



The Australia New Zealand Therapeutic Products Authority Project Newsletter Number 2 June 2007



Message from the Transitional Director

As governments, industry and other stakeholders maintain their efforts to establish a single trans-Tasman regulatory regime it is all too easy to lose sight of the fact that this initiative is part of a broader, and longer-running, process which is seeking to strengthen ties between Australia and New Zealand.

The Australia New Zealand Closer Economic Relations Trade Agreement came into force on 1 January 1983. Its objectives are to:

- strengthen the broader relationship between Australia and New Zealand;
- develop closer economic relations between the Member States through a mutually beneficial expansion of free trade between New Zealand and Australia;
- eliminate barriers to trade between Australia and New Zealand in a gradual and progressive manner under an agreed timetable and with a minimum of disruption; and
- develop trade between New Zealand and Australia under conditions of fair competition.

The Trans Tasman Mutual Recognition Arrangement, which is one of the arrangements that gives effect to Closer Economic Relations, came into effect in 1998. For its part, it seeks to “enhance the international competitiveness of Australian and New Zealand enterprises, increase the level of transparency in trading arrangements, encourage innovation and reduce compliance costs for business” by removing regulatory barriers to the movement of goods and service providers across the Tasman.

Until now, therapeutic goods have been exempted from mutual recognition provisions but both Governments are committed to removing the barriers to the movement of therapeutic products from New Zealand to Australia and vice versa.

With that in mind, Health Ministers agreed in 1999 that harmonisation of regulatory requirements under a joint Authority and joint regulatory scheme would be the best way forward. That agreement, in turn, has led to Australia and New Zealand working together to establish a trans-Tasman regulatory scheme for therapeutic products under a new authority to be known as the Australia New Zealand Therapeutic Products Authority (ANZTPA).

Experience of mutual recognition in other sectors has been generally positive and there is clear evidence that the Closer Economic Relations Trade Agreement has boosted trade and investment between the two countries.

While the establishment of ANZTPA is one more, important step towards enhancing our closer economic relationships, it also ensures that both Australia and New Zealand have a world class joint regulatory scheme for therapeutic products that safeguards public health and safety in a way which meets international best practice standards.

Our current work can thus be viewed as the latest in a series of initiatives which seek to deliver important social and economic benefits to our joint community of some 25 million people.

Philip Davies, Joint Agency Establishment Group

Consultation Continues

The third phase of the ANZTPA stakeholder consultation programme is gaining momentum with draft Orders continuing to be released and stakeholder consultation workshops recently being held in Australia and New Zealand.

The workshops were well attended with approximately 150 people coming together to discuss the consultation documents on the proposed regulation of In-Vitro Diagnostic Devices (IVDs) and the proposed Human Cellular and Tissue Therapies framework.

The workshop presentations and questions and answers raised at the workshops are now available on the ANZTPA website and submissions on these consultation papers close on Wednesday 13 June 2007.

Analysis is now underway on the recently closed submissions related to the consultation paper on the proposed clinical trial regulatory arrangements under ANZTPA.

A new draft Order on Packing Requirements for Specified Therapeutic Products was released for consultation on Wednesday 30 May 2007 and submissions will close on Friday 13 July 2007.

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

The Governance and Organisational Structure of the ANZTPA

Both the New Zealand and Australian Governments have had significant input into the design of the governance framework of the new Authority and the joint regulatory scheme that it will administer. Fundamental to the design is the fact that both nations' sovereignty must be recognised and respected. That, in turn, leads to two key principles which underpin the proposed governance arrangements. They are:

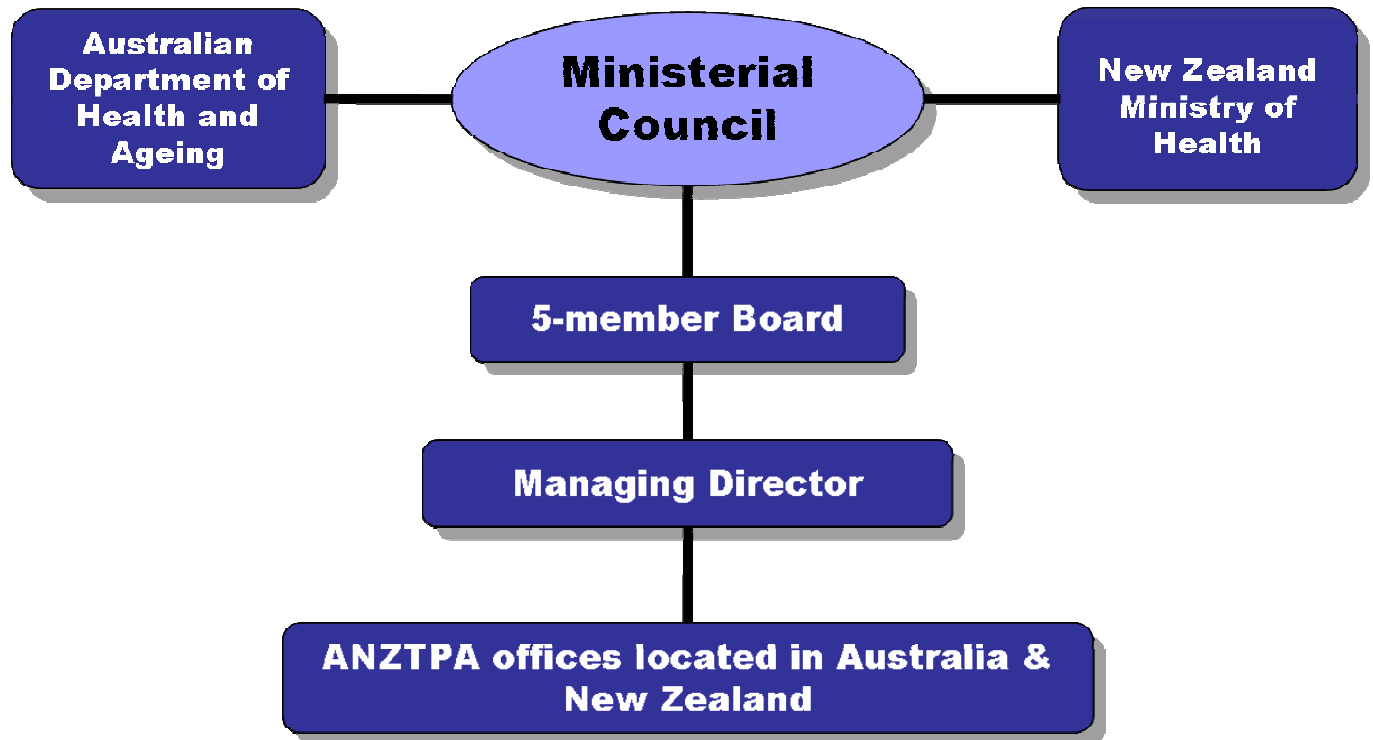
- ensuring that the New Zealand and Australian Ministers have an **equal say** in the oversight of the Authority and in the content and operation of the proposed regulatory framework; and
- ensuring that that the new Authority is **equally accountable** to the Governments, Parliaments and public of both countries.

The new Authority will replace both the Australian Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) and will assume responsibility for their regulatory functions with regard to therapeutic products.

Its role will be to safeguard public health and safety through regulation of the quality, safety and efficacy or performance of therapeutic products in both Australia and New Zealand. It will do this by administering a single, joint regulatory scheme for therapeutic products that will impose uniform requirements in both countries.

The ANZTPA itself will be established by legislation in both countries as a new type of agency. It will be neither an Australian Commonwealth Authority nor a New Zealand Crown Entity. It will, however, have offices in Canberra and Wellington, be recognised and bound by the laws of both countries, be accountable to both countries' Governments, and comply with both countries' accountability and transparency regimes.

ANZTPA will be governed by a Therapeutic Products Ministerial Council which will appoint the Board and members of expert advisory committees and make Ministerial Council Rules. The Ministerial Council will have just two members – the Australian and New Zealand Health Ministers. (This contrasts with the Australia and New Zealand Food Regulation Ministerial Council which comprises Ministers from New Zealand and all Australian Federal, State and Territory Governments.)



The Board of ANZTPA will consist of five members and will be responsible for the Authority's financial viability, its effectiveness and its overall strategic direction. One of the members of the Board will be the Managing Director of ANZTPA who, in turn, will be responsible for the day-to-day management of ANZTPA and will be the regulatory decision-maker.

ANZTPA will be the first of a kind: a truly bi-national regulator, acting on behalf of two sovereign nations and affording equal voice to both.

ANZTPA Project Website Updates (www.anztpa.org)

Recent additions to the project website include:

- Questions & answers about the regulation of Human Cellular and Tissue Therapies (HCTs) under ANZTPA
- Questions & answers about In Vitro Diagnostic Devices (IVDs) as included in the draft Medical Devices Rule
- Presentations from the May 2007 ANZTPA Stakeholder Workshops
- Draft Order on Packing Requirements for Specified Therapeutic Products

To subscribe to the ANZTPA-UPDATE email list 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>