territory legislation.

The Therapeutic Goods Administration (TGA), a business unit of the Australian Department of Health and Ageing, is responsible for administering the Act.

2. DEFINITION OF THERAPEUTIC PRODUCT

A therapeutic product is broadly defined as a product that is represented in any way to be, or is likely to be taken to be, for therapeutic use, unless specifically excluded or included under Section 7 of the Act. It includes prescription, non-prescription, and complementary medicines (vitamins, minerals, herbal and some homoeopathic preparations) and medical devices.

For the purposes of evaluation and assessment, a therapeutic good is a product for use in humans that is used in, or in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury;
- influencing inhibiting or modifying a physiological process;
- testing the susceptibility of persons to a disease or ailment;
- influencing, controlling or preventing conception;
- testing for pregnancy; or
- replacement or modification of parts of the anatomy.

3. WHY A SPECIFIC REGULATORY ARRANGEMENT FOR THERAPEUTIC PRODUCTS

All therapeutic products carry some intrinsic level of risk depending on the nature of the product and the seriousness of the condition for which it is intended to be used. For example, the product itself may pose risks – ingredients in the product, the product dosage form, strength of the product, side effects, toxicity, potential harm through prolonged use etc. The way a product is manufactured may also pose risks – poor manufacturing processes can mean the product does not contain the ingredients it should, contains contaminants etc.

The national regulatory framework is therefore designed to enable the risks to be identified, analysed and evaluated based on all the available scientific and other relevant data – a task generally beyond the knowledge and skills of the consumer. The Therapeutic Goods Administration (TGA) has developed a nationally agreed approach with the States and Territories to ensure an efficient and effective expedition of recall action for Australia.

4. AN OVERVIEW OF THE REGULATORY FRAMEWORK

Overall control of the supply of therapeutic products is exercised through four main processes:

- pre-market assessment
- licencing of manufacturers
- post-market monitoring and enforcement of compliance
- the maintenance of a register of all products approved for supply in Australia

• Pre-market assessment and registration of approved products

Products assessed as having a higher level of risk (prescription medicines, some non-prescription medicines and medical devices) are evaluated for quality, safety and efficacy. Once approved for marketing in Australia these products are included in the Australian Register of Therapeutic Goods (ARTG) as 'registered' products and are identified by an AUST R number.

Products assessed as being lower risk (many non-prescription medicines including most complementary medicines and low risk medical devices) are assessed for quality and safety. Once approved for marketing in Australia, these products are included in the ARTG as 'listed' products and are identified by an AUST L number.

In assessing the level of risk, factors such as the strength of a product, side effects, potential harm through prolonged use, toxicity and the seriousness of the medical condition for which the product is intended to be used, are all taken into account.

• Licensing of manufacturers

Australian manufacturers of therapeutic products must be licensed. Their manufacturing processes must comply with principles of good manufacturing practice (GMP). The aim of licensing and standards is to protect public health by ensuring that medicines and medical devices meet definable standards of quality assurance and are manufactured in conditions that are clean and free of contaminants.

- **Post marketing vigilance**

Post marketing activities include investigating reports of problems, laboratory testing of products on the market and monitoring to ensure compliance with the legislation.

TGA has recently issued comprehensive document outlining the risk management approach that is used in conducting its activities. A copy of the Risk Management Approach document is attached¹. It provides a detailed outline of the pre- and post-market assessment of all therapeutic products.

5. Recall procedures for therapeutic products

The national Uniform Recall Procedure for Therapeutic Goods (URPTG), agreed with the States and Territories, defines the action to be taken by health authorities and sponsors when therapeutic products for use in humans, for reasons relating to their quality, safety or efficacy, are to be removed from supply or use, or subject to corrective action.

Recall action is underpinned by the Act and, in accordance with the provisions of the Act, the TGA, where necessary in conjunction with State and Territory authorities, may require the recovery of therapeutic products.

A copy of the current edition of the URPTG is attached².

6. Future arrangements under the trans-Tasman Regulatory Agency

The Australian and New Zealand Governments have signed a Treaty to establish a single, bi-national agency to regulate therapeutic products, including medical devices and prescription, over-the-counter and complementary medicines.

The single agency, which will replace the Australian Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe), will be accountable to both the Australian and New Zealand Governments. The agency is expected to commence operation in 2005.

The Treaty under which the Agency is established will bring into force the foreign affairs powers of the Australian Constitution and the new legislation will thus include to natural persons as well as incorporated bodies throughout Australia. The extension of the TGA's existing recall powers will thus establish a nationally uniform approach.

7. Issues to consider

The Discussion paper sets out a series of issues to consider. In terms of TGA's interaction with the Consumer Safety Unit and the operation of the *Trade Practices*

¹ A electronic copy of the Risk Management Approach can also be downloaded from <http://www.tga.gov.au/about/tgariskmnt.htm#pdf>

² An electronic copy of the URPTG can also be downloaded from http://www.tga.gov.au/recalls/urptg_rev.htm

Act, there are issues that could be streamlined or improved, only some of which are reflected in the list of issues provided.

- **Double regulation – the need for clarity in responsibility for the recall of therapeutic products**

Representations have been made to the TGA about the double regulation of recalls, with requirements under the *Trade Practices Act* as well as the *Therapeutic Goods Act 1989 (the Act)*. Product sponsors point out that the *Trade Practices Act's* recall powers appear to add nothing to the recall process except additional paperwork. For organisations that undertake numerous recalls, such as those relating to cellular blood products, it generates a substantial amount of additional work.

In New Zealand, recalls undertaken under the supervision of Medsafe do not have to be notified to the Commerce Commission as well. It is desirable that a recall executed pursuant to the Act or the URPTG does not have to be notified again to the Competition and Consumer Policy Division of Treasury. Unless there are sound reasons to do otherwise, it would be relatively simple for the TGA (and its successor, in due course) to provide the necessary statistical information on all therapeutic product recalls.

Although the TGA has a database of all approved products, it does not support the development and maintenance of a centralised database covering every type of consumer product as any benefits would likely be outweighed by the costs involved.

- **Timeliness – the need for the power to act while risk assessment is undertaken**

In a review of the TGA recall procedures, the need to quarantine goods while the risk assessment is undertaken was identified as providing an intermediate power between doing nothing and implementing a full recall.

Creating a power of quarantine for other goods may be worthwhile.

- **Audit**

TGA supports the need for a power to audit the effectiveness of product recalls. There should be a power to audit any recall, whether mandatory or undertaken voluntarily, if necessary. In the case of voluntary recalls the power could be linked to any recall notified to the relevant authority, or any situation that was a recall whether notified or not.

- **Recall of goods when the manufacturer or supplier (sponsor) is insolvent**

One difficulty that can occur is the recall of goods where the Australian supplier or manufacturer is insolvent. Powers might be considered that allowed the regulator to order a previous sponsor, or a current sponsor if the previous sponsor cannot be identified or is insolvent, to undertake a recall of therapeutic products if the previous sponsor was the sponsor at the time of the distribution of the product.

The regulator could also have, as a last resort, a specific power to undertake a recall and recover costs from any party that was involved in the sale or supply of the goods, as appropriate.

8. Summary

The TGA has an efficient and effective risk management system for therapeutic goods, including a recall system that works well and is strongly supported by the States, Territories and the industry. TGA is concerned that any proposed changes to the *Trade Practices Act* as a result of this review do not duplicate or impose additional, unnecessary requirements to the existing arrangements for therapeutic products.