# Medicines Australia

# Submission to the Regulation Taskforce:

# Reducing the Regulatory Burden on Business

## Summary

Medicines Australia appreciates the opportunity to make a submission to the Regulation Taskforce *Reducing the Regulatory Burden on Business*. We are conscious of the fact that there are currently two major developments underway with respect to the regulation of pharmaceuticals; the so-called *Galbally Review* has reduced much of the overlap and duplication between the legislation of the Commonwealth and States & Territories, and the introduction of a new joint Trans Tasman regulatory scheme will see the introduction of new pharmaceutical legislation. Nevertheless, there are some areas that we believe impose an unnecessary compliance burden on business. Our concerns relate chiefly to:

- The overlap and duplication of regulation between different levels of Government.
- The imposition of regulatory requirements (or regulatory barriers) that are not consistent with the objects of quality, safety, efficacy and timely availablility.
- Some Australian-specific requirements that are not required by other comparable major overseas agencies.

## Introduction

The pharmaceutical industry is subject to a high level of regulation in Australia, as it is in most developed countries. In Australia, there is a large body of legislation controlling prescription medicines (Appendix A). The broad framework of the current drugs, poisons and controlled substances legislation covers two levels of government – Commonwealth and State and Territory. Local government is involved in areas such as storage, handling and disposal but, in practice, there is very little relevant regulation at this level.

The primary legislation, the *Therapeutic Goods Act 1989* and *Therapeutic Goods Regulations 1990*, is supported by a number of Orders, Codes, Standards and Determinations, which are either referenced in the Commonwealth legislation or adopted into State and Territory legislation, as relevant.

In 2000, the Council of Australian Governments (COAG) undertook a review of the existing drugs and poisons legislation (the *Galbally Review*).[1] The Review was concerned with the Commonwealth controls in so far as they relate to, or overlap with, the State and Territory legislation, and made 27 recommendations aimed at: reducing the level of regulation in some areas; introducing a co-regulatory approach where appropriate; improving the efficiency of the regulatory system; developing a uniform approach across jurisdictions, and ensuring that the interface between various pieces of legislation is rational and avoids overlap and duplication.

The Galbally Review has the potential to eliminate many of the problems resulting from differences between legislation of the Australian States and Territories. Whilst the recommendations of the Galbally Report are currently being implemented, this is not completed and most of the States and Territories have yet to amend their legislation.

In December 2003, the Governments of Australia and New Zealand signed a Treaty to establish a joint scheme for the regulation of therapeutic products. The new Trans Tasman Agency is due to start on 1 July 2006 and will be governed by a Ministerial Council drawn from both countries. The development of the final details of the regulatory framework and the legislation underpinning the joint agency have not yet been completed. Aspects of Therapeutic Goods regulation that will be harmonized relate to the manufacture, evaluation, registration, labeling, standards, scheduling and access to unapproved therapeutic goods. Identical legislation will be adopted by both the Australian and New Zealand governments. Other legislation, such as import/export, intellectual property and trade practices legislation will remain, as currently, under the separate jurisdictions.

The draft legislation for the new Trans Tasman regulatory scheme has not yet been completed. It is hoped that the opportunity will been taken to streamline the legislation and to ensure that the new Trans Tasman legislation will not overlap or conflict with State and Territory or other related Australian legislation. It is important that the new legislation is developed in accordance with the principles of good regulatory practice, and that Industry is fully consulted and involved in developing the legislation.

## Anomalies in the implementation of the Therapeutic Goods Act

The Therapeutic Goods Act and Regulations are designed to control the quality, safety, efficacy and timely availability of therapeutic goods in Australia. The legislation covers the manufacture, assessment, registration and supply of therapeutic goods in Australia. The TGA, through its expert advisory committees, makes recommendations to the Minister for Health and Ageing on applications for registration (marketing approval).

[1] *National Competition Review of Drugs Poisons & Controlled Substances Legislation*. Commonwealth of Australia. 2000.

The legislation also controls access by Australians to unapproved therapeutic goods, including products undergoing clinical trials in Australia.

Decisions by TGA to allow the supply of therapeutic goods in Australia are made on the basis of clinical and scientific evidence, and not on ethical, moral or religious grounds or community pressures. Ethical issues, including the ethics of conducting research in humans (clinical trials), are the responsibility of the National Health and Medical Research Council (NHMRC). Thus, while TGA makes recommendations on the safety and efficacy of medicines, the bioethical debate surrounding issues such as stem cell research or the availability of mifepristone sit squarely with the NHMRC. However, we are concerned that in recent years it appears that regulatory decisions are being made at the Government level, and these decisions appear to by-pass the mandate of the TGA, conferred under the objects of the Therapeutic Goods Act 1989, to evaluate and recommend marketing approval for new medicines. The effect is either to diminish the legitimacy and effectiveness of the Therapeutic Goods legislation or, alternatively, to extend the scope of the legislation to include matters relating to moral, ethical and religious questions.

**EXAMPLE 1**

An amendment to the Therapeutic Goods Act requires sponsors to declare (and include in the product information and consumer medicine information) whether human embryonic stem cells have been used in the research, development, testing or manufacture of the product. The process of finding out whether stem cells have been used in the research and development of a product, perhaps 20-30 years previously, is difficult and may be impossible. This amendment places an unnecessary burden on the Industry, and the benefit is unclear, since it is doubtful whether a prescriber would alter a decision to prescribe, or a consumer to consume, an essential prescription medicine on the basis of this statement.

**EXAMPLE 2**

Recently, the Government renewed a ban on the drug mifepristone, first banned 10 years ago. Mifepristone has now been used in about 2 million terminations in more than 30 countries, including European nations, the US and Britain. Its prohibition has baffled doctors, who point to growing scientific evidence proving the drug's efficacy and safety. During the last 10 years, medical evidence in favour of mifepristone has continued to grow. However, the ban, recently renewed by the Government, apparently on the basis of moral arguments, remains.

## The growth in quasi-regulation and Australian-specific requirements

The primary legislation is supported by a number of Standards and guidelines. Compliance with these requirements is a condition of registration. The growth in regulation of the pharmaceutical industry occurs primarily via an increase in this quasi-regulation.

The data requirements for an application for marketing approval for prescription medicines are similar to those of the European Union, and Australia adopts many of the EU Guidelines following their introduction in Europe. However, many of these are adopted with specific Australian notation. A perusal of the 68 Quality guidelines that have been adopted in Australia shows that 14 have additional Australia-specific notation. The most lengthy of these relates to the requirement for stability studies in hotter climatic zones (III and IV), which includes Australia (see box overleaf). Neighbouring countries to the North and East (including New Zealand) do not have special requirements over and above the EU guidelines. The EU guidelines have been adopted without amendment or annotation by New Zealand and the ASEAN countries. Most pharmaceutical companies are multinational. Having to prepare unique data sets for Australia, when the standard data requirements are accepted by other major agencies, is unnecessarily burdensome for the Industry.

In preparation for the new Trans Tasman Agency, new guidelines and standards are currently being developed by Expert Committees, which have the task of harmonizing Australian and New Zealand requirements. We are concerned that these committees may have little continuity or experience with existing systems in Australia and New Zealand, and little experience of the practicalities of manufacturing medicines. As a result, even though the primary legislation may be adequate, the resulting quasi-legislation may not reflect the principles of good regulatory practice.

**EXAMPLE 3**

The requirements for the registration of prescription medicines are outlined in the *Australian Registration Guidelines for Prescription Medicines*. Appendix 12 lists the kinds of changes to the quality information of registered medicines that require notification, self-assessment or prior approval. A minor change to the manufacturing process made by an overseas manufacturer may not require prior approval by the Agency in that country, but require prior approval in Australia.

A company in Australia, on receipt of a batch of product from overseas can suddenly find that such a change to manufacturing process has been made, and is then unable to supply the product in Australia until prior approval has been received by TGA. This takes an average of 6 weeks, and may result in temporary shortages or out-of-stock situations.

As the new Trans Tasman therapeutic goods legislation is developed, there is the opportunity (and a pressing need) to examine the existing legislation to identify any remaining areas of overlap or duplication of legislation, or additional Australian-specific regulatory requirements which unnecessarily add to the regulatory burden on industry. It would be most unfortunate if it were to go ahead without these factors being taken into account.

**EXAMPLE 4**

**CPMP/ICH/421/02 Note for Guidance on Stability Data Package for Registration in Climatic Zones III and IV**
Published: TGA Internet site
Effective: 17 September 2004
**Adopted in Australia, with annotation:**

"This guideline has been adopted by the TGA because a significant portion of Australia lies in climatic zones III and IV. The guideline requires at least 12 months stability testing at 30°C/65% rh, 6 months testing at 40°C/75% rh, 3 months testing at 50°C (in certain circumstances) and 3 months testing at 25°C/80% rh (for solid dosage forms in water-vapour permeable packaging). However, the TGA allows some alternatives to these requirements, as follows:

1. Testing at 50°C is not required.
2. Testing at 25°C/80% rh is not required if the product shows satisfactory stability during long term testing at 30°C/65% rh.
3. If a product does not show satisfactory stability for at least 3 months at 40°C/75% rh, there are several acceptable options:
    - argue that, as the container is designed to provide a barrier to water vapour, further investigation of stability under conditions of high humidity is not necessary; or
    - demonstrate, by testing at least 3 batches, that the product is stable for 3-6 months at 30°C/75% rh; or
    - package the product in a container/closure system that is less permeable to water vapour; or
    - label the product "Store below 25°C".
4. If a product is labelled "Store below 25°C", the TGA will accept:
    - long term stability testing at 25°C/60% rh in place of 30°C/65% rh; and
    - 6 months testing at 25°C/80% rh or 30°C/65% rh (at least 3 batches) in place of 40°C/75% rh. Nevertheless, initial testing of the product should be conducted in accordance with the guideline, ie, at 30°C/65% rh and 40°C/75% rh. If stability is inadequate under these conditions (and, if tested, the alternative condition of 30°C/75% rh) the use of more protective packaging should be considered before the option of labelling the product "Store below 25°C".

Generally, if a product shows satisfactory stability for at least 3 months at a high humidity test condition (40°C/75% rh, 30°C/75% rh, 30°C/65% rh or 25°C/80% rh, as appropriate), then the TGA will consider a shelf life of up to 2 years, subject to satisfactory long term stability data. If a product is stable for 6 months under these conditions then a shelf life in excess of 2 years will be considered. [Any of these four storage conditions would be acceptable for high humidity testing of a product labelled "Store below 25°C", but only 40°C/75% rh or 30°C/75% rh would be acceptable for a product labelled "Store below 30°C".]"

## Conclusion

The pharmaceutical industry acknowledges that a high level of regulation is appropriate to this sector, and have supported the Government and the Therapeutic Goods Administration in initiatives that will enhance the international status of Australia's regulatory system.

Our concerns are: that the regulation that applies in Australia (and that which is under development for the new Trans Tasman Agency) should not be more complex or onerous than comparable major overseas regulatory authorities; that the regulatory agency has the legitimacy to ensure the quality, safety, efficacy and timely availability of therapeutic goods; and that decisions on the availability of new medicines are made on the basis of scientific and clinical evidence, and not on moral or religious grounds.

In this context, it is important that the new Trans Tasman legislation (and accompanying quasi-legislation) is developed in accordance with the principles of good regulatory practice, and that Industry is fully consulted and involved in developing the legislation.

## Contact

Dr Narelle Bowern
Manager, Scientific & Technical Affairs
Medicines Australia
16 Napier Close, Deakin ACT 2600
Tel: (02) 6122 8560;
Fax: (02) 6282 6299
Email: narelle.bowern@medicinesaustralia.com.au

Appendix A

## Therapeutic Goods and Related Legislation

*Acts*
Therapeutic Goods Act 1989 and amendments; and
Therapeutic Goods (Charges) Act 1989 and amendments.

*Regulations*
Therapeutic Goods Regulations 1990 and amendments
Therapeutic Goods (Charges) Regulations and amendments.

*Orders*
Therapeutic Goods (Groups) Order No. 1 of 1992;
Therapeutic Goods (Excluded Goods) Order No. 1 of 1998;
Therapeutic Goods Order No. 20, 29, 48, 56 and 63.

*Determinations*
Therapeutic Goods (Manufacturing Principles) Determination No. 1 of 1999.

*Trans Tasman*
Trans Tasman Mutual Recognition Act 1997

*General*
- National Health Act 1954 and amendments
- Veteran's Entitlement Act 1986 and amendments

*Standards*
Standard for the Uniform Scheduling of Drugs and Poisons
British Pharmacopoeia 2004

*State and Territory Legislation*

**NSW** Poisons and Therapeutic Goods Act 1966 and Poisons and Therapeutic Goods Regulations 2002,
**QLD** The Health (Drugs and Poisons) Regulations 1996.
**SA** Controlled Substances (Poisons) Regulations 1996
**WA** Poisons Act 1964
**TAS** Poisons Act 1971 and Poisons Regulations 2002
**VIC** Drugs, Poisons and Controlled Substances Regulations 1995.
**NT** Therapeutic Goods and Cosmetics Act 1997
**ACT** Poisons and Drugs Act 1978

*Advertising*

- Therapeutic Goods Advertising Code
- Broadcasting Services Act 1992
- Trade Practices Act 1974 and amendments
- Trade Practices Regulations and amendments
- Relevant State / Territory Acts which govern advertising, e.g. New South Wales
- Fair Trading Act
- Medicines Australia Code of Conduct

*Manufacturing*

- Australian Code of Good Manufacturing Practice for Therapeutic Goods - Medicinal Products.

*Importing / Exporting*

- Customs Act 1901 and amendments
- Quarantine Act 1908 and amendments
- Wildlife Protection (Regulation of Imports and Exports) Act 1982
- Customs (Prohibited Imports) Regulations
- Customs (Prohibited Exports) Regulations.
- Narcotic Drugs Act 1975