



The Australia New Zealand Therapeutic Products Authority Project Newsletter Number 3 July 2007



Message from the Transitional Director

The establishment of the Australia New Zealand Therapeutic Products Authority (ANZTPA) has been a long-term project and priority of both the New Zealand and Australian Governments.

Since the last newsletter, the New Zealand Government Administration Select Committee (the Select Committee) has released its report.

A copy of the report (which was published on 15 June 2007) is available on the [New Zealand Parliamentary website](#).

It appears that the Select Committee divided along party lines in presenting its report with the advice that members had been “unable to reach agreement and therefore cannot recommend that the Bill be passed”. This was not necessarily unexpected – and, of course, being “unable to agree” is very different from recommending against the Bill. Nor does it signal that the Bill has been rejected by the New Zealand Parliament. The Bill is in the hands of the New Zealand Government, and no doubt the Government is continuing to work to secure passage of the legislation.

Meanwhile, the submissions received on the exposure draft of the *Australian Therapeutic Products Bill* are under consideration by the Department of Health and Ageing (DoHA).

While waiting for the outcome of these processes, officials in both countries are continuing to work together to develop the infrastructure for ANZTPA and the regulatory scheme. The consultation process with industry and other interested parties is continuing, and an update is provided in this newsletter.

The legislative process is taking longer than may have originally been anticipated but this is a very complex exercise. Indeed, it would be fair to refer to it as unique – this is a “first” in Australian and New Zealand legislative activity. So, clearly, it’s important to take the time to get it right. While I cannot give you precise dates for the passage of each country’s legislation, or even a guarantee that either or both of the Bills will be passed, both governments have announced that they are working to establish ANZTPA in 2007. The new regulatory scheme itself would then come into operation some time in 2008.

With that in mind, this newsletter includes a high level overview of the expected process from passage of the legislation to establishment of ANZTPA and then to commencement of the joint scheme.

Philip Davies, Joint Agency Establishment Group

Consultation Continues

The on-going and extensive consultation program, allowing stakeholders to review and comment on the Rules and Orders for the joint regulatory scheme is continuing, with further documents being released for stakeholder feedback.

Documents recently released, as part of this third and final phase of consultation include two more draft Orders relating to the standards for medical devices. In addition, the draft Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) and the draft Scheduling Policy Framework were released for consideration by stakeholders, with a deadline for submissions of 25 July 2007.

Analysis is currently underway on the recently closed submissions relating to the consultation documents on the proposed regulation of In-Vitro Diagnostic Devices (IVDs) and the proposed Human Cellular and Tissue Therapies framework.

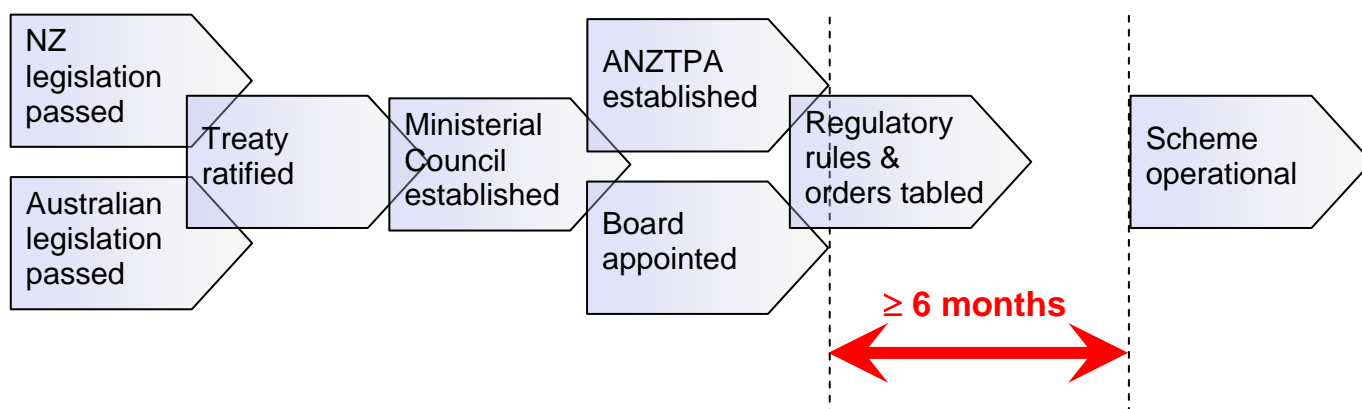
Drafts of further key Orders are expected to be released shortly, in addition to a document outlining the proposed medicine label statements for ANZTPA.

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

Looking Forward...

While the implementing legislation is progressing through the political and parliamentary processes in Australia and New Zealand, officials in both countries are working towards the establishment of ANZTPA.

Following the passage of legislation in both countries, a number of additional steps must occur before the Authority can be established. There will then need to be a further phase of activity before the new joint regulatory scheme can start. Until that point, the TGA and Medsafe will continue to administer the existing Australian and New Zealand regulatory schemes, respectively. The overall process is depicted below.



Once legislation is passed by both countries' Parliaments, the way will be clear for formal ratification of the 2003 Treaty which will be achieved by means of an exchange of diplomatic notes between Australia and New Zealand. At that point the Ministerial Council will be established, the Board of the Authority can be appointed and the new Authority will formally come into being.

There will inevitably be a period of time between the establishment of the new Authority and the introduction of the new regulatory scheme. Ministerial Council Rules and Authority Orders, which are currently the subject of consultation, will need to be tabled and subject to disallowance arrangements in both Parliaments.

There will also be a number of important tasks in respect of developing new business processes, setting up appropriate financial systems and ensuring organisational readiness which will have to be completed to ensure that ANZTPA is able to provide an efficient and effective service to industry on both sides of the Tasman. While many aspects of that organisational change process are already under way, there are some other key components that cannot be started until the new Authority exists.

Ministers indicated last year that they would provide industry with at least six months notice of the start of the new scheme. That means, in effect, that there will be at least that time between the establishment of ANZTPA and the point at which it takes over from the TGA and Medsafe and starts to administer the new scheme. In making that commitment, Ministers were not only considering the work that needs to be done by ANZTPA but they were also aware that industry would need time to prepare for the new environment.

ANZTPA Project Website Updates (www.anztpa.org)

Recent additions to the project website include:

- Final Draft Order: Medical Device Standards for Risk Management
- Final Draft Order: Conformity Assessment Standards for Quality Assurance Techniques for Animal Tissues and their Derivatives Utilised in the Manufacture of Medical Devices
- Proposed Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)
- Proposed Scheduling Policy Framework for Medicines and Poisons
- Draft Order: Conformity Assessment Standard for Quality Management Systems and Quality Assurance Techniques for the Manufacture of Medical Devices
- Draft Order: Medical Device Standards for Medical Devices Required to be Sterile
- Outcomes from the third meeting of the Joint Interim Expert Advisory Committee on Standards (JIEACS) and the third & fourth meetings of the pharmacopoeial subcommittee of the JIEACS.

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>