



The Australia New Zealand Therapeutic Products Authority

Stakeholder Information Session Regulation of Prescription and Over the Counter Medicines

June 2006



Programme

Welcome	5 mins
Overview of ANZTPA and the Joint Regulatory Scheme	15 mins
Opening message from Ministers	10 mins
Regulation of Prescription and Over the Counter Medicines	45 mins
Questions for the panel	20 mins
Cost recovery arrangements	20 mins
Questions for the panel	10 mins
Next Steps	10 mins



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

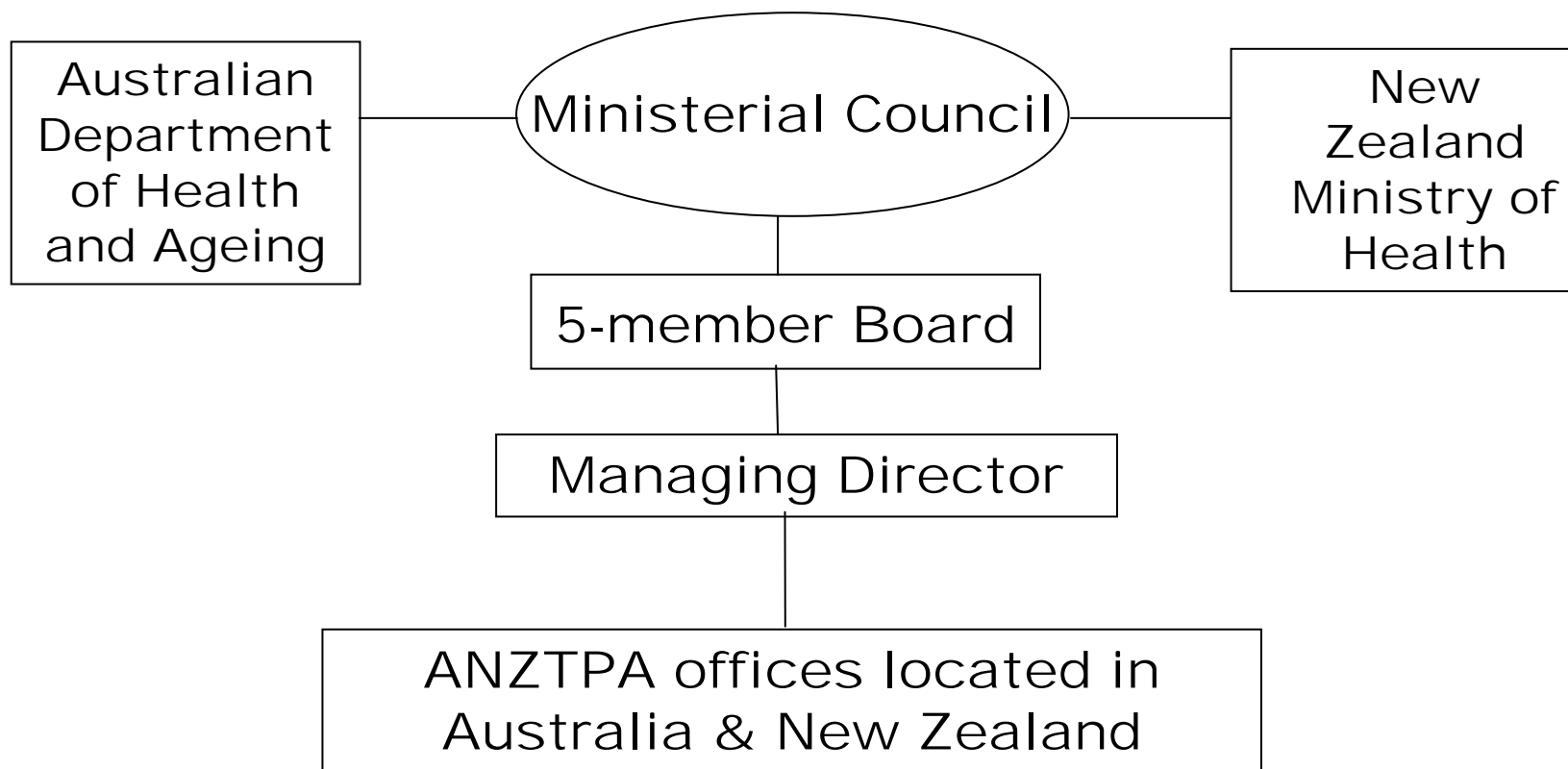
- Appointed by Ministerial Council
- Responsible for finance, effectiveness, strategic direction

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 (ANZTPA)

Regulation of Prescription and Over the Counter Medicines

Presentation Outline

- General overview
- Risk classification of medicines
- Product licensing
- Manufacturing assessment
- Pharmacovigilance and post-market regulatory activities
- Transition to the joint regulatory scheme



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Prescription & OTC Medicines



General Overview

Consistent with international best practice ANZTPA will regulate

- the quality, safety, and efficacy or performance of therapeutic products
- the manufacture, supply, import, export and promotion of therapeutic products

Key elements of the regulatory scheme

- Audit and licensing of manufacturers
- Pre-market assessment and licensing of products
- Post-market regulatory activities



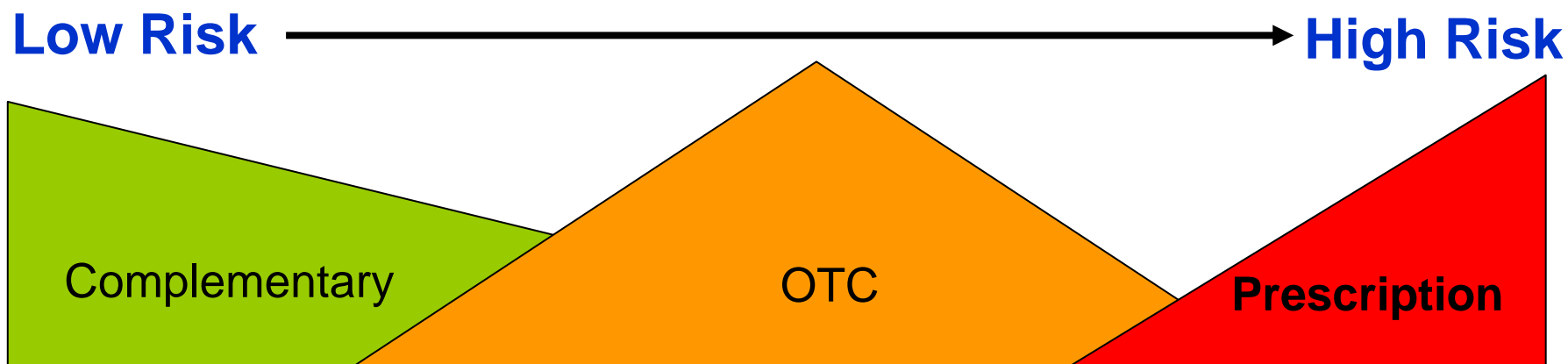
Risk Classification of Medicines

**Applying appropriate regulation
based on risk**

Determinants of risk

- Ingredients (e.g. toxicology, biological activity, history/patterns of use, adverse reactions)
- Dosage form and/or route of administration
- Indications/claims and potential for inappropriate self medication
- Significance of side effects and/or effects of prolonged use

Medicines risk continuum



Tiered regulatory system based on risk

Medicines regulated as

- **Class 1** medicine (low risk)

or

- **Class 2** medicine (higher risk)



Class 1 Medicine

- **Ingredients** must be pre-approved, low risk, unscheduled and may be subject to restrictions (e.g. dosage, route of administration, type of preparation)
- **Claims** restricted to non-serious and self-limiting conditions and appropriate label advisory statements
- **Electronic lodgement** and checking of applications
- Sponsors **certify** they hold required evidence of efficacy and product meets all Class 1 medicine criteria
- Random **post-market audit** by ANZTPA

Class 2 Medicine

- Products **individually evaluated** for quality, safety and efficacy
- Separate **risk-based regulatory processes and guidelines** for Class 2 prescription medicines, OTC medicines and complementary medicines
- Separate **expert advisory committees** for complementary medicines, OTC medicines and prescription medicines



Australian Government
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Prescription & OTC Medicines



Product licensing

OTC Medicines

Characteristics

- Suitable for self-treatment of minor ailments or symptoms capable of being self-monitored
- Usually a long history of safe use with a low incidence of adverse effects, no significant drug interactions and high therapeutic index
- Normally low potential for abuse/misuse

OTC Medicines

- **NOT** a complementary medicine or cosmetic
- May be “General Sale”, “Pharmacy only ” or “Pharmacist only” medicines
- Label or pharmacist is primary source of information with minimal or no involvement of doctor
- Often extensively advertised to the public

OTC Medicines

Examples:

- Common analgesics
- Cough and cold remedies
- Topical antifungals and antivirals
- Topical hair loss treatments
- Antiseptics
- Emergency contraception

OTC Medicines

Product licence application requirements

- For well-documented active ingredients, further information on safety and efficacy not required
- Clinical data usually only required for new substance, indications, dose, dose form or modified release

OTC Medicines

Product licence application requirements

- DMF not required and manufacturing process validation data only evaluated for higher-risk OTC products
- GMP not required for active ingredients (manufacturer responsible for quality of starting materials)

OTC Medicines

Product licence application requirements

- Data sheet (PI) and CMI required for “pharmacist only” but **not** for “pharmacy only” medicines

Product licence granted subject to conditions

Prescription Medicines

- Pre-market evaluation of quality, safety and efficacy by ANZTPA
- Data requirements based on international standards (e.g. CTD)
- Use of ICH guideline documents (as published by CHMP)
- Abridged applications in certain circumstances

Prescription Medicines

- Evidence of bioequivalence required for all generic medicines
- Scheduling considered during pre-market evaluation
- Product licence granted subject to conditions (may include conditions specific to a particular product)

Prescription Medicines

Orphan therapeutic products scheme available

Exemption from product licensing for medicines used:

- in clinical trials
- under special access arrangements



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Prescription & OTC Medicines



Manufacturing Assessment

Office of Manufacturing Compliance

- Responsible for manufacturer licensing
- Auditors based in Wellington, Adelaide, Melbourne, Sydney and Canberra operating under a single quality management system
- Audit teams specialising in particular product types to enhance consistency and audit practice

Office of Manufacturing Compliance

- Improved interface with industry via expert reference groups (**Manufacturing TERGs**) with Australian and New Zealand industry representation
- Focus on GMP audit and practice consistency, transparency and increased collaboration with industry

Audit and licensing of manufacturers

- Medicine manufacturers required to comply with *Australia New Zealand Code of GMP for Medicinal Products* in order to obtain a manufacturing licence
- Separate licence required for each manufacturing site

Audit and licensing of manufacturers

- Initial compliance ascertained through pre-licensing audits
- Ongoing re-audits of manufacturers to ensure continued compliance



Prescription & OTC Medicines

Pharmacovigilance and post-market regulatory activities

Risk-based approach

Post-market activities include:

- Desk-based audits of Class 1 medicines
- Pharmacovigilance and monitoring of adverse reactions
- Laboratory testing programme
- Ongoing audits for compliance with GMP

Risk-based approach

- Effective, responsive and timely recalls procedure
- Product problem reporting and investigation
- Surveillance in the market place
- Controls on advertising



Prescription & OTC Medicines

Transition to the joint regulatory scheme

Transition

Product licences

- Sponsors of therapeutic products
 - included on the ARTG
 - with Ministerial consent in New Zealand
 - otherwise lawfully supplied

will receive a transitional approval in the form of an Interim Product Licence

Product licences continued

- 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

Transition

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



Prescription & OTC Medicines

For further 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

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
- 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

Cost Recovery Proposals

Fee proposals - Class 2 medicines

- Pre market fees based on a fee for service
 - Evaluation of new chemical entities, generic products and/or clones
 - Evaluation and processing of variations to licences
 - Certifications/evaluations for clinical trials
- Annual licence charges for prescription biologics, prescription non-biologics and non-prescription medicines reflect the cost of monitoring and testing

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



Questions for the Panel



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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

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