A PROPOSAL FOR A TRANS TASMAN AGENCY TO REGULATE THERAPEUTIC PRODUCTS

DISCUSSION PAPER

JUNE 2002

FOREWORD

This discussion paper has been prepared to seek comment from stakeholders in Australia and New Zealand on a proposal for a trans-Tasman joint agency for the regulation of therapeutic products.

The proposal for a joint agency has been developed against the background of the Trans Tasman Mutual Recognition Arrangement and initiatives to harmonise the regulation of therapeutic products between Australia and New Zealand.

Australian and New Zealand Governments have agreed in principle to progress the proposal to bring the two regulatory arrangements for therapeutic products closer together, thereby removing unnecessary barriers to trade for Australian and New Zealand therapeutic products industries.

We will continue to work with stakeholders in further refining the proposal over the coming months. Subject to a final decision from both Governments to proceed with the establishment of a joint agency, draft legislation will be developed and further input from stakeholders will be sought as this process continues.

We encourage you to give full consideration to the proposals in this paper and to provide comment that will inform the development of new regulatory arrangements that will work well for consumers, industry sectors, health professionals and Governments in both countries.

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June 2002

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June 2002

SUBMISSIONS ON THIS DOCUMENT

This discussion paper has been published to allow further opportunity for informed public comment on the proposals developed by the project team. Your submissions on the proposals in this paper are invited and will help shape the proposed joint agency for the regulation of therapeutic products in Australia and New Zealand.

This document is available on the following websites:

www.jtaproject.com
www.health.gov.au/tga
www.medsafe.govt.nz
www.moh.govt.nz

Further copies can also be obtained on request from the project team at the addresses given below.

HOW TO MAKE A SUBMISSION

Submissions should be made to one of the addresses given below by

Friday 2 August 2002

Where possible, your submission should contain relevant evidence to support your views.

Submissions will be available to the public. Any information that you do not wish to be made public should be sent separately and clearly marked CONFIDENTIAL.

Addresses for submissions or for further information:

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EXECUTIVE SUMMARY

This discussion paper contains proposals for

- the establishment of a joint Australia/New Zealand agency for the regulation of therapeutic products; and
- the regulatory scheme that would be administered by such an agency.

During 2000, the Australian and New Zealand Governments gave in-principle agreement to the establishment of a joint agency for the regulation of therapeutic products (which include prescription and over-the-counter medicines, medical devices, complementary medicines and many dietary supplements) as a means of implementing the Trans Tasman Mutual Recognition Arrangement (TTMRA). This is subject to Australia and New Zealand being able to reach agreement on the establishment, governance, reporting requirements and accountability arrangements for the agency, and the regulatory framework to be administered by the agency. It is also dependent on the outcome of an analysis of the costs and benefits of the proposed scheme.

It is expected that a final decision on whether to proceed with the establishment of a joint agency will be made by each Government in the second half of 2002. If a joint agency is to be established, work will proceed on developing new legislation to be introduced to Parliaments in 2003. The earliest date for commencement of operation of a joint agency is expected to be mid to late 2004.

WHAT WILL THE AGENCY'S ROLE BE?

The proposed Australian/New Zealand agency for the regulation of therapeutic products (the Agency) would be responsible for ensuring the quality, safety, efficacy and timely availability of therapeutic products manufactured or supplied in Australia and/or New Zealand or exported from the Australia/New Zealand market.

HOW WILL THE AGENCY BE DESIGNED?

The Agency would be overseen by a Ministerial Council of two Ministers - the Australian and New Zealand Ministers of Health. The Ministerial Council would appoint the Board and would be responsible to the two Parliaments for the operation of the Agency.

The Agency would have a Board of five members, responsible to the Ministerial Council for the Agency's strategic direction and financial management. The Board would not make decisions in relation to technical matters, or individual therapeutic product licensing applications.

The Managing Director would be a member of the Board, the chief executive of the Agency responsible to the Board for financial and administrative matters, and the "statutory decision-maker" responsible for making decisions in relation to therapeutic products.

The Agency would be accountable to the Governments and stakeholders in both countries for its performance.

The Agency would have offices in both Australia and New Zealand. It is proposed that the Agency's internal organisation would be based broadly on a scheme of regulation by type of product.

HOW WILL THE AGENCY BE ESTABLISHED?

Three basic approaches to establishing the Agency have been identified. Each would involve Australia and New Zealand entering into a treaty in relation to the institutional and regulatory framework for the joint agency, and each country legislating to give effect to aspects of these arrangements. In particular, under any of these approaches both countries would enact legislation that would recognise the Agency as the therapeutic products regulator for that country, and would give effect to the regulatory decisions of the Agency.

The difference between the three approaches lies in the extent to which issues relating to the establishment and legal personality of the Agency are addressed in the treaty or in national legislation. Final decisions on establishment options will be made following the conclusion of negotiations between the two Governments.

Under the proposed approach, the standards and requirements that would apply to therapeutic products would be prescribed by a treaty and by new legislation in Australia and New Zealand. This new framework would replace the existing *Australian Therapeutic Goods Act 1989*, and Regulations and Orders, and the existing *New Zealand Medicines Act 1981* and Regulations.

The Treaty described above would set out broad enduring principles and goals for the scheme.

An Act in each country would contain the broad regulatory matters and obligations that must be contained in primary legislation, such as making it an offence to supply therapeutic products that have not been licensed by the Agency or which do not comply with requirements and standards prescribed in the Rules and Orders.

A single set of Rules made by the proposed Ministerial Council, which would be analogous to regulations in the current systems, would contain much of the detail of the regulatory requirements. For example, the Rules would set out the mandatory requirements for obtaining a licence to supply a therapeutic product.

Orders would be made by the Agency's Managing Director in relation to more technical issues, such as manufacturing standards and labelling requirements.

It is proposed that the Ministerial Council and the Agency's Managing Director would be given the power to make delegated legislation in the form of Rules and Orders. This delegated legislation would have direct effect in both countries, without needing to be incorporated into domestic legislation.

HOW WILL THE REGULATORY SCHEME WORK?

The Agency would regulate products used for a therapeutic purpose. Therapeutic products would include:

- prescription and over-the-counter (OTC) medicines;
- medical devices; and
- products currently regulated in Australia as complementary medicines; and
- products marketed as dietary supplements in New Zealand (other than food-type dietary supplements), including herbal and homoeopathic medicines.

The regulatory activities of the Agency would include pre-market assessment or evaluation, product licensing, post-market surveillance, licensing of manufacturers, setting of standards and communicating decisions and information.

Whilst the regulatory scheme is designed to deliver common regulatory outcomes in the two countries, it is recognised that the scheme would need to enable either country to 'opt out' of a common regulatory decision in extraordinary circumstances (eg. to accommodate differing public health policy imperatives).

The Agency would regulate therapeutic products using a risk management approach, in which the degree of regulatory control would be proportional to the risk associated with use of the product.

Prescription and OTC medicines, complementary medicines and dietary supplements (other than food-type dietary supplements)[1] would be classified according to risk into one of three classes based on ingredients, intended purpose and type of product. Class I would comprise low-risk products (eg. most complementary healthcare products and sunscreens). Class II (medium risk) would include most over-the-counter medicines. Class III products would include prescription medicines and other specified products (eg. vaccines, biotechnology products, radiopharmaceuticals, injectable dosage forms and products intended to carry indications for serious diseases). The Agency's internal organisation would be based on a scheme of regulation by type of product. In such a scheme there would be separate regulatory units within the Agency for regulation of prescription, OTC and complementary healthcare products.

Medical devices would also be classified according to risk into one of six classes, using the manufacturer's intended purpose and a set of risk-based classification rules, consistent with the framework recommended by the Global Harmonisation Task Force (GHTF).

It is proposed that the Agency would operate a cost recovery scheme in which cost recovery arrangements would be consistent with government policy and relate to the range of regulatory activities including pre-market evaluation or assessment of products and/or substances, post-market surveillance, standard setting, and the auditing and licensing of manufacturers.

[1] For convenience complementary medicines and dietary supplements (other then food-type dietary supplements) are referred to in the discussion paper as 'complementary healthcare products', further discussion of the terminology to be used to describe this type of product is provided in Part F of the paper.

The Agency would consult with industry representatives to ensure that fees and charges accurately reflected the cost of regulating a particular industry sector or a product group and were borne equitably within and across the relevant sector or product groups.

Activities that the Agency may perform under contract (eg. chemical hazard and risk assessments for Australia or pharmacy audits for New Zealand) would be outside the scope of the joint scheme and would be funded separately from payments under those contracts.

Product licensing

It is proposed that authorisation to import, export or supply therapeutic products would be granted by a product licence issued by the Agency, unless the product was specifically exempted from the requirement for a product licence. The product licence (PL) holder or their authorised agent would be the sponsor of the product.

Each PL would carry a unique number and, generally, a separate PL would be issued for each new product, although it would be possible to 'group' more than one product in the same PL in certain circumstances. The Agency would maintain a register of licensed products.

The product licence document would provide a summary of the particulars of the product and set out or refer to the conditions under which the product could be supplied.

In order to obtain a product licence, the sponsor would be required to submit an application to the Agency. The application processes, data requirements and evaluation/assessment processes would be different for different types of products and different risk classifications. Class I products would be granted a product licence on the basis of self-certification by the sponsor, using an electronic application lodgement and assessment system.

The Agency would set timeframes for evaluating and processing applications. Appropriate mechanisms would be put in place to allow accelerated evaluation to occur in defined circumstances. An orphan medicines programme would facilitate the availability of medicines for use in rare diseases.

Expert advisory committees

Expert advisory committees would be established to provide the Managing Director of the Agency with scientific and regulatory advice. Members would be selected from relevant experts in both countries. Committees would be established to provide advice on matters such as standards for therapeutic products, matters relating to the evaluation and licensing of products (with a separate committee for each broad category of product), adverse reactions and scheduling.

Licensing of manufacturers

Manufacturers of medicines and complementary healthcare products would be required to comply with specified manufacturing principles. The Agency would audit manufacturers

for compliance with the code and would issue manufacturing licences. Evidence of compliance with manufacturing principles would also be required for any overseas site manufacturing a medicine or complementary healthcare product.

Post-market surveillance

The Agency would use a systematic, risk-based approach to post-market surveillance of therapeutic products. Post-market surveillance activities would include: random and targeted testing of products; adverse reaction monitoring; medical device incident monitoring; product problem reporting and recalls; auditing of manufacturing facilities; audits of applications (eg. those relying on sponsor self-certification or self-assessment); and monitoring of products in the market place to ensure they are being marketed in compliance with the terms and conditions of the product licence.

Clinical trials and access to unlicensed therapeutic products

Use of therapeutic products in clinical trials would be regulated under a joint clinical trial scheme. All clinical trials, including those using licensed products, would require the approval of the relevant institutional ethics committee(s) and would have to be notified to the Agency. Clinical trials would also require scientific approval. Comment is sought on different options for obtaining scientific approval of clinical trials.

A number of mechanisms would be put in place to allow patients access to unlicensed therapeutic products in defined circumstances.

Therapeutic products for export

Therapeutic products that are not the subject of a product licence but are to be exported from Australia or New Zealand to a third country would require an export only licence, and the Agency would provide appropriate export certification to meet international requirements. Comment is sought on specific options for administering the export licensing scheme.

Advertising

Under a joint agency, advertisements for therapeutic products directed exclusively to healthcare professionals would be governed by industry codes of practice, which would be consistent with an Australia/New Zealand therapeutic products advertising code.

The regulatory scheme that would apply to direct-to-consumer advertising is currently under review as part of the joint agency project. It is anticipated that the regulatory arrangements for direct-to-consumer advertising of therapeutic products would be co-regulatory and simplified wherever possible. That approach would be based on:

- a single Australia/New Zealand advertising code and advertising oversight body;
- a single pre-clearance system for advertisements;
- single administrative and complaints arrangements; and
- joint (Australia/New Zealand) industry codes of practice.

Scheduling of medicines

The proposals set out in the paper advance the recommendations of the Galbally Review[2] in Australia relating to scheduling.

It is proposed that under a joint agency, there would be a single scheme for the scheduling of medicines and substances in medicines. The initial scheduling decision would be made as part of the evaluation and approval process for the substance or medicine.

An expert advisory committee on medicine scheduling would advise the Managing Director on scheduling matters; would consider proposals to change the scheduling classification of a medicine; and would be able to review scheduling decisions made by the Managing Director.

HOW WILL PRESCRIPTION MEDICINES BE REGULATED?

Under a joint agency, the application and evaluation processes and the data requirements for prescription medicines would be similar to those currently applied in both countries, and would be consistent with international best practice. It is proposed that the legislation would set timeframes for processing applications, with cost penalties for the Agency if the timeframes were not met.

Strict criteria would be set down by the Agency in relation to requirements for demonstrating bioequivalence for generic medicines.

HOW WILL OTC MEDICINES BE REGULATED?

Under a joint agency, the application and evaluation processes and the data requirements for OTC medicines would be similar to those currently applied in both countries, and would be consistent with international best practice. It is proposed that the Agency would set timeframes for processing applications.

HOW WILL COMPLEMENTARY HEALTHCARE PRODUCTS BE REGULATED?

There is no universally accepted collective term or definition for the groups of products often referred to as complementary healthcare products, complementary medicines or natural health products. These products fall under the broad definition of "medicine" because of the way in which they act. However, some stakeholders do not agree with the use of the term "medicine". Comment is sought on appropriate terminology and definitions to be used in the legislation.

In Australia, complementary healthcare products are regulated as complementary medicines under therapeutic goods legislation. In New Zealand, they are generally marketed as dietary supplements and controlled under food legislation.

[2] A Review of Drugs, Poisons and Controlled Substances Legislation.

It is proposed that a joint agency would regulate complementary healthcare products as therapeutic products, using a risk-based approach. Most complementary healthcare products (around 95%) would be low-risk (Class I), and therefore could be licensed quickly on the basis of sponsor self-certification using an electronic system.

Safety of ingredients used in low-risk complementary healthcare products would be controlled by the Agency maintaining a list of permitted ingredients that had been assessed as being safe for use in Class I products. Any products falling into Class II (medium risk) or Class III (high risk) would be evaluated by the Agency for safety, quality and effectiveness before a product licence was granted.

HOW WILL MEDICAL DEVICES BE REGULATED?

Consistent with the endorsed recommendations of the GHTF, all medical devices would have to meet a set of essential principles relating to their design, manufacture and clinical performance before a product licence could be granted. The level of regulation would be proportional to the degree of risk involved in the use of the device.

For the lowest risk devices, a product licence would be granted on the basis of sponsor self-certification. For the higher risk classes, the Agency would be able to take account of documentation from overseas bodies in which it had confidence. Where adequate evidence was not available, or where the device presented specific types of risks (eg. contained material of human or animal origin), the Agency would undertake evaluation of the medical device before granting a product licence.

Mechanisms would be developed to allow access to unlicensed medical devices in appropriate circumstances. A medical device exported from Australia or New Zealand to a third country would require an export only licence.

HOW WILL COMPLIANCE BE MONITORED AND ENFORCED?

The Agency would have responsibility for monitoring compliance with the regulatory system it administered, and would have the power to request information, to request samples for testing, and to search premises and seize goods. The Agency would also have the power to impose sanctions (eg. cancel a product licence or recall a product) and prosecute offences.

HOW WILL REGULATORY DECISIONS BE REVIEWED?

It is proposed that the Agency's regulatory decisions would be open to challenge in two ways:

- through a two-stage merits review process, consisting of a right to ask the Agency to carry out a review of one of its decisions, with a further right to ask for a review of a decision to be carried out by a merits review panel external to the Agency; and
- through judicial review proceedings brought in the courts of either country.

WHAT WILL THE TRANSITIONAL ARRANGEMENTS BE?

Following the passage of legislation implementing a new joint regulatory scheme for therapeutic products and commencement of operation of the Agency, there would need to be a period of transition to the new system. At commencement of operation of the Agency, therapeutic products legally on the market in Australia could continue to be supplied in Australia and therapeutic products legally on the market in New Zealand could continue to be supplied in New Zealand.

For certain types of products (eg. medical devices and complementary healthcare products in New Zealand) the initial permission to supply would lapse at the end of a defined transition period. Because these products had not previously been subject to pre-market regulation, continued supply would be subject to the sponsor applying for and being issued with a product licence based on evaluation or assessment in accordance with the requirements of the Agency.

Considerable further work and consultation will need to occur over the next few months as the details of appropriate mechanisms and durations for transition are developed. The following principles have been developed to guide this work.

The transition arrangements would:

- provide adequate assurance about the safety, quality and efficacy of products on the product licence register, without requiring extensive re-evaluation of data,which cannot be justified on public health and safety grounds;
- ensure that manufacturers and sponsors of therapeutic products in both countries are treated in a fair and equitable way, taking into account relevant past regulatory practices;
- impose the lowest possible compliance costs consistent with adequately protecting public health and safety;
- permit sponsors already in the market in either country to continue to market in that country during the transition period without having to apply for a dual-country licence; and
- facilitate early reduction of existing trade barriers.

Australian and New Zealand officials will present recommendations on the proposed joint regulatory scheme to their respective Governments later this year after considering stakeholder comments on the proposals in this paper.