



The Australia New Zealand Therapeutic Products Authority

Stakeholder Information Session Regulation of Medical Devices

June 2006

Welcome	5 mins
Overview of ANZTPA and the Joint Regulatory Scheme	15 mins
Opening message from Ministers	10 mins
Regulation of Medical Devices	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

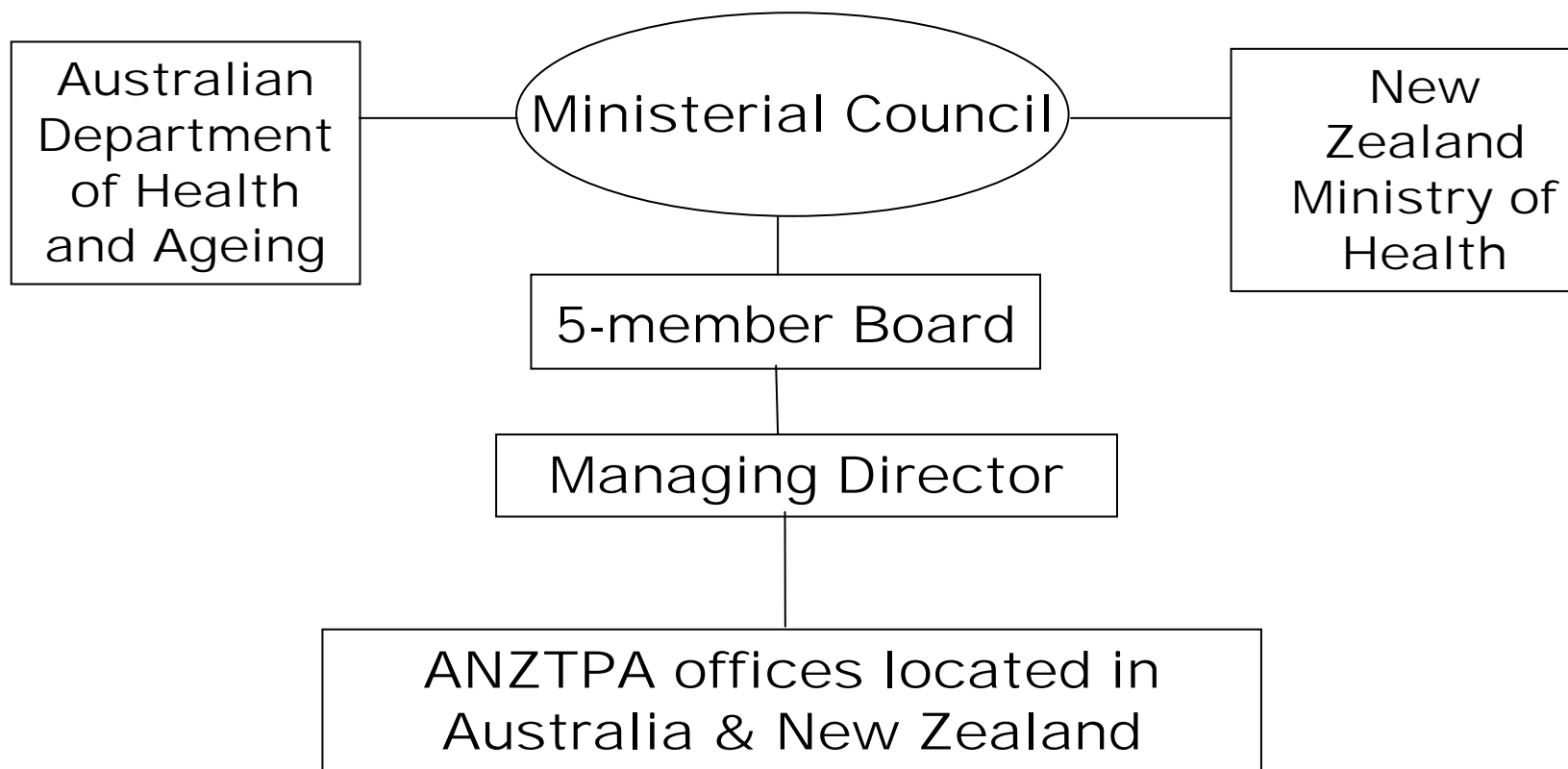
- Appointed by Ministerial Council
- Responsible for finance, effectiveness, strategic direction

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 Medical Devices

Presentation Outline

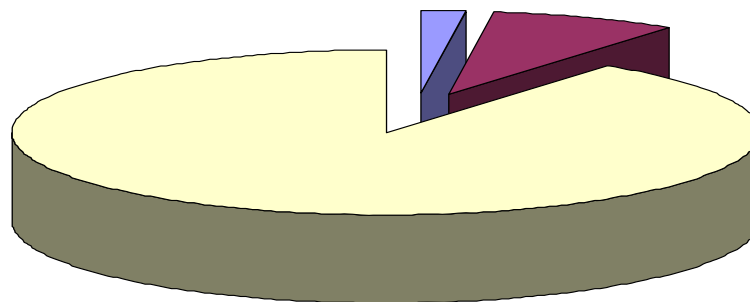
- **Key deliverables**
- **Key concepts**
 - Scope
 - GHTF Model
- **Key players and roles**
- **Key elements of the framework**
 - Essential Principles
 - Classification
 - Standards
 - Conformity Assessment
 - Product licensing
 - Post-market Monitoring
 - Expert Advisory Committee on Medical Devices
- **Transition arrangements**

Key Deliverables

- Risk based regulation of medical devices is based on a globally harmonised model:
- 90% of applications are expected to be approved in around 20 days for low to medium risk devices
 - Export Only products are self certified
 - ANZTPA conformity assessments will open up key overseas markets
 - ANZTPA recognition of MRA / MOU partners will reduce regulatory burden



Conformity Assessment - ~2% Application Audit - ~8%



Licence issued without further review - ~ 90%

What will the proposed scheme mean for manufacturers and suppliers?

- Importers
- Exporters
- Manufacturers

Key concepts

Export only devices - self certified, 5 days

Imported CE Marked devices – about 90%

- Class I, around 10 days
- All classes with MRA certificates, around 5 days
- Non-MRA applications require manufacturer's evidence to be approved prior to product application, around 20 days

Imported CE Marked devices for review – about 8 % ('application' audit) of prescribed devices, 30 – 60 days depending on risk class

Conformity assessments - about 2 %

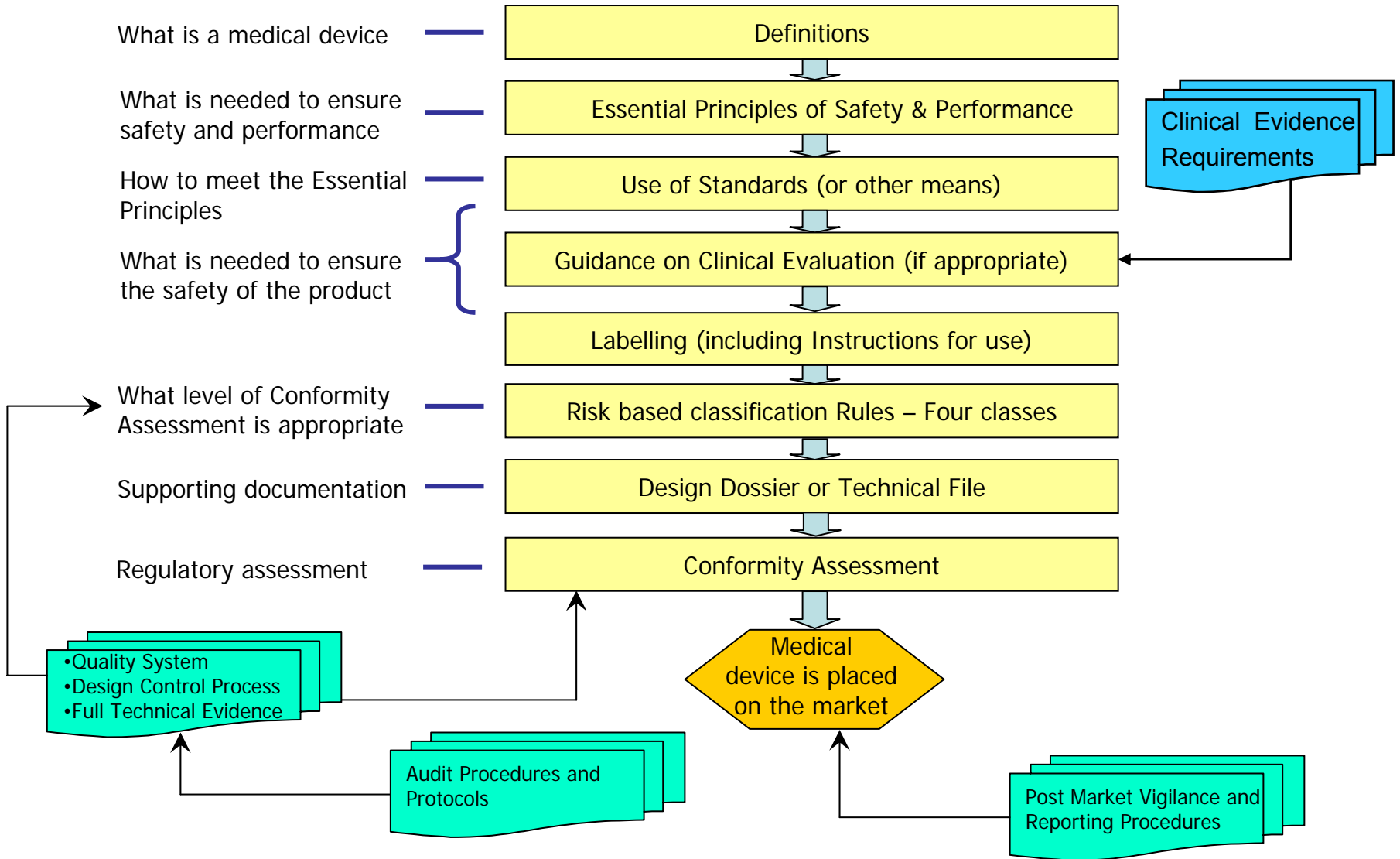
- Following application acceptance, manufacturer audit and product approval, 60-90 days, and for Class III / AIMD additional 60 days if device requires review by expert committee.

The regulatory model

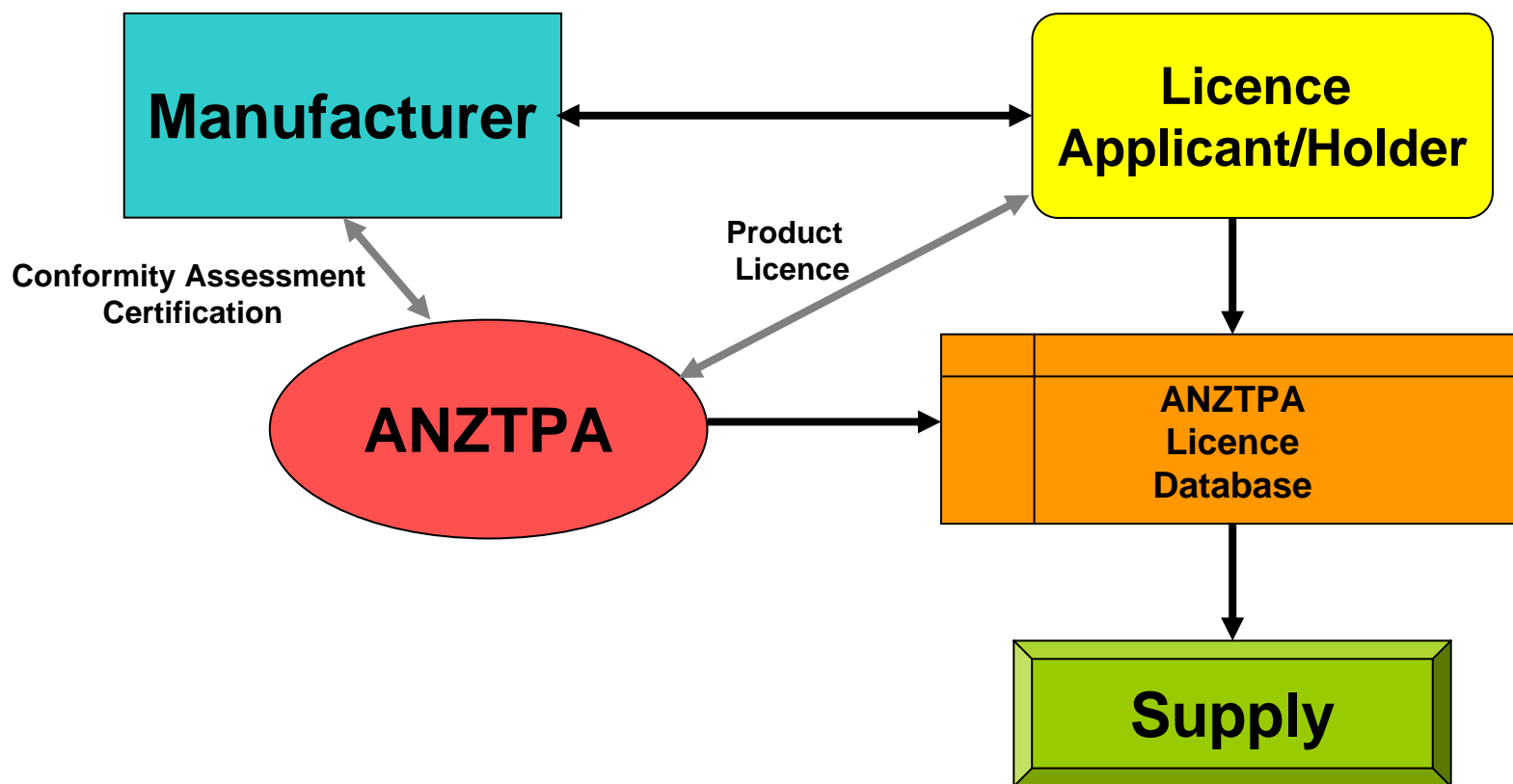
- Based on GHTF principles
 - GHTF is a forum of regulators and industry associations from the EU, USA, Canada, Japan and Australia, established in 1992
 - Objective is the convergence of regulatory requirements to reduce duplication,
- Utilises Mutual Recognition Agreements with EU/EFTA countries
- Will utilise MoU with Canada on manufacturer Quality Systems

GHTF Model

Pre-market Technical Requirements



Key players and roles



Key players and roles

Manufacturer

- Must show products conform to safety and performance principles (the Essential Principles) by:
 - ensuring initial and on-going conformity (using Conformity Assessment Procedures aligned with those in the EU)
 - meeting quality management system requirements as appropriate
 - meeting post-market monitoring, adverse event investigation and reporting requirements

Licence Applicant/Holder

- Applies for ANZTPA Product Licence
 - submits the manufacturer's evidence of conformity for all devices except Class I
 - certifies that a manufacturer has met their obligations
- Establishes and maintains information flows to and from the manufacturer
- Accepts responsibility for the supply of product in joint market

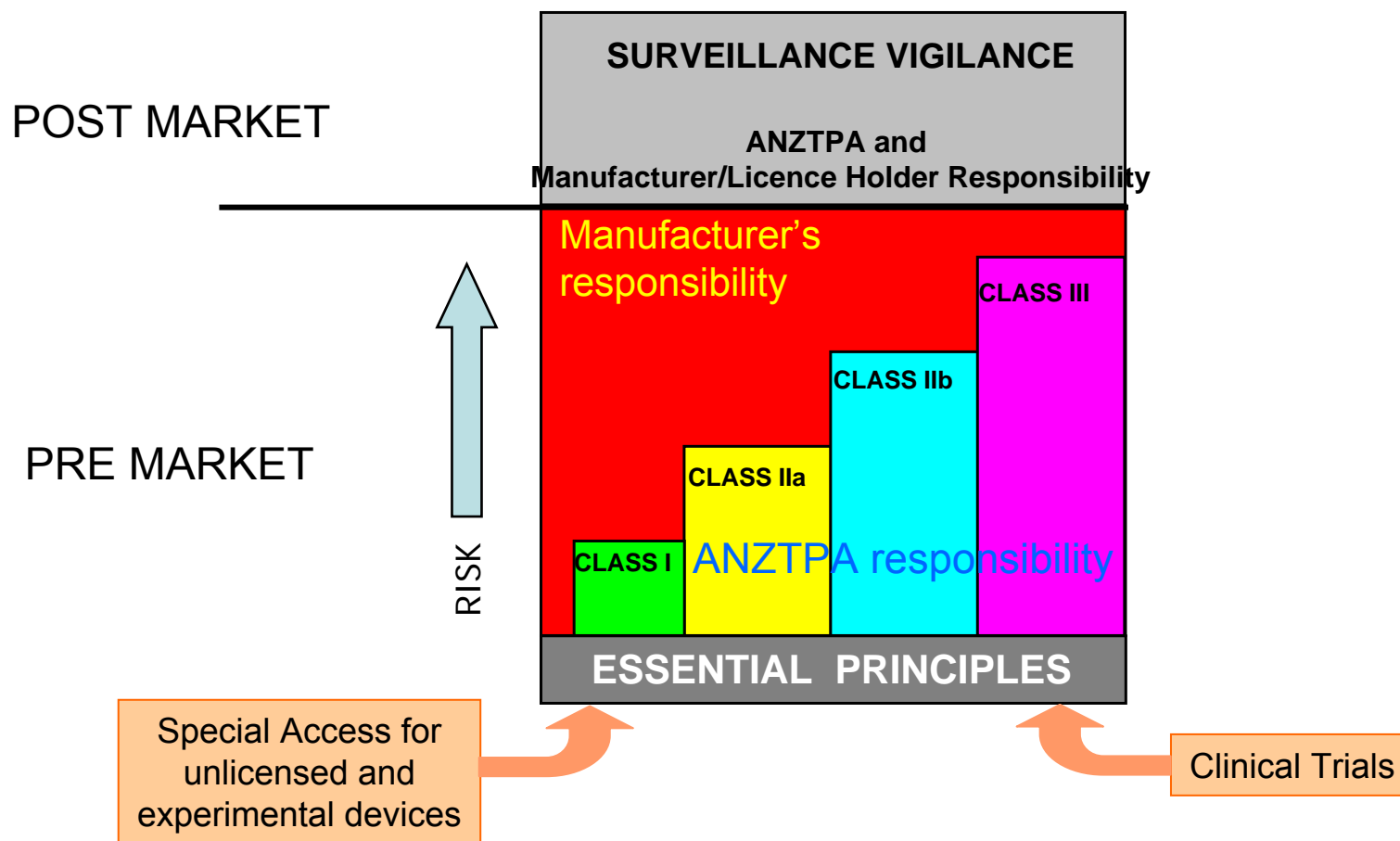
ANZTPA

- Issues conformity assessment certificates to manufacturers
- Undertakes
 - abridged pre-market assessments ('application audits') for lower risk devices, and
 - conformity assessment on prescribed higher risk devices
- Issues product licences
- Seeks independent expert advice
- Provides special access scheme for unlicensed and experimental devices

ANZTPA (cont'd)

- Sets standards (e.g. advertising and labelling)
- Undertakes post-market reviews for low to medium risk devices (imported products)
- Undertakes investigation of adverse event reports
- Co-ordinates recalls
- Enforces the regulatory scheme
- Suspends and/or revokes conformity assessment certificates and product licences

Key players and roles

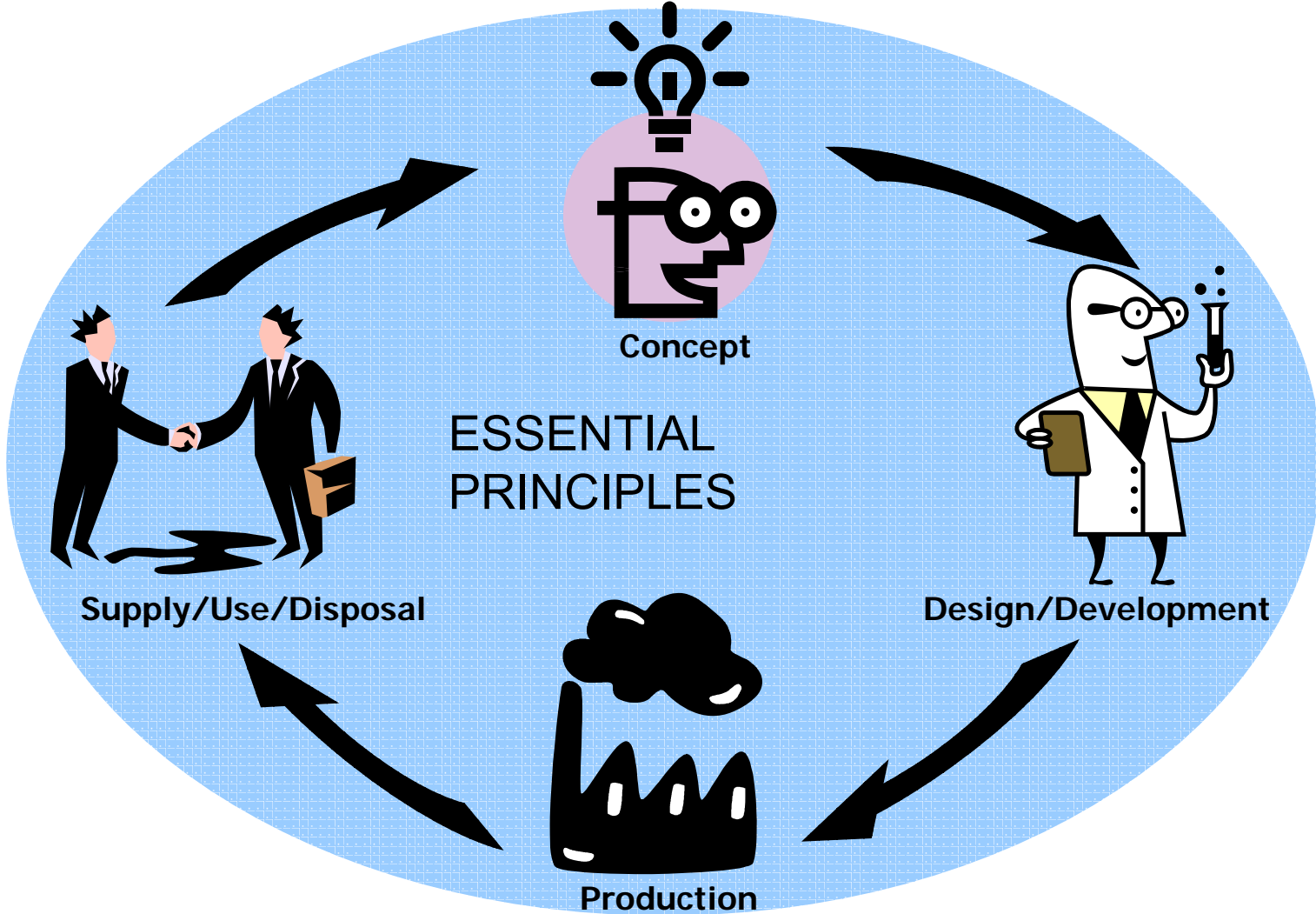


Key elements of the Framework

- Essential Principles
- Product Classification
- Standards
- Conformity Assessment Procedures
- Post market surveillance



Medical Devices



Essential Principles for quality, safety and performance

General principles – apply to all devices

- Risks vs benefits are acceptable
- Take account of generally acknowledged state of the art
- Apply the following principles when selecting design solutions
 - inherent safe design
 - fail safe mechanisms
 - document the residual risk

Essential Principles for quality, safety and performance

General principles – cont'd

- Devices must achieve the intended performance
- Devices must not be adversely affected by normal conditions of use
- Devices must not be adversely affected by transport and storage

Essential Principles for quality, safety and performance

Principles for Specific Devices

- Chemical, physical & biological properties
- Infection & microbial contamination
- Construction and environmental function
- Protection against radiation
- Devices with a measuring function
- Devices supplied sterile
- Devices connected to or equipped with an energy source
- Information supplied by the manufacturer
- Clinical evidence

Classification

- Defines the level of conformity assessment
- Based on:
 - the manufacturer's intended use
 - a set of risk criteria (to the patient, the user, the environment)
 - the relationship between the device and its application to the body
- Classification rules accommodate new technology

Classification

- Class III & AIMD (high risk)
- Class IIb (medium risk)
- Class IIa (medium risk)
- Class Im & Is (low risk, but sterile or measuring function)
- Class I (low risk)

Classification

- **General Rules based on**
 - **Duration of use**
 - transient < 1 hour
 - short term < 30 days
 - long term > 30 days
 - **Degree of invasiveness**
 - non-invasive
 - through body orifices
 - surgically invasive
 - Implantable
 - **Presence (or otherwise) of an energy source**

Classification

Special rules

- For recording X-ray images class IIa
- Disinfectants and sterilants class IIb
- Contact lens cleaning solutions class IIb
- Contraceptive or for prevention of STDs class IIb
- Blood bags class IIb
- Incorporating a medicine class III
- Animal origin class III
- Microbial/recombinant origin class III
- Active implants AIMD

Standards

- Standards are not mandatory
 - but they are the foundation of the framework
- Recognised national / international standards eg, ISO, IEC, EN, AS, NZS adopted through
 - product Medical Device Standards Orders (MDSO) mapped to relevant Essential Principles;
 - compliance with MDSO deems compliance with relevant elements of Essential Principles
 - manufacturing Conformity Assessment Standards Orders (eg, CASO for QMS - ISO 13485)

Conformity Assessment

- The process the manufacturer follows to show compliance with essential principles and other regulatory requirements
- Procedures are flexible and dependant upon the product type and experience of the manufacturer:
 - Use of appropriate Quality Management System or
 - Type Testing
- The process conclusions are subject for review by the Authority

Conformity Assessment

Manufacturer

- Provides a Declaration of Conformity that
 - the product(s) complies with the applicable Essential Principles
 - the appropriate conformity assessment procedure has been followed
- Notifies the Authority of changes to QMS (including scope)
- Undertakes post market monitoring of devices
- Keeps records

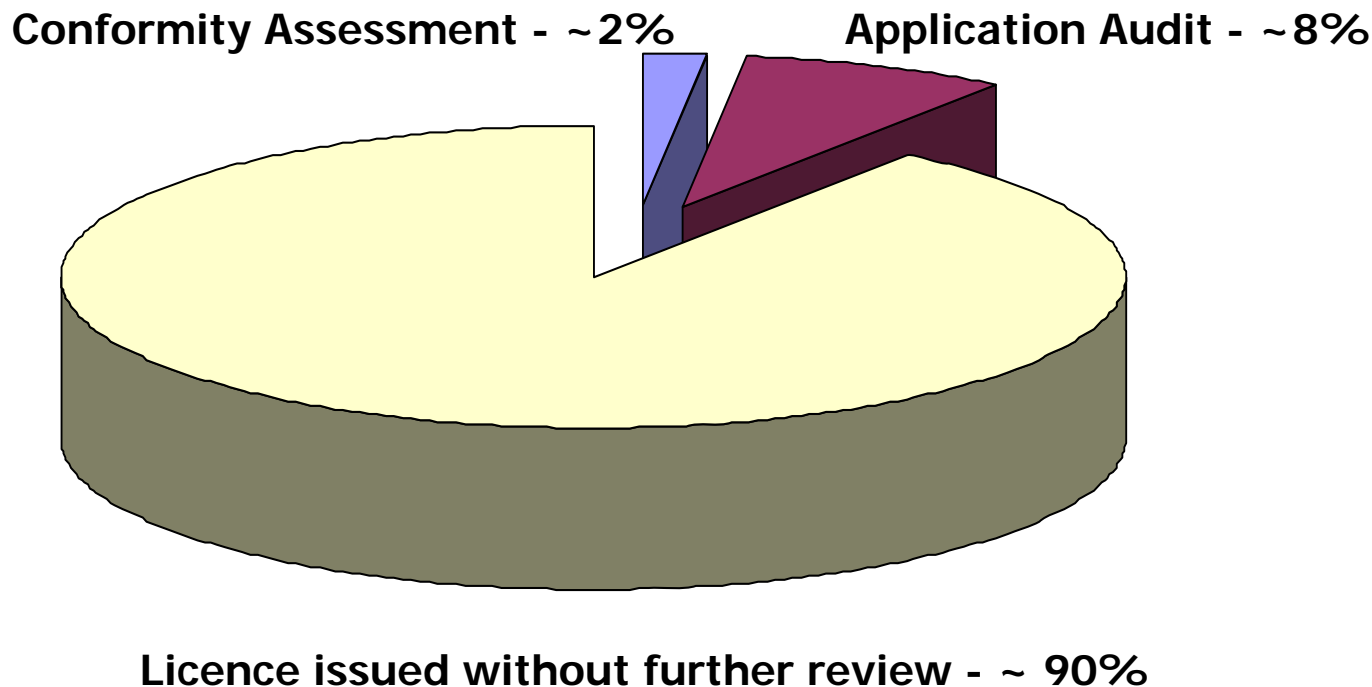
Conformity Assessment by ANZTPA

- Devices containing biological materials
- Devices containing medicines
- Australian and New Zealand manufacturers

However, the Authority will

- take into account conformity assessment reports by key overseas regulators
- reduced fees will reflect the reduced effort

Product Licensing – Types of Assessment



Product Licensing – Streamlined Process

- It is anticipated that approximately 90% of applications of CE Marked devices will be issued with product licences through the streamlined electronic licensing facility.
 - Class I based on licence applicant's self certification.
 - Applications with MRA certificates, irrespective of Class, on licence applicant's self certification.
 - Non-MRA verified applications require manufacturer's evidence to be approved prior to product application

Product Licensing - Application Audit

- Performed at the time that an applicant applies for a product licence
- Shorter process than Conformity Assessment
- Desk audit of documentation
- Undertaken to –
 - verify the applicant's Declaration made at time of application
 - sight the documentation and review completeness
 - generated by the CE Marking process in Europe,
 - supporting Declaration of Conformity to Authority's requirements
 - demonstrate that the links between the manufacturer and applicant are in place

Selection for Application Audit

Mandatory

- Barrier contraceptive
- Implantable contraceptive device
- Implantable breast prosthesis
- Instrument grade disinfectant
- Active implantable medical device
- Implantable intra-ocular lens
- Intra-ocular visco-elastic fluid
- Class III device not assessed under an MRA

Non-mandatory

- Applications suspected of containing false information
- Where the device incorporates a new, different or emerging technology
- Questionable regulatory history
- Random selection

NOTE - Also undertaken post-market – ie, at any time after product has been placed on the market

Types of Application Audits

Level 1

- Original or notarised Declaration of Conformity
- Original or notarised evidence of third party certification of the quality system - eg EC or and/or design exam certificates
- Labelling

Types of Application Audits

Level 2

- Level 1 documents plus -
 - Risk analysis performed by manufacturer
 - Summary of clinical evidence
 - Essential principles checklist
 - Most recent QMS audit report or re-audit report including close-out of non-conformities
 - Design examination or type examination report (if applicable)
 - Special process validations

Post-market Monitoring

Manufacturer

- monitors post-market device performance
- keeps records – QMS, distribution, etc
- reports incidents to ANZTPA (direct or through sponsor) within mandatory timeframes

Licence Holder

- maintains incident report log
- reports to manufacturer
- reports to ANZTPA within mandatory timeframes

Post-market Monitoring

ANZTPA

- Undertakes post-licensing audits of manufacturers and product licence holder's records
- Interacts with the product licence holder / manufacturer and users to discuss significant incident reports
- Conducts surveillance programme including:
 - Desk audits
 - Laboratory testing

Post-market Monitoring

Adverse Event Reporting Timeframes to the Authority

- 48 hours – serious threat to public health
- 10 days – serious injury or death
- 30 days – ‘near miss’ event

Expert Advisory Committee

Will be made up of:

- Independent Members drawn from Australia and New Zealand
- Broadly based expertise

May establish sub-committees eg. to review adverse event reports and investigations

Transition Arrangements

New Zealand

- Existing WAND Notifications
 - Interim NZ Only Product Licence (automatic)
 - Move to ANZTPA Product Licence within 3 years
 - requires an application (not automatic)
- Existing manufacturers
 - Authorised to continue activities for 3 years (automatic)
 - Move to ANZTPA Conformity Assessment Certificate within 3 years
 - requires application within 2 years (not automatic)
- New manufacturers require ANZTPA Conformity Assessment Certificate before commencing manufacturing activities

Transition Arrangements

Australia

- Existing ARTG Inclusions
 - Interim Australia Only Product Licence (automatic)
 - Move to ANZTPA Product Licence within 3 years
 - requires an application (not automatic)
- Existing Conformity Assessment Certificates
 - Interim Australia Only Conformity Assessment Certificate (automatic)
 - Move to ANZTPA Conformity Assessment Certificate within 3 years
 - requires application (not automatic)
- New manufacturers require ANZTPA Conformity Assessment Certificate before commencing manufacturing activities



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 – Medical Devices

- Scheme designed on Global Harmonisation Taskforce recommendations
- Pre market fees
 - Application fee for product licence (electronic lodgement)
 - Conformity assessment and application audit fees
- Annual licence charges to reflect the cost of monitoring, incident reporting, managing recalls and maintaining the regulatory scheme for a class of device

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



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

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