



The Trans Tasman Therapeutic Products Agency

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The Australian and New Zealand Governments have decided

- To create a single market for therapeutic products (including complementary medicines)
- To sign a Treaty to establish a joint scheme to regulate therapeutic products
- To establish a single regulatory agency to operate in both countries and administer the regulatory scheme



Why?

- **Emerging technologies**
- **Regional and international pressures and opportunities to strengthen collaboration and harmonise approaches**
- **CER / TTMRA**



What is CER?

- In March 1980 the concept of "closer economic relations" between Australia and New Zealand, to improve living standards and international competitiveness, was introduced in a joint communique issued by Prime Ministers Malcolm Fraser and Robert Muldoon.



What is CER?

- **The CER Agreement (Australia New Zealand Closer Economic Relations Trade Agreement also known as ANZCERTA) is a free trade agreement between Australia and New Zealand.**
- **It covers trans-Tasman trade in goods and services.**



AUSTRALIA NEW ZEALAND CLOSER ECONOMIC RELATIONS TRADE AGREEMENT

- Entry into force: 1 January 1983

The objectives of the Member States in concluding this Agreement are:

- (a) to strengthen the broader relationship between Australia and New Zealand;
- (b) to develop closer economic relations between the Member States through a mutually beneficial expansion of free trade between New Zealand and Australia;
- (c) to 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
- (d) to develop trade between New Zealand and Australia under conditions of fair competition.



What is the TTMRA?

ARRANGEMENT BETWEEN

- THE COMMONWEALTH OF AUSTRALIA
- THE STATE OF NEW SOUTH WALES
- THE STATE OF VICTORIA
- THE STATE OF QUEENSLAND
- THE STATE OF WESTERN AUSTRALIA
- THE STATE OF SOUTH AUSTRALIA
- THE STATE OF TASMANIA
- THE AUSTRALIAN CAPITAL TERRITORY
- THE NORTHERN TERRITORY OF AUSTRALIA

AND

- NEW ZEALAND

RELATING TO TRANS-TASMAN MUTUAL RECOGNITION



What is the TTMRA?

- The TTMRA was signed by the Prime Minister of Australia, State Premiers and Territory Chief Ministers at the meeting of the Council of Australian Governments (COAG) on 14 June 1996. It was subsequently signed by the Prime Minister of New Zealand on 9 July 1996.
- The scheme commenced operation on 1 May 1998 on the coming into force of legislation in Australia and in New Zealand.



What is the TTMRA?

Under the TTMRA:

- a good that may legally be sold in Australia may be sold in New Zealand; and
- a good that may legally be sold in New Zealand may be sold in Australia.



What is the TTMRA?

- **The purpose of the Arrangement is to give effect to a scheme implementing mutual recognition principles between the Parties relating to the sale of goods and the registration of occupations, consistent with the protection of public health and safety and the environment.**



Exceptions to the TTMRA

Special Exemptions

- therapeutic goods;
- hazardous substances, industrial chemicals and dangerous goods,
- electromagnetic compatibility and radiocommunications standards;
- road vehicles; and
- gas appliances.



Special Exemptions

- **Obligation to cooperate to remove the grounds for the exemption**
- **Last for 12 months only**
- **Extension periods need the agreement of two-thirds of the Heads of Government of the participating jurisdictions.**



Removal of the Special Exemption

The Special exemption can be removed in one of three ways:

- **Mutual Recognition**
- **Harmonisation**
- **Permanent Exemption**



Harmonisation

1999 - Australian and NZ Health Ministers agreed that harmonisation under a joint agency was likely to be the best approach.



Stakeholder Consultation

- **Stakeholder Consultation Papers were released in:**
 - **June 2000**
 - **December 2001**
 - **June 2002**



Where are we now?

- Treaty signed on 10 December 2003
- Treaty Tabled in both Parliaments
- August 2004 JSCOT supports the Treaty and recommends “binding action”
- NZ Government response to the Health Select Committee consideration supports the Treaty
- Interim Ministerial Council established
- Legislation is being drafted



Treaty Objectives

- Primary objective 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 quality, safety and efficacy or performance of therapeutic products and of their manufacture, supply, import, export and promotion.



The Agency

- Established as a body corporate under Australian legislation in accordance with the Treaty
- Function:
 - to administer the Scheme in Australia and New Zealand



Ministerial Council

- Australian and NZ Health Ministers
- Functions include:
 - oversight of the Agency
 - appointing the Board
 - making the common Rules
 - establishing and appointing expert committees
- Will be the decision making body for the establishment of the Agency



The Board

- Members:
 - Chair
 - Managing Director
 - New Zealander with public health and regulatory experience
 - Australian with public health and regulatory experience
 - person with commercial experience
- Appointed by the Ministerial Council
- Responsible for finance, effectiveness and strategic direction



Managing Director

- Chief Executive of the Agency
- Responsible for regulatory functions of the Agency
- Responsible to the Board for management of the Agency
- Makes technical Orders



Acts

- **Acts in each country**
- **Australian Act will establish the Agency**
- **Each Act will contain offences and penalties**
- **Each Act will contain provisions for imposing fees and charges**



Ministerial Council Rules

Rules include

- **Regulatory requirements**
- **Requirements for gaining approvals**
- **Definitions**
- **Some aspects of governance and accountability**



Managing Director's Orders

- **Orders will contain detailed technical matters such as labelling requirements**



Funding

- **Fees will recover full costs of the Agency's operations**
 - consistent with government cost recovery principles
- **Consultation with stakeholders on fees**



Scope of the Scheme

- **All medicines and medical devices**
 - including complementary medicines
- **Approvals relating to manufacture, supply, import, export, promotion**
- **Standards**
- **Post-market monitoring**
- **Enforcement**



What is New ?

- **Product licensing**
- **Decision making (by MD)**
- **Labelling**
- **Advertising**
- **Scheduling**
- **Class I and Class II medicines**
- **New definition of “complementary medicine”**
- **Regulation of IVDs**
- **Sole-traders**
- **Suspension of product licences**



Class I Medicines

Are low-risk medicines that:

- Contain permitted ingredients only;
- Do not contain scheduled ingredients;
- Are not required to be sterile;
- Do not carry indications that make an implied or direct reference to a serious disease, disorder or condition; and
- Do not carry indications that offer to treat, cure, prevent or manage a disease, disorder or condition unless specifically permitted.



Obtaining a Class I Medicine Product Licence

The applicant will be required to certify that:

- The medicine is a Class I medicine;
- The medicine is safe for its intended purpose;
- The applicant holds evidence to support any claim in relation to the medicine.



Current Status

- **Treaty signed on 10 December 2003**
- **First interim Ministerial Council meeting held on 12 December 2003**
- **Seventh meeting was scheduled for 31 August 2004**

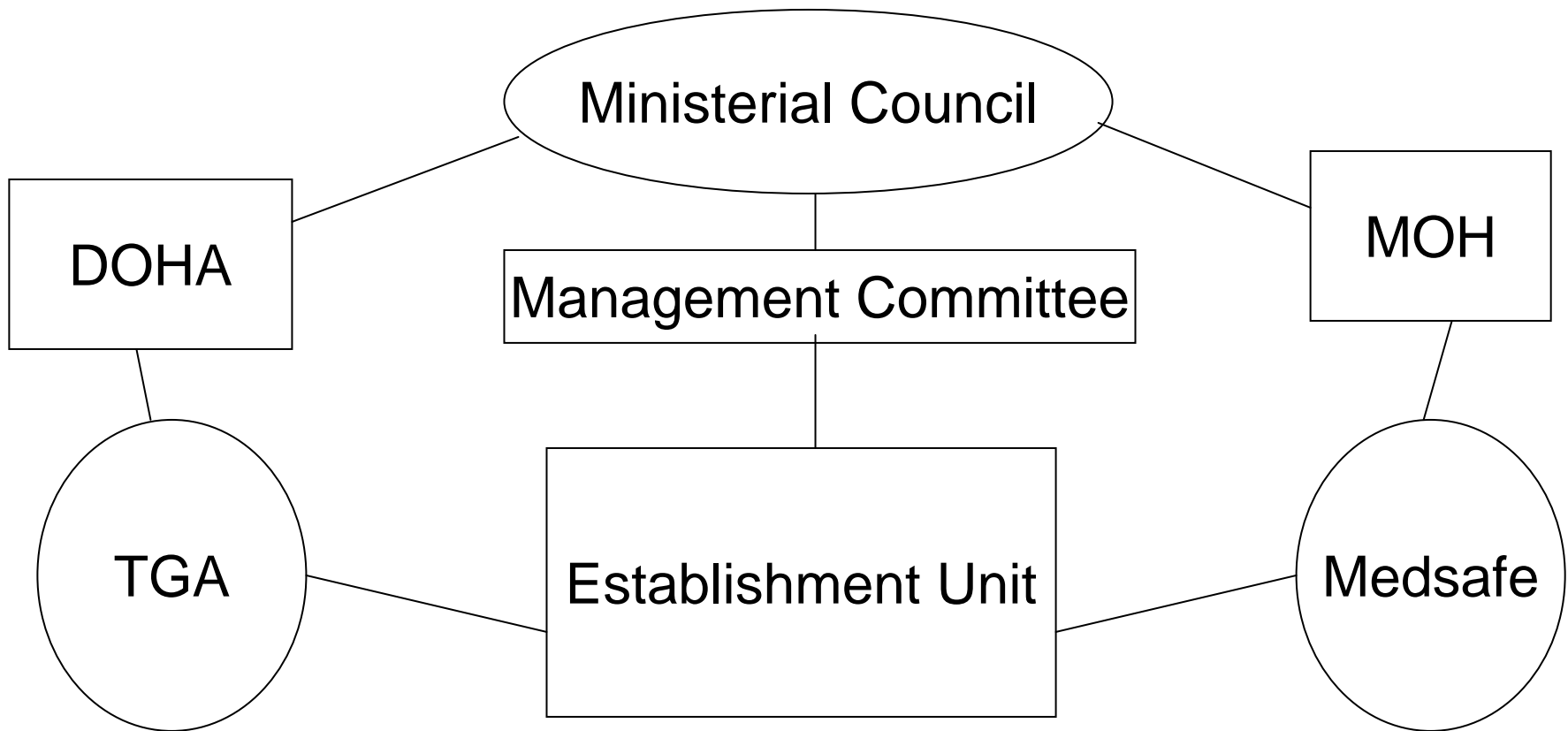


Next Steps

- **Exposure drafts of Aust and NZ bills**
- **Guide to regulatory requirements**
- **Rules prepared after stakeholders consulted**
- **Bills passed**
- **Treaty commences**
- **Agency opens doors**



Managing the Implementation





Transition Begins From 'Go-Live'

At start-up:

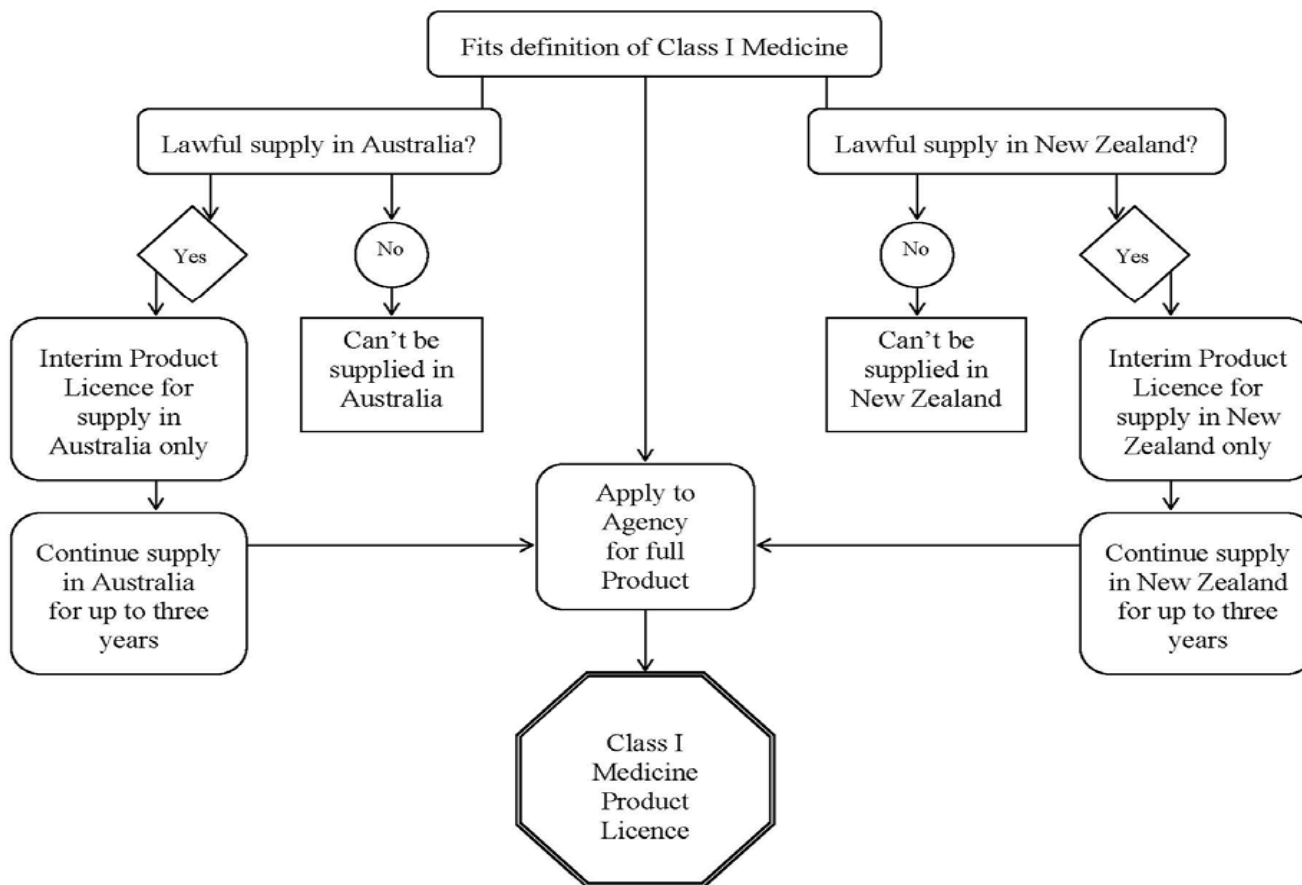
- Transitional approvals for continued supply of products legally on the market in Australia or NZ

During transition period:

- Full product licences (allowing supply in both countries) issued by the Agency when compliance with Agency standards demonstrated



Class I Medicines at Commencement





Class I Medicines During Transition

