



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

The Australia New Zealand Therapeutic Products Authority Project Newsletter Number 1 May 2007



Message from the Transitional Director

As Transitional Director of the trans-Tasman project group charged with managing the establishment of the proposed Australia New Zealand Therapeutic Products Authority (ANZTPA) and the new joint regulatory scheme, I am keen to keep stakeholders informed of progress.

This e-newsletter is the first edition of a monthly update that will be available on the ANZTPA website and sent to subscribers to the ANZTPA List Server. It aims to provide you with information on project milestones, current consultations and planned activities as well as giving answers to some of the questions which have been put to the project team.

I am sure you will be aware that consultation is now under way in both Australia and New Zealand on each country's respective legislation to establish ANZTPA and set up the proposed new regulatory scheme.

New Zealand's *Therapeutic Products and Medicines Bill* is currently before the Government Administration Committee, having been introduced to the Parliament on 5 December 2006. The Committee will report on the Bill by 15 June 2007.

In Australia, an exposure draft of the *Therapeutic Products Bill* has now been released. Submissions on the Draft close on 4 May 2007.

I encourage anyone who has not yet done so to familiarise themselves with these important documents.

The current round of consultation is the latest in a series which has been running since May last year. During that time, there has been extensive public consultation on many aspects of the proposed, new trans-Tasman regulatory scheme, and this newsletter provides details of further draft documents which, in addition to the two Bills, have recently been released for consultation.

Officials from New Zealand's Medsafe and Ministry of Health, and Australia's Therapeutic Goods Administration and Department of Health and Ageing have been analysing the many submissions received so far. Feedback on submissions will be made available to stakeholders shortly.

I appreciate that, with so much consultation going on, and so many different documents in circulation, it can sometimes be difficult to see the 'big picture' of how they all fit together. With that in mind, this newsletter also includes a brief overview of the legislative framework for the proposed regulatory scheme.

I welcome suggestions for information that you would like included in future newsletters, whether it relates to the scheme itself, the proposed Authority, the underpinning legislation or any other aspect of this challenging and important initiative. You can contact me via consultation@anztpa.org

Philip Davies, Joint Agency Establishment Group

Recent Appointments

New Parliamentary Secretary Appointed

In Australia, Senator the Hon Brett Mason was recently appointed Parliamentary Secretary to the Minister for Health and Ageing. Dr Mason is a Barrister who has been a Senator for Queensland since 1998. He takes over from the Hon Christopher Pyne and joins the Therapeutic Products Interim Ministerial Council alongside the Hon Annette King from New Zealand.

New Interim General Manager of Medsafe

Dr Stewart Jessamine has been appointed as the Interim General Manager of Medsafe. He has been working at Medsafe since 1993 and brings to the project extensive experience in pharmacovigilance, clinical trials and the regulation of medicines. Dr Jessamine's predecessor, David Nicholson, recently took up a new role as a Director in New Zealand's Tertiary Education Commission (TEC) / Te Amorangi Matauranga Matua. During his time at the helm of Medsafe David made a substantial contribution to the ANZTPA establishment project.

Phase 3 Consultation Underway

The third and final phase of the stakeholder consultation programme on the proposed regulatory framework started in mid-April. There will be a staged release of documents over the coming months.

The first documents released as part of this phase were Draft Orders dealing with standards for medical devices.

The release of those documents was followed in late April by:

- the In-Vitro Diagnostic Devices (IVD) Revision Draft of the proposed Australia New Zealand Therapeutic Products Regulatory Scheme (Medical Devices) Rule 2007; and
- a consultation paper on the proposed Regulation of Human Cellular and Tissue Therapies under ANZTPA.

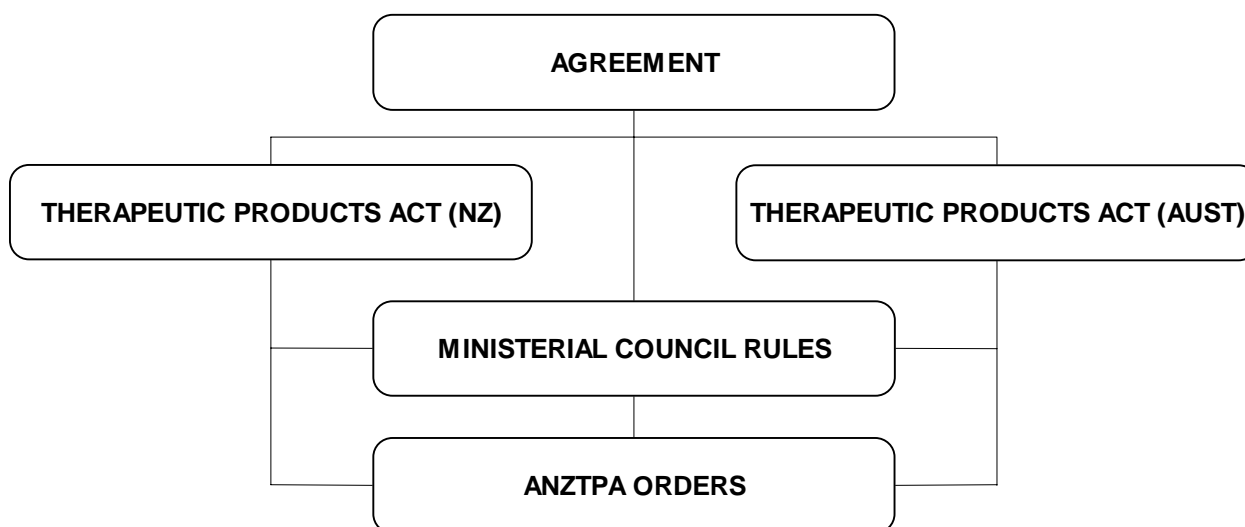
Closing dates for written submission on current consultation papers are:

- Draft Order: Medical Device Standards for Clinical Evidence - Friday 4 May
- Draft Order: Medical Device Standards for Risk Management - Friday 4 May
- Draft Order: Conformity Assessment Standards for Quality Assurance Techniques for Animal Tissues and their Derivatives utilised in the Manufacture of Medical Devices - Friday 4 May
- In-Vitro Diagnostic Devices (IVD) Revision Draft of the proposed Australia New Zealand Therapeutic Products Regulatory Scheme (Medical Devices) Rule 2007 - Wednesday 13 June
- Consultation Paper: The Regulation of Human Cellular and Tissue Therapies - Wednesday 13 June

Copies of the documents can be found at <http://www.anztpa.org/consult/index.htm>

Understanding the ANZTPA Legislative Framework

The key elements of the proposed ANZTPA legislative framework are depicted in the diagram below.



The origins of ANZTPA and the new scheme lie in the *Agreement between the Government of Australia and the Government of New Zealand for the establishment of a joint scheme for the regulation of therapeutic products* which was signed 10 December 2003, available at <http://www.anztpa.org/about/treatytext.pdf>.

That Agreement, which was negotiated in the context of earlier Agreements on Closer Economic Relations and Trans-Tasman Mutual Recognition, has as its primary objective “establishing and maintaining a joint scheme consistent with international best practice for the regulation of the quality, safety, and efficacy or performance of therapeutic products, and of their manufacture, supply, import, export and promotion”.

New Zealand and Australia will each have an Act of Parliament that implements the scheme. These will be based on the Bills on which consultation is currently taking place.

Once the legislation has been passed in both countries, the Agreement will be ratified and come into force. As it does so, it will establish the Ministerial Council, comprising the Health Ministers of both countries, and the Board of the Authority.

Ratification of the Agreement will also allow ‘Ministerial Council Rules’ and ‘ANZTPA Orders’ to be formally made and Board members appointed. Much of the detail of the joint regulatory scheme will be contained in Rules and Orders. They will be joint instruments, made under the Agreement, and given the force of law in each country by the implementing legislation.

Rules will be similar to regulations – for example, there will be a ‘Medicines Rule’ and a ‘Medical Devices Rule’. They will be made by the Ministerial Council.

Orders will contain the more technical detail of the regulatory scheme – for example, there will be a ‘Labelling Order’. They will be made by the Managing Director on behalf of the Authority.

Public consultation has been underway on the Rules and Orders since May 2006. Rules and Orders must be tabled, in their final form, in both the New Zealand and Australian Parliaments where they will be subject to scrutiny and possible disallowance. If a Rule or Order is disallowed by either country’s Parliament, it will cease to have effect for both countries.

ANZTPA Project Website Updates (www.anztpa.org)

A very good source of up to date information is the project website which is updated on a regular basis.

Recent additions to the project website include:

- Current open consultations including ANZTPA Draft Orders and the In-Vitro Diagnostic Devices (IVD) Revision Draft of the proposed Australia New Zealand Therapeutic Products Regulatory Scheme (Medical Devices) Rule 2007 and the Consultation Paper: The Regulation of Human Cellular and Tissue Therapies (HCTs)
- A guidance tool for assessing the appropriate regulatory coverage for products at the food-medicine interface
- Minutes from the second meeting of the Advertising Implementation Steering Group
- Questions and answers raised during the consultation workshops on the proposed regulation of blood, proposed arrangements for product vigilance and proposed medicines scheduling provisions
- Updated fact sheets

To subscribe to the ANZTPA-UPDATE List Server and receive emails containing information updates about the progress towards the Australia New Zealand Therapeutic Products Authority (ANZTPA) go to <http://www.anztpa.org/new/anztpa-update-subscribe.asp>