



# The Australia New Zealand Therapeutic Products Authority

## Stakeholder Information Session Regulation of Complementary Medicines

**June 2006**

<b>Welcome</b>	<b>5 mins</b>
<b>Overview of ANZTPA and the Joint Regulatory Scheme</b>	<b>15 mins</b>
<b>Opening message from Ministers</b>	<b>10 mins</b>
<b>Regulation of Complementary Medicines</b>	<b>45 mins</b>
<b>Questions for the panel</b>	<b>20 mins</b>
<b>Cost recovery arrangements</b>	<b>20 mins</b>
<b>Questions for the panel</b>	<b>10 mins</b>
<b>Next Steps</b>	<b>10 mins</b>



## Presentation Outline

- Background to establishment of a joint therapeutic products regulatory scheme and agency
- The Agreement
- ANZTPA
- The joint regulatory scheme
- Cost recovery



## 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

## 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

## Objectives of the Agreement

### 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 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
- Main offices in Canberra and Wellington
- A new type of agency (not a Commonwealth Authority or Crown Entity)
- Accountable to Governments and Parliaments of both countries



# 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

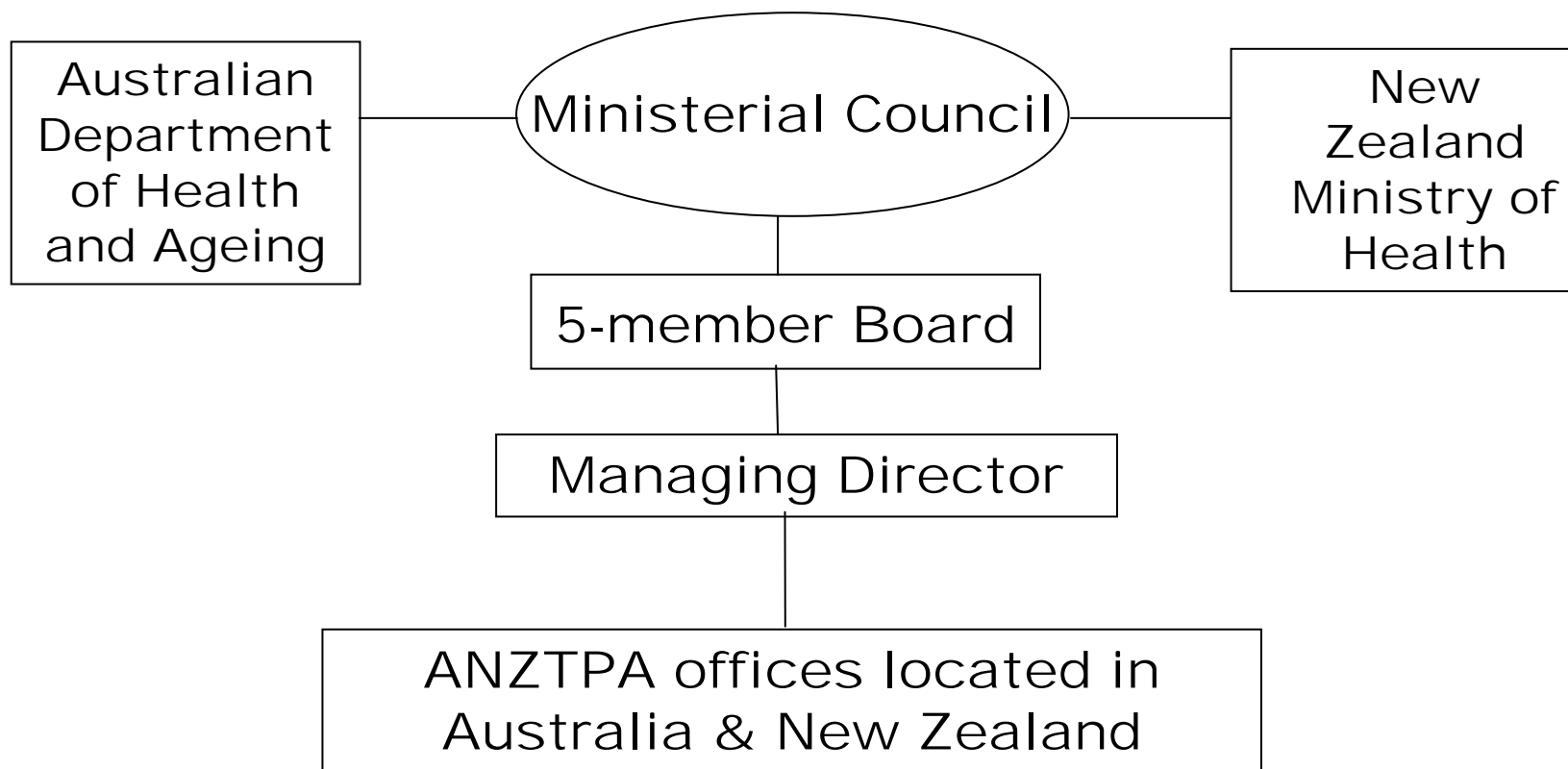
- Appointed by Ministerial Council
- Responsible for finance, effectiveness, strategic direction

### 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 an Australian Commonwealth Authority or a NZ Crown Entity
- Subject to the requirements of other legislation in both countries; e.g.
  - Official Information/Freedom of Information
  - Privacy
  - Ombudsmen



## 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

## 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

## 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

- Risk-based pre-market assessment
- Application of standards
- Manufacturing assessment
- Controls on advertising
- Pharmacovigilance requirements
- Laboratory testing
- Scheduling
- Recall and problem reporting schemes
- Access to unlicensed therapeutic products (including Special Access Scheme and Clinical Trials)

## 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



# The Australia New Zealand Therapeutic Products Authority

## Regulation of Complementary Medicines



## Presentation Outline

- Operation and functions of the Office of Complementary Medicines (OCM) within ANZTPA
- Proposed regulatory framework for complementary medicines
- Approach to standards for quality, safety and efficacy of complementary medicines

## The Office Of Complementary Medicines

### Operation

- separate operational area within ANZTPA with responsibility for the regulation of complementary medicines
  - one of three medicines regulators
- staff located in both Australia and New Zealand
- seamless operation

## Purpose

- provide a focus of expertise for the regulation of complementary medicines in Australia and New Zealand
- increase awareness and transparency of regulation
- work with stakeholders to ensure confidence in the regulatory framework and processes for complementary medicines

## Functions

- evaluate complementary medicines ingredients and products
- support the **Expert Advisory Committee on Complementary Medicines**
- advise Ministers, Ministerial Council, Managing Director, DoHA, MoH, and ANZTPA on complementary medicines matters
- consult and liaise with stakeholders

## Functions continued

- undertake post-market reviews
- maintain and support the electronic licensing system for Class 1 medicines (ELF)
- in consultation with stakeholders, maintain and develop regulatory guidance documents
- participate in international regulatory forums

## Expert Advisory Committee On Complementary Medicines

Australian and New Zealand experts appointed by Ministerial Council to advise on complementary medicines regulation:

Complementary medicine practice

Consumer issues

Herbal medicine

Nutrition and nutritional medicine

Pharmacology

Epidemiology

Manufacture of medicines

Medical practice

Naturopathy

Pharmacognosy

Toxicology

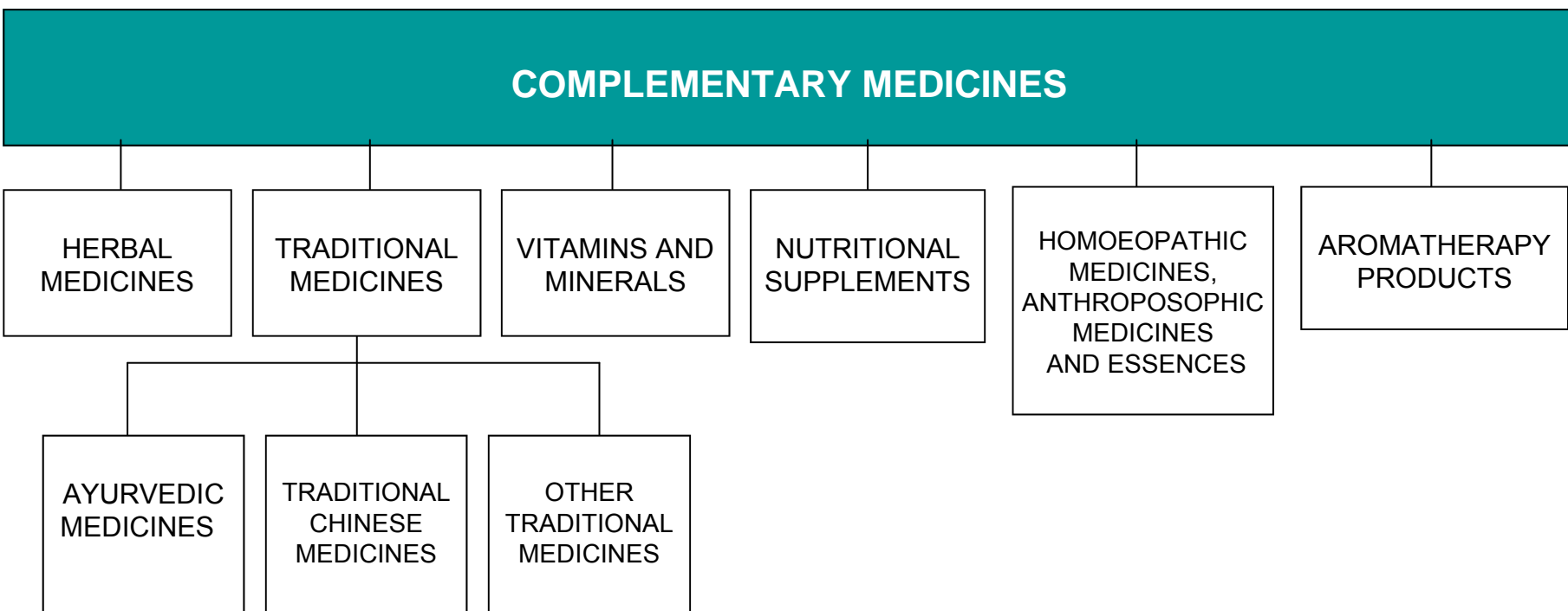
## Expert Advisory Committee On Complementary Medicines

Australian and New Zealand experts appointed by Ministerial Council to advise on complementary medicines regulation:

**May establish subcommittees  
for advice on specific matters**



# Complementary Medicines



## Regulatory Framework

### Risk-based approach to regulation

- applies a level of regulation commensurate with potential risks to public health and safety
- balance risks and potential benefits
- ensures consumers have sufficient and accurate information to select and use therapeutic products safely and effectively

## Regulatory Framework

- ANZTPA will regulate manufactured complementary medicines
- ANZTPA will not regulate dispensed or extemporaneously compounded complementary medicines
  - healthcare practitioners (eg naturopaths and homoeopaths) may prepare certain medicines for individual patients that will not require a Product or Manufacturing Licence
- ANZTPA will not regulate complementary healthcare practice or practitioners

## Regulatory Framework

### Codex Alimentarius

- The ANZTPA regulatory framework for complementary medicines will not be subject to standards and guidelines of the Codex Alimentarius Commission
  - **vitamin and mineral supplements under ANZTPA regulated as medicines**
    - not subject to Codex limitations

## Regulatory Framework

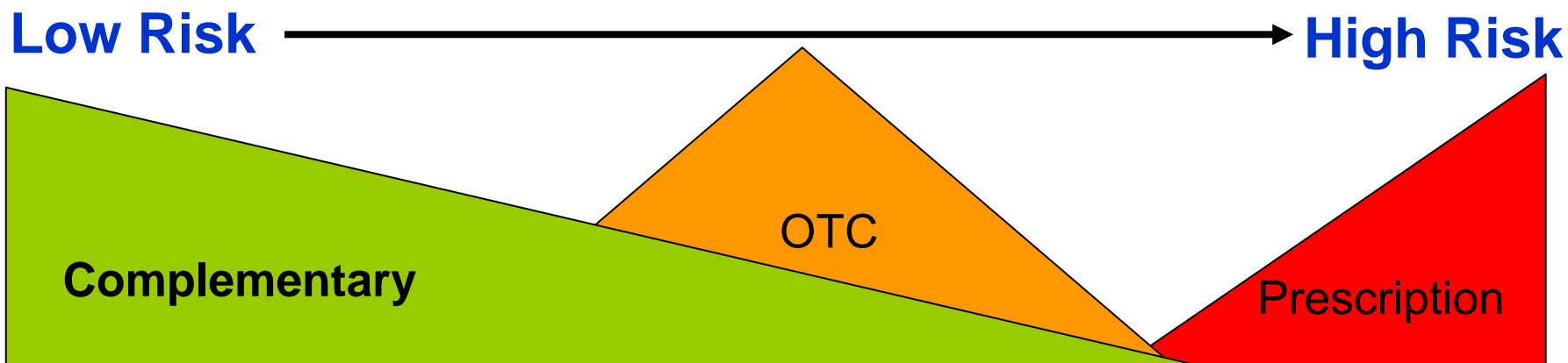
### Two-tiered regulatory system based on risk

- Level of regulatory control depends on risk
- Complementary medicines regulated as:
  - **Class 1 medicines (low risk) or**
  - **Class 2 medicines (higher risk)**

## Determinants of Risk

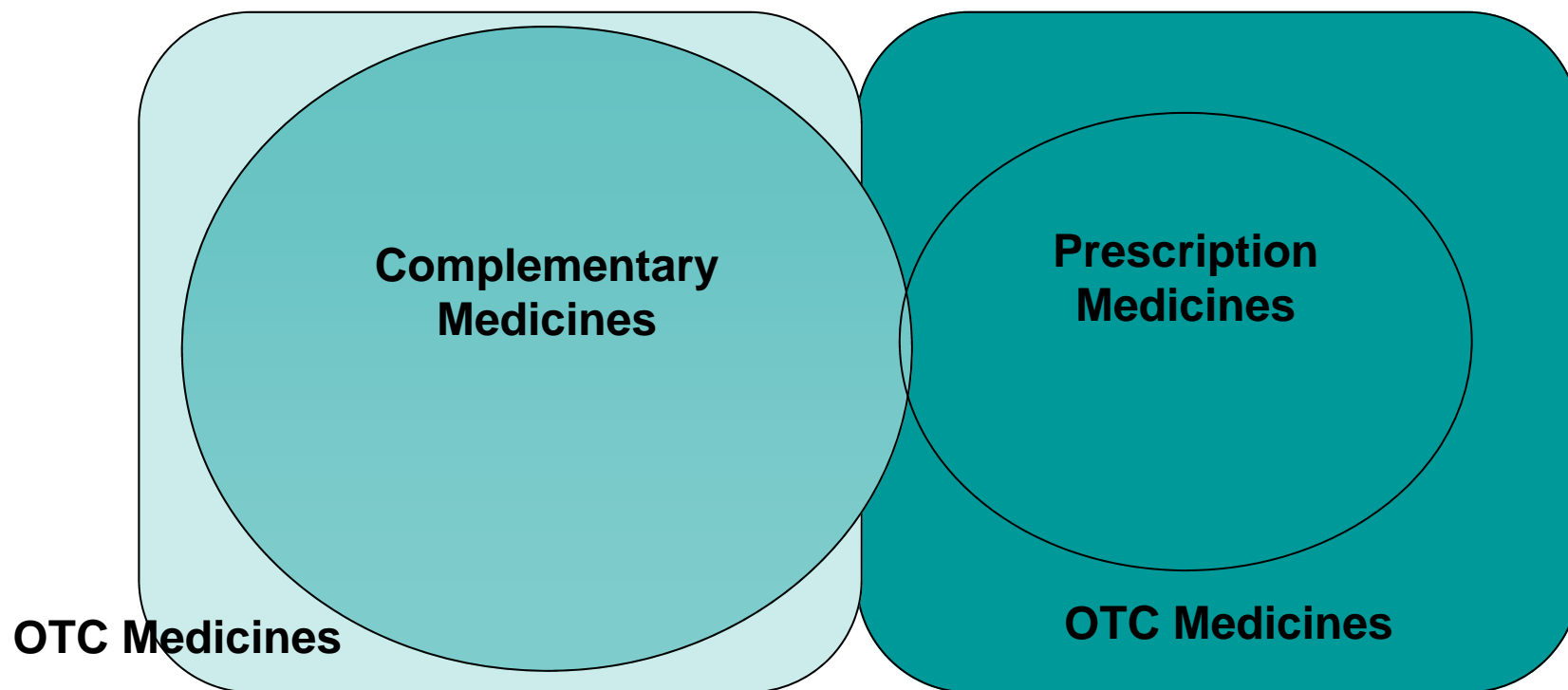
- Ingredients
- Indications and claims
- Dosage form
- Significance of side effects
- Effects of prolonged use or from inappropriate self-medication

## Medicines risk continuum



## Class 1 medicines

## Class 2 medicines



## Class 1 Medicines

### Are low-risk medicines:

- May contain ingredients selected from wide range of permitted Class 1 ingredients
- Not subject to restrictions on consumer access
- Have a level of pre-market assessment facilitating timely market access while providing assurance of quality and safety

## Class 1 Medicines

- Are not evaluated for efficacy prior to supply
- Indications and claims permitted include:
  - Reduction in risk or frequency of a disease/disorder
  - Aids/assists in managing symptoms/disease/disorder
  - Relief of symptoms
  - Health enhancement
  - Health maintenance, including nutritional support

## Class 1 Medicines – Indications

- May help reduce joint inflammation associated with arthritis (M)
- May assist peripheral circulation (G)
- May assist in the management of boils (M)
- Temporary relief of the cough of bronchitis (M)  
(Warning required)
- Relief of the symptoms of colds (M) (Warning required)
- Relief of mucous congestion (G) (Warning required)

## Class 1 Medicines – Indications

- Liver tonic. Aids digestion (G)
- Assists in the treatment of indigestion (M)
- Maintenance of healthy eyes (G)
- May assist in management of medically-diagnosed irritable bowel syndrome (M)
- May assist in the management of constipation (M)
- Temporary relief of headaches (G)

## Class 1 Medicines

- May be subject to restrictions such as:
  - dosage limit
  - routes of administration or dosage form
  - plant part or component, type of preparation, solvent, etc
  - label advisory statements
  - container type
- May not carry indications referring to serious diseases, disorders or conditions, unless specifically permitted

## Complementary Medicines Guidelines

- Provide guidance on the regulatory requirements and processes for Licensing Class 1 and Class 2 complementary medicines
  - enhances transparency
- Indicate minimum requirements to support quality, safety and efficacy

## Guidelines

### Recognise most complementary medicines:

- are low risk
- have a tradition/history of use
- active components often not known
- composition may be complex and variable
- indications and safety for Class 1 medicines may be scientific and/or traditional evidence

## Regulatory Framework

### Key elements of the regulatory scheme

1. Pre-market assessment of ingredients and licensing of products
2. Compliance with standards
3. Licensing and audit of manufacturers
4. Post-market regulatory activity

## 1. Pre-Market Assessment- Class 1 Medicines Ingredients

**Ingredients permitted to be used in Class 1 medicines  
evaluated for quality and safety**

- New ingredients: application to ANZTPA
  - Guidelines Part III – *Evaluation of Complementary Medicine Substances*
    - » Details evaluation process
    - » Characterisation, Quality and Safety
    - » Searching the literature, Critical evaluation

## 1. Pre-Market Assessment- Class 1 Medicines Ingredients

- Currently more than 2300 ingredients permitted to be used as active ingredients in Class 1 medicines  
[www.tga.gov.au/docs/html/listsubs.htm](http://www.tga.gov.au/docs/html/listsubs.htm)
- New Zealand Permitted Ingredients List (PIL) project
  - assist transition of New Zealand nutritional supplement sector to ANZTPA regulatory system
  - objective to evaluate a prioritised list of ingredients in New Zealand nutritional supplements not permitted in Listed (Class 1) medicines in Australia

## 1. Pre-Market Assessment- Class 1 Medicines Product Licensing

- Sponsor applies to ANZTPA via an electronic licensing facility (ELF) and certifies that the product meets all requirements for Class 1 medicines
- ELF electronically validates entered data complies with the requirements for Class 1 medicines
- Provides rapid approval for Class 1 medicines to be supplied in, or exported from, Australia and New Zealand

## 1. Pre-Market Assessment- Class 1 Medicines Product Licensing

**Sponsor Certification for Class 1 medicines via ELF includes:**

- The medicine is safe for the purpose for which it is designed to be used
- Each step in manufacture has been carried out by the holder of a licence to carry out that step
- The medicine complies with applicable quality and safety criteria
- The applicant holds evidence to support all claims

## 1. Pre-Market Assessment– Class 1 Medicines Evidence

- Risk-managed approach requires evidence commensurate with strength of promise to consumer and indication(s)
- Guidelines for determining type and level of evidence required to support indications/claims for Class 1 medicines
- Guidelines recognise scientific evidence and evidence based on traditional use suitable for supporting indications/claims for complementary medicines

## 1. Pre-Market Assessment- Class 1 Medicines Product Licensing

### Grouping Order:

- Facilitates transition from one product to another –whilst maintaining the unique product licence identifier

### Export Only Licence:

- Assessment is based on sponsor certification including that the product meets the requirements of the importing country



## 1. Pre-Market Assessment– Class 2 Medicines

- Medicines assessed as higher risk on medicines - risk continuum, individually evaluated for quality, safety and efficacy
- Separate, risk-based process and guidelines for Class 2 complementary medicines
- May be indicated for treatment, prevention, or management of serious diseases, disorders or conditions
- May be restrictions on consumer access

## Regulatory Framework

### Key elements of the regulatory scheme

1. Pre-market assessment of ingredients and licensing of products
2. Compliance with standards
3. Licensing and audit of manufacturers
4. Post-market regulatory activity

## 2. Compliance with standards

### Standards

- **Quality**
  - Ingredient and products
- **Labelling**
- **Packaging**

## Regulatory Framework

### Key elements of the regulatory scheme

1. Pre-market assessment of ingredients and licensing of products
2. Compliance with standards
3. Licensing and audit of manufacturers
4. Post-market regulatory activity

## 3. Licensing and Audit of Manufacturers

- Manufacturers to comply with the *Australian & New Zealand Code of GMP for Medicinal Products* to obtain a Manufacturing Licence
- Compliance ascertained by pre-licensing audits and thereafter by ongoing re-audits of manufacturers
- Each manufacturing site will require a separate licence; *status quo* for New Zealand, new for Australia
- **Office of Manufacturing Compliance** will be responsible for manufacturer licensing

## Office of Manufacturing Compliance

- GMP audit and practice consistency, transparency and increased collaboration with industry are paramount
- Improved interface with industry via Manufacturing Technical Expert Reference Groups (TERGs):
  - complementary medicine TERG
  - with Australia and New Zealand industry representation

## Regulatory Framework

### Key elements of the regulatory scheme

1. Pre-market assessment of ingredients and licensing of products
2. Compliance with standards
3. Licensing and audit of manufacturers
4. Post-market regulatory activity

## 4. Post-Market Regulatory Activity

Streamlined process for market access for Class 1 medicines supported by enhanced, risk-based post-market monitoring and review to provide assurance of quality, safety and effectiveness

## 4. Post-Market Regulatory Activity

### Risk-based approach includes:

- random and targeted desk-based audits of Class 1 medicines
- targeted laboratory testing of products and ingredients
- random and targeted surveillance in market place
- pharmacovigilance and monitoring of adverse reactions
- effective, responsive and timely recalls procedure

## Regulatory Proposals

### Consultation in Australia and New Zealand 2005:

- definitions and regulation of complementary, homoeopathic and anthroposophic medicines and essences

### New definitions & other provisions in Draft Rules

- followed further consultation with industry peak bodies, specialist groups and CMEC
  - **other matters in Managing Director Orders and Guidelines**

**Workshops to be held in Australia & New Zealand to explain details and address outstanding issues**

## Transitional Arrangements

### Product Licences

- Sponsors of therapeutic products included on the ARTG, with Ministerial consent in New Zealand, or otherwise lawfully supplied, will receive an interim product licence valid for a period of three years from the commencement of the joint regulatory scheme
- Interim product licences will be valid in either Australia or New Zealand (not both)
- Sponsors will have **3 years** from start of the joint regulatory scheme to obtain a full ANZTPA product licence, allowing supply in both countries

## Transitional Arrangements

### Manufacturing Licences

- Manufacturers previously licensed by TGA or Medsafe will receive an interim manufacturing licence that will be issued under the same terms and conditions as the existing licence
- Manufacturers will have **2 years** from the start of the joint regulatory scheme to obtain a full ANZTPA manufacturing licence

## Transitional arrangements

### Manufacturing Authorisations

- Lawful manufacturers not previously licensed by TGA or Medsafe will be deemed to have an interim manufacturing authorisation valid for 3 years
- These manufacturers will have **2 years** from the start of the joint regulatory scheme to apply for a full ANZTPA manufacturing licence
- Products manufactured under a deemed interim manufacturing authorisation are not eligible for a full ANZTPA product licence

## Transitional Arrangements

### Other Provisions

- Upon commencement of the joint scheme:
  - products
  - persons
  - activitiesthat were exempt from regulatory requirements under Therapeutic Goods Act or Medicines Act will continue to be exempt for the duration of the transition period
- At the end of the transition period, if the joint scheme no longer exempts the products, persons or activities, then compliance with the relevant requirement will need to be demonstrated



## Summary

- A specialist Office of Complementary Medicines will be established within ANZTPA
- Low risk of most complementary medicines recognised
- The nature of complementary medicines recognised
- The OCM receives complementary medicines advice from expert committees and advisers and from industry, academia, consumers and practitioners through consultation
- Framework underpins a level playing field

## Conclusion

The establishment of ANZTPA provides an opportunity for all stakeholders to have input into the development of a new regulatory system for complementary medicines

More information: <http://www.anztpa.org>



## Questions for the Panel



# The Australia New Zealand Therapeutic Products Authority (ANZTPA)

## Cost Recovery

# Cost Recovery Arrangements

## Outline of presentation

- Consultation document
- Cost Recovery Policy
- Fees and charges design
  - Key assumptions
  - Fees and charges proposals

## 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](http://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

### Article 15 of the 2003 Agreement:

- Fees and charges may be levied by the Agency
  - designed to recover costs in an efficient and equitable manner
  - incentives for efficient determination of applications
  - comply with principles or requirements in the Rules
- Ministerial Council Fees and Charges Rule
  - Board to consult with stakeholders first
  - Ministers' agreement to the fee schedule

## 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

## Cost Recovery Policy

### Design of Fees and Charges:

- Application and processing fees
- Evaluation and assessment fees
- Manufacturer auditing fees
- Certificate fees
- Annual charges

## Assumptions

### Licence and activity volumes

- Companies only need to submit one application, and will only need to hold one licence per product.
  - Fewer annual applications than TGA/Medsafe combined
  - Conservative assumptions for NZ complementary medicines and medical device volumes
  - Extent of interim licences for similar/same products
  - Rates of transition to full licences over three years
- Assumptions ‘tested’ with industry associations

## Cost Base

Financial targets for cost recovery based on ANZTPA forecasts

- Take account of current TGA and Medsafe costs
- Full regulatory operations in both countries
- Formation of Board and Joint committees
- Expected efficiencies in evaluation effort and corporate costs
- Transitional costs over three years to grant full licence

## Cost Recovery Proposals

### General cost recovery issues

- Same fees – adjusted for currency exchange
- Common pricing points and rounding of fees
- Performance linked fees
- Administration (refunds, instalment payment)
- Arrangements for unlicensed and orphan therapeutic products

# Cost Recovery Proposals

## Annual Licence Charges

- Charges to reflect cost of post-market monitoring, adverse events reporting, recalls and maintaining the regulatory scheme
- Apply to all licences issued (interim and full)
- No charge in first year of approval
- Separate charge for products ‘yet to be supplied’
- Low product turnover arrangements

# Cost Recovery Proposals

## Manufacturing Audits

- All sites required to hold a licence
- Proposals to implement a fee per audit
  - Reflect the size and scale of operations and complexity of manufacturing
  - Consistent fees for domestic and overseas audits
- No annual charge for manufacturing licence
- Pre-clearance fees for overseas certification to be cost reflective

# Cost Recovery Proposals

## Transition

- Fees paid on applications in progress at the commencement of the scheme may be transferred to an application for an ANZTPA product licence
- All products legally supplied before commencement will be issued an interim licence and will be liable for an annual licence charge
- No transfer fees for obtaining an ANZTPA product licence unless an additional evaluation or assessment is required (eg. medical device conformity)

## Cost Recovery Proposals

### Fee proposals - Class 1 medicines

#### Pre market fees

- Fee for product licence applications lodged electronically
- Set evaluation fee for new substances (ingredients)
- Annual licence charge to reflect the cost of monitoring and testing and the excess cost of evaluating new substances

## Closing remarks

Indicative fees for each product sector are set out in the consultation paper.

- Set in Australian dollars
- 2005-06 prices (for comparability)
- Exclude GST

Joint Agency Establishment Group is seeking views:

- Assess the fee proposals
- Assess the potential impact for your business
- Send your comments and suggestions
- Response forms available at [www.anztpa.org](http://www.anztpa.org)



# Questions for the Panel



# 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**



## For further information....

Go to: [www.anztpa.org](http://www.anztpa.org)

Email submissions and/or queries to:  
[consultation@anztpa.org](mailto:consultation@anztpa.org)