FACT SHEET

AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS AGENCY (ANZTPA)

Why is ANZTPA being created?

The Australian and New Zealand Governments have agreed to proceed with a joint scheme for regulation of therapeutic goods (ie medicines, medical devices, etc).

The creation of a joint regulatory scheme across both countries will safeguard public health and safety, while encouraging economic integration and benefitting industry in both countries.

Over time, the joint arrangements will be administered by a single regulatory agency, the Australia New Zealand Therapeutic Products Agency, which will absorb the current regulators - Australia’s Therapeutic Goods Administration and New Zealand’s Medsafe.

How will the transition to a joint regulator be implemented?

A 3 staged approach over a period of up to 5 years will be adopted to progressively achieve this goal.

1. The two countries’ regulators, TGA and Medsafe, will immediately begin a program of work-sharing and increased joint operations. This will enable the separate regulatory systems of each country to be enhanced by sharing of data and information, training, and establishing centres of expertise in each country.

2. Building on this, a single entry point for industry will be established and a common trans-Tasman regulatory framework will be agreed.

   During these two preliminary phases, each country will retain its own regulator and continue to make its own regulatory decisions, but business will benefit from a significant reduction in red tape with only one set of requirements to operate in two countries.

3. As business operations become increasingly integrated and a following a review of progress, the single regulator will be established.

When will ANZTPA start operations?

From July 2011, both countries will immediately begin to share resources, expertise and information, building the regulatory capacity in both countries.
A Transition Agency will be established to oversee implementation of the joint arrangements. This Transition Agency will advise a select Ministerial Council on the joint scheme, which will include the Australian and New Zealand Health Ministers and other relevant ministers.

Following a review of progress and final confirmation of arrangements, the separate national regulators will be absorbed into a new joint agency.

The new ANZTPA is expected to be operational within five years.

This approach to implementation will deliver prompt and progressive benefits for consumers, industry and governments.

**What are the benefits of a single trans Tasman regulatory system?**

A single regulatory framework will provide health benefits for consumers, reduced regulatory costs for industry and greater efficiency for governments.

The new world class scheme is expected to enhance the reputation of New Zealand and Australian therapeutic products on the world market.

**When did Australia and New Zealand originally agree to a joint therapeutic goods regulator?**

Agreement for a joint regulatory scheme was first reached in 2003. However, the joint scheme was not able to proceed as New Zealand was unable to pass enabling legislation.

Negotiations between the countries were suspended in July 2007. However, the Treaty between Australia and New Zealand remained in place and allowed both countries to resume negotiations at any time.

**Will all therapeutic products be regulated by ANZTPA?**

The 2003 Treaty envisages a common regulatory framework for all therapeutic goods.

However, during the first stages of this joint scheme, the Australian Government acknowledges that the NZ Government is introducing a separate scheme to regulate certain natural health products (complementary medicines) in the New Zealand market. Regulation of complementary medicines was the stumbling block to implementing the joint scheme when it was first agreed. On 16 June 2011, New Zealand announced it has developed a stand-alone framework for domestic regulation of low risk complementary medicines. A review of this proposed scheme for natural health products in five years’ time will consider whether or not to maintain a separate scheme for certain natural health products in New Zealand.

The staged approach to ANZTPA will provide an opportunity for NZ natural health product manufacturers to choose to be integrated into ANZTPA regulation, which will be a ‘gold’ standard internationally for safety and quality. This would allow them to market their products internationally (including in Australia) using this endorsement.
Until a common regulatory framework is agreed, all therapeutic goods to be supplied into the Australian market will still need to meet Australian standards.

**How will the new ANZTPA be funded?**

Each country will be responsible for meeting the costs associated with the early phases of this joint ANZTPA work program. Over time, the cost of regulation will be integrated into the cost recovery arrangements with industry.

At this stage, TGA and Medsafe will continue their usual cost recovery arrangements from industry.