



The Australia New Zealand Therapeutic Products Authority

Consultation Hui

Te Ao Marama

Rotorua

10 July 2006



Our purpose today

To explain that ANZTPA will **NOT** regulate:

- Rongoa
- Traditional healers
- Cultivation of plants

That the joint scheme will **NOT** impact on:

- The Wai 262 claim
- IP rights
- Te Tiriti o Waitangi

Our purpose today

To explain:

- What ANZTPA **will** do
- Why a joint regulator is needed
- How the proposals protect sovereignty

To invite your submissions on the proposals



Presentation Outline

- What is being established
- Scope of the Joint Scheme
- Why establish a joint regulator
- Explaining ANZTPA & its governance
- The joint regulatory scheme
- Cost recovery
- Next steps
- Where to go for more information

What is being established

- A new regulatory scheme for therapeutic products
- A new agency to administer the scheme to be called:

The Australia New Zealand Therapeutic Products Authority (ANZTPA)

Scope of the Joint Scheme

Products to be regulated:

- Medicines
 - Prescription medicines
 - Non-Prescription medicines
 - Complementary medicines
- Medical Devices
- Blood and blood components
- Cell and Tissue therapies



Scope of the Joint scheme

ANZTPA will NOT regulate:

- Rongoa
- Traditional healers
- Cultivation of plants
- Personal imports

ANZTPA will regulate:

- Products sold through wholesale/retail systems
- Manufacturers producing for commercial supply

In order to assure:

- Safety
 - Quality
 - Effectiveness
- of commercial products

Why establish a joint regulator?

- Enhance future regulatory capacity in both countries
- Avoid costly duplication of effort
- Maintain a voice in international fora on therapeutic product regulation
- Minimise barriers to trade

Why establish a joint regulator?

- Closer Economic Relations (CER) Agreement -1983
- Trans Tasman Mutual Recognition Arrangement (TTMRA) -1998
 - Agreements seek to remove regulatory barriers and facilitate trade
 - Therapeutic goods exempted from TTMRA until closer cooperation arrangements agreed



The Australian and New Zealand Governments have.....

- Signed an Agreement in December 2003
- Made a commitment to progress the establishment of a single, world class therapeutic products regulatory agency, operating in both countries and administering a joint regulatory scheme



Primary Objective of the Agreement

To **safeguard public health and safety** in Australia and New Zealand by 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



ANZTPA

- Set up to administer the joint regulatory scheme in both countries
- Accountable to Governments and Parliaments of both countries
- A new type of agency (not a Crown Entity)
- Main offices in Canberra and Wellington



Overview



Governance of ANZTPA

Therapeutic Products Ministerial Council

- 2 members – the Australian and New Zealand Health Ministers
- Responsible for oversight of ANZTPA
- Appoint the Board and members of expert advisory committees
- Make Ministerial Council Rules

Governance of ANZTPA

5-member Board

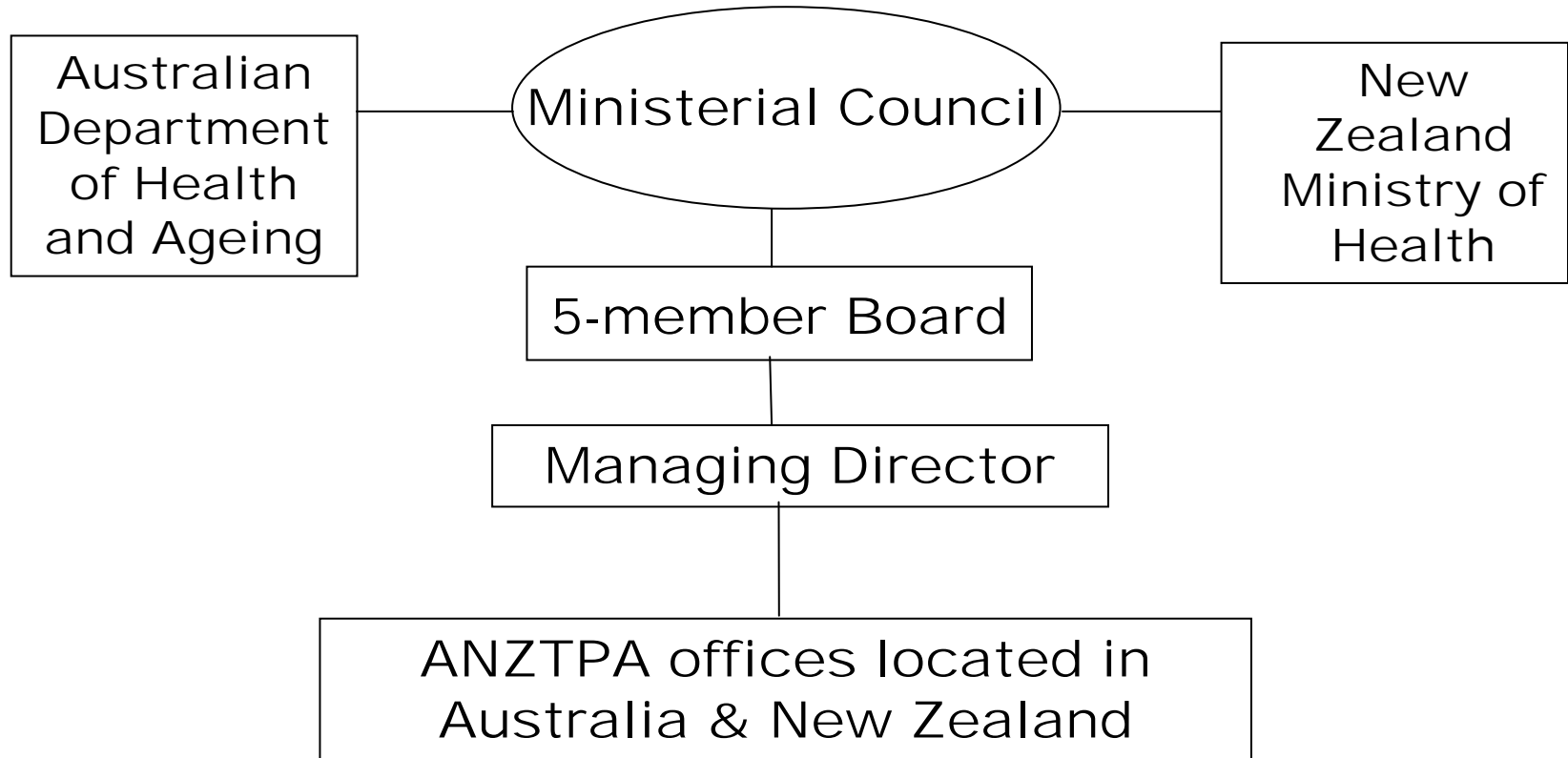
- Appointed by Ministerial Council
- Responsible for finance, effectiveness, strategic direction

Managing Director

- Member of the Board
- Regulatory decision-maker
- Responsible for management of ANZTPA
- Makes technical Orders (Managing Director's Orders)



Overview





Accountability

- Accountable to the Australian and New Zealand Governments and Parliaments
- No less accountable than a NZ Crown Entity (or an Australian Commonwealth Authority)
- Subject to the requirements of other legislation in both countries; e.g.
 - Official Information/Freedom of Information
 - Privacy
 - Ombudsmen
 - Auditor-General



Legal Instruments

- An Implementing Act in each country
 - Normal Parliamentary processes apply in each country
- Ministerial Council Rules
 - Disallowable by either Parliament
- Managing Director's Orders
 - Disallowable by either Parliament



Risk-based approach to regulation

Level of regulatory control applied depends on the type of product and level of risk associated with its use

Tools used

- Require products to be assessed before sale
- Apply standards
- Assess Manufacturers
- Place controls on advertising
- Monitor adverse reactions
- Conduct laboratory testing
- Set appropriate access restrictions through Scheduling
- Recall defective products
- Investigate complaints
- Provide supervised access to unlicensed therapeutic products

Exemptions

The focus of the joint scheme is on products produced for commercial supply.

ANZTPA will NOT regulate:

- Rongoa
- Practitioners (e.g. traditional healers, naturopaths)
- Cultivation of medicinal plants
- Personal imports

Resources

ANZTPA will:

- Have offices in Australia and New Zealand
- Use internal experts for auditing, review, testing and assessment
- Seek advice from expert advisory committees
- Use external experts for reviews, assessments and testing as required

Cost Recovery

Full cost of administering the joint regulatory scheme to be recovered through fees and charges paid by the regulated industry

Consultation Document

“Fees and Charges under the Australia New Zealand Therapeutic Products Regulatory Scheme”

- Sets out policy objectives for cost recovery
- Describes the cost base for ANZTPA
- Details fees and charges proposals
- Seeks views on fee options and potential impacts

Response forms available at www.anztpa.org

Cost Recovery Policy

Both the Australian and New Zealand Government have existing cost recovery policies:

- Cost recovery should be used where it is efficient
- Fees and charges should reflect the full cost of activities (and avoid cross subsidisation)
- Cost recovery arrangements should be cost-effective
- Must have appropriate legal authority
- Consult stakeholders during development
- Mechanisms for monitoring net cost recovery

Cost Recovery Policy

Our aims in designing fees and charges:

- Cost reflective (fees and licence charges)
- Equitable (avoid cross subsidisation)
- Incentives for timely evaluation
- Encourage compliance with Rules
- Cost efficient (and easy to understand)
- Predictability for industry budgeting



The Australia New Zealand Therapeutic Products Authority (ANZTPA)

Next Steps

Process

- New Zealand Bill introduced to Parliament. Public consultation occurs through Select Committee process
- Australian Bill exposure draft released for consultation prior to later commencement of Parliamentary process

Process

Following passage of legislation in both countries

- Treaty ratified
- ANZTPA and Ministerial Council established
- Managing Director and Board members appointed
- Rules and Orders signed and tabled in both Parliaments
- Rules and Orders come into effect
- Joint regulatory scheme commences

Process

Consultation on

- Draft Medicines Rule
- Draft Medical Devices Rule
- Key components of draft Administration Rule
- Consultation paper on fees and charges

closes 15 August 2006

Process

Phase 2 consultation on

- Draft Advertising Rule
- Draft Rule for Blood and Blood Components
- Remainder of draft Administration Rule

commences mid-September 2006

Process

- Phase 3 Consultation (eg. draft Orders) commences **March 2007**
- Consultation on draft Guidelines will occur **during 2006/07**

Summary overview

ANZTPA will NOT regulate:

- Rongoa
- Traditional healers
- Cultivation of plants

It will NOT impact on:

- The Wai 262 claim
- IP rights
- Te Tiriti o Waitangi



For further information....

Go to: www.anztpa.org

Email submissions and/or queries to:
consultation@anztpa.org



Question time