Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

The Assessment Process & Product Licensing

Mike Flood
Head, Application Entry & Co-ordination Section
Office of Devices, Blood and Tissues
TGA

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

The Participants –

- Manufacturer
  - has an obligation to show that products conform to safety and performance principles
    - GHTF Essential Principles
  - has an obligation to follow an assessment procedure
    - to ensure the initial and on-going conformity to the Essential Principles
    - includes quality management system requirements
    - includes post-market monitoring, investigation and reporting requirements
    - similar to the EU Conformity Assessment Procedures

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

The Participants –

- Sponsor
  - certifies that a manufacturer has met their obligations
  - ensures information flows to and from the manufacturer
  - accepts the responsibility for the supply of product
  - assists the manufacturer to comply with the obligations on the manufacturer
  - submits the manufacturer's evidence of conformity to the Agency
  - applies for an entry for the manufacturer's product on the Agency Product Licence Register

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

The Participants –

- The Regulator
  - the Trans-Tasman Agency
  - performs selected full pre-market assessment
  - performs selected short pre-market assessments
  - performs post-market vigilance and investigation

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

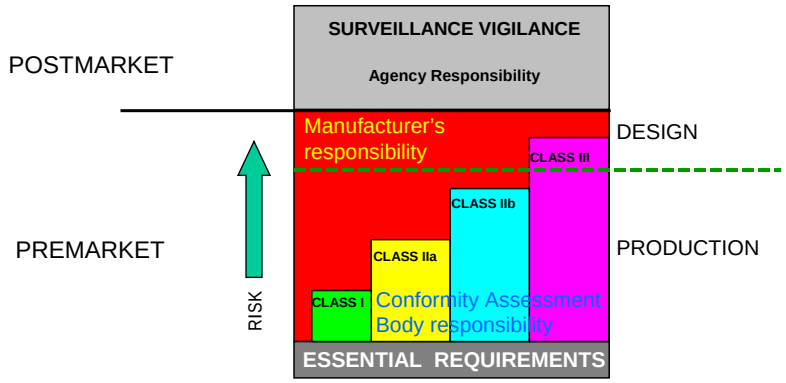
Key elements

- 14 Essential Principles for safety and performance
- 22 Rules of Classification based on Risk to user and/or patient
- Quality Systems – eg - ISO 13485
- Independent Assessment and on-going surveillance of Quality Systems
- Postmarket Surveillance

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Responsibilities



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Assessments

- All medical devices must comply with the Essential Principles regardless of Class
- All manufacturers must apply a conformity assessment procedure
- Many of the procedures require an independent assessment of a product or a Quality Management System

But, how are the assessments performed? .....

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Assessment Mechanisms

- The assessment mechanisms of
  - conformity assessment certification
  - the consideration of overseas assessment reports; and
  - application audits

… would not be possible without harmonised definitions of

  - the classification rules;
  - the conformity assessment procedures; and
  - the essential principles.

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Assessment Mechanisms

- Conformity Assessment Certification
  - The Agency must perform the assessment as selected by the Medical Devices Rule for
    - Selected types of devices
    - Selected types of manufacturers
  - For all other assessment the Agency will take into account the assessments performed by other regulators performing similar assessments overseas.
  - The Agency will decide if the products are suitable for supply in the Trans Tasman market

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Assessment Mechanisms - Conformity Assessment Procedures

- A set of activities that the manufacturer must do
  - procedure is selected by the manufacturer
    - based on the risk class of the product
    - using classification rules similar to GHTF and EU rules with some additional special rules.
  - procedures are available for devices used for a special purpose
    - custom made
    - procedure packs
  - Combination device - medicine products
    - Must confer with Agency medicines regulator
    - Must meet regulatory requirements for medicines

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Assessment Mechanisms - Conformity Assessment Procedures

- Types of Manufacturers
  - products from New Zealand and Australian manufacturers
- Types of Products
  - contains tissues of animal origin
  - contain tissues, cells or substances of microbial origin or recombinant technology
  - incorporating stable derivatives of human blood or human plasma
  - incorporates a medicine with an ancillary action

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Assessment Mechanisms - Conformity Assessment Procedures

- Procedures require
  - application of a quality management system (QMS)
  - design or type examination assessments, by the Agency
  - manufacturer's post-market review:
    - Corrective & Preventative Action (CAPA) and adverse event reporting
  - initial and surveillance audit of the QMS, by the Agency
  - the keeping of records
  - a declaration of conformity referencing Trans Tasman regulatory requirements

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Assessment Mechanisms - Conformity Assessment Procedures

- The Agency issues a "Conformity Assessment Certificate" at the successful conclusion of an assessment
- Scope of certificate is specified in terms of GMDN Code for relevant devices

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Entry of Products on to the Product Licence Register

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Entry of Products on to the Product Licence Register

- Step 1
  - Submit Manufacturer's Quality System evidence
    - Agency Issued Conformity Assessment Certificate
    - MRA Certificate
    - EC Certificate issued by an EU Notified Body
    - Declaration of Conformity
      - » System and Procedure packs
  - Not Acceptable
    - ISO 9001
    - ISO 13485
    - FDA Certification, audit reports, etc

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Entry of Products on to the Product Licence Register

- Step 2
  - Make application for entry of a kind of medical device
    - Class I devices – no mfr evidence required
    - All other classes – will require supporting mfr evidence

Proposed -

- Electronic copy of licence will be issued
- Downloaded from Certificate database on website

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Assessment Mechanisms – Application Audit

- may be performed when the Agency has not performed the full conformity assessment certification
- mandatory and randomly selected documentation audits
- performed at the time that a Sponsor applies for an entry on the Product Licence Register

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Assessment Mechanisms – Application Audit

- Shorter process
- Desk audit of documentation -
  - Essential Principles checklist
  - Risk Analysis
  - EC Certification(s)
  - Design Exam Report (Class III & AIMD only)
  - Audit Report (Full QMS audit & most recent surveillance audit)
  - Summary of Clinical Evidence (expert report)
  - Labelling
  - DOC to Trans Tasman Regulatory Framework

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Selection for Application Audit

Mandatory

- barrier contraceptive
- implantable contraceptive device
- implantable breast prosthesis
- instrument grade disinfectant
- active implantable medical device
- prosthetic heart valve
- 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
- devices that were previously unregulated
- questionable regulatory history
- Random selection

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Application Audits - level 1

- Original or notarised Declaration of Conformity (to the Agency rule for medical devices)
- Original or notarised evidence of third party certification of the quality system - eg EC or and/or design exam certificates
- Labelling
  - General labelling
  - Instructions for use
  - Advertising material

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Application Audits - level 2

- Level 1 audit data **plus** -
- Risk analysis performed by mfr
- Summary of Clinical evidence
  - expert report
  - trial report
  - literature report
- Essential principles checklist (Trans Tasman, not EU)
- Most recent QS Audit or re-audit report
- including close out of non-conformities
- Design Exam or Type Exam report (if applicable)
- Special Process validations

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

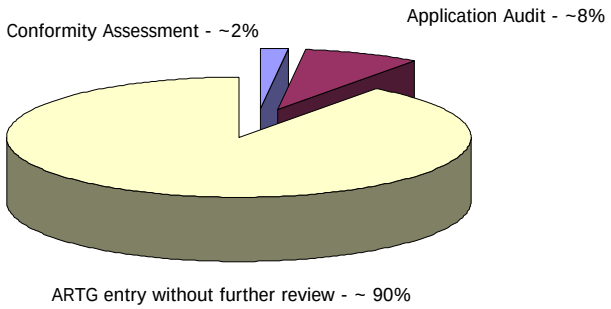
Assessment Mechanisms – Entry onto the Product Licence Register

- Sponsor submits copies of EC certificate(s) as Conformity Assessment evidence
  - Register evidence database is scoped using GMDN
- Sponsor applies for entry of device(s) on to the Product Licence Register
  - Binding declarations made at time of application
    - Correct classification
    - Correct conformity assessment procedure has been applied
    - Complies with essential principles
    - Mechanism in place to obtain info from manufacturer on request by the Agency
    - Postmarket processes in place
      - Etc, etc
- Product Licence is issued and Device is entered on to the Product Licence Register without further review

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

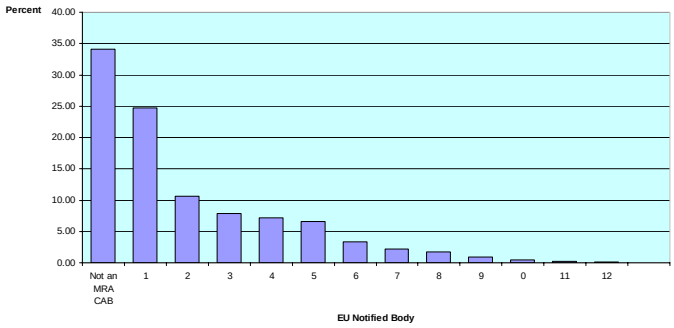
Assessment Mechanisms – Entry onto the ARTG



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Source of EU Conformity Assessment Certification



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

- MRA's
- MOU's
- Other co-operative arrangements

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Maintenance and implementation of MRAs

Progress

- EU/EFTA MRA's
  - medical devices sectoral annex review completed
  - Implementation program reviewed
  - Draft confidence building program forwarded to the EU
- MoU with Swissmedic on cooperation
  - advanced draft - February 05
  - on target for completion by October 05
- MOI with Malaysia – preliminary discussions Dec 04
- US FDA and Japan- commenced dialogue Feb 05

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Australia - Canada MOU on medical devices

Progress

- Agency developing an MoU with Canada on quality management systems certification for medical devices
- Negotiations commenced June 04
- For completion prior to commencement of the trans Tasman agency -
  - The majority of planning has been completed.
  - The Business Case, Project Plan, MoU and tools for Confidence Building Exercise (CBE) completed
  - 5 Agency auditors completed the CMDCAS training to audit manufacturers to Canadian requirements

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Global Medical Device Nomenclature System

- Work commenced in 1993
- Developed from -
  - NKKN (Norwegian system)
  - ISO Aids for the Disabled
  - EDMA system for IVD's
  - UMDN (ECRI) System
- Published as EN/ISO 15225 in 2001

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Global Medical Device Nomenclature System

- 14 Categories of devices
- ~ 1000 **template** terms
- ~ 8500 **preferred** terms
- ~ 8000 **synonym** terms
- Maintenance Agency Policy Group to provide regular updates to the data base

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

- Three types of Terms –
  - Template Term – used for Class I devices
  - Preferred Term – used for all other classes of device
  - Synonym Term – 'pointer' to preferred term

GMDN	Term	Synony	T/Cha	Definition
31813	Tweezers, dental, articulation paper	0	0	A dental instrument having two spring-loaded jaws which is used for holding articulation paper.
31814	Tweezers, dental, dressing	0	0	A hand-held dental instrument having two narrow, pointed spring-loaded jaws. When these are approximated (closed), the instrument is used to grasp a dressing which is being applied orally.
35420	Tweezers, <specify>	0	10	A hand-held instrument having two spring-loaded jaws. When these are approximated (closed), the instrument is used to grasp an object. The shape of the jaws may be pointed, rounded or flat, according to the intended purpose for which the instrument is des
35079	Forceps, <specify>	0	9	A surgical instrument designed with two blades, which are closed upon the object to be held. The handles may be permanently joined together (pivoted as a pinsett, tweezers or scissors) or conjoined, usually by pressure, during use, e.g. some kinds of obst
39186	Forceps, articulation paper	31813	0	
11775	Forceps, biopsy	0	0	A scissors-like, ring handled surgical instrument whose blades distal to the pivot point are extended in length. The distal tip is specially designed to remove samples of tumours or other tissues to enable analysis.
15670	Forceps, bone	0	0	A surgical instrument with strong blades and teeth used for grasping, cutting, or crushing bone.
38791	Forceps, dental, <specify>	0	17	A hand-held dental instrument used in the mouth for different gripping applications.
35851	Forceps, dental, rubber dam clamp	0	0	A dental instrument used to apply and remove rubber dam clamps.
35552	Forceps, dental, tooth extraction	0	0	A dental instrument shaped like a kind of pincers for the extraction of teeth.
32136	Forceps, disconnect	35079	0	
39187	Forceps, dressing, dental	31814	0	

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Kind of Medical Device

- A device is the same kind of device as another device, if it has the same
  - Manufacturer
  - Sponsor
  - Classification
  - **GMDN Code**
- For a Product Licence Register entry for Class IIIs and AIMDs
  - must also have the same **Unique Product Identifier (UPI)**
- For the manufacturers Declaration of Conformity
  - must state the **GMDN** and the **Unique Product Identifier (UPI)**
  - **regardless of Class**

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Kind of Medical Device

- Detail held, increases with classification -
  - Class I
    - 12340 Light for medical use
    - 35079 Forceps
  - Class IIa & IIb
    - 16668 Bur, dental, carbide
    - 16669 Bur, dental, steel
    - 16670 Bur, dental, diamond
  - Class III & AIMD
    - 34615 Dressing, absorbable, Collatape
    - 34615 Dressing, absorbable, Collacote
    - 34615 Dressing, absorbable, Collaplug

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Experience to date

- aka - *the Australian Experience !!*
- Our first transition period

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Experience to date

- October 2004 – first transition in our new framework
  - Previously exempt devices had to be on ARTG by 5 October 2004
- > 7,000 applications in 4 months

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Rejections – ~20% !!

- Insufficient intended purpose
- Incorrect GMDN codes (does not agree with intended purpose)
- Incorrect class
- Incorrect mfr address (postal, not street address)
- Incorrect type of application (eg listed, not included)
- Device GMDN's does not match Mfr scope of EC certificate
- Inability to supply supporting data for audit

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Lessons Learned

- **Manufacturers …….**
  - Will leave it until the last minute !!
  - Do not have a good grasp of
    - The Regulatory Framework
    - QMS
    - Risk analysis (trying to apply retrospectively !)
  - Pre-emptively apply for C/Assessment (distract Agency resources from those who are ready for assessment)
  - C/Assessment for Overseas products has been relatively straightforward

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Lessons learned

- **Sponsors** ……
  - Will leave it until the last minute !!
  - Will guess at GMDN codes
  - Will guess at classification
  - Have not read User doco for DEAL
  - Do not understand declarations made, and their ongoing ramifications

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Lessons learned –

- **TGA** –
  - Everybody leaves it until the last minute !!
  - Application rate is highly variable
  - Do not introduce IT systems 4 months before a transition deadline
  - Reserve capacity
    - Staffing levels
      - » Contract staff
      - » temp staff
    - Preparedness
    - Training

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Postmarket Monitoring

- Shared responsibility
  - Sponsor
  - Manufacturer
  - Regulatory Agency

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Postmarket Monitoring

- Obligations
  - Manufacturer's postmarket monitoring
  - Sponsor's reporting to mfr, and reporting to Agency
- Agency
  - postmarket monitoring
  - Product sampling and testing
  - vigilance programs
  - Recalls

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Postmarket Activities

- Random compliance audits of product in the market
  - Desk audits
  - Laboratory testing
- QMS Surveillance audits of manufacturers
- Incident monitoring
  - User reporting (voluntary)
  - Sponsor/manufacturer reporting (mandatory)

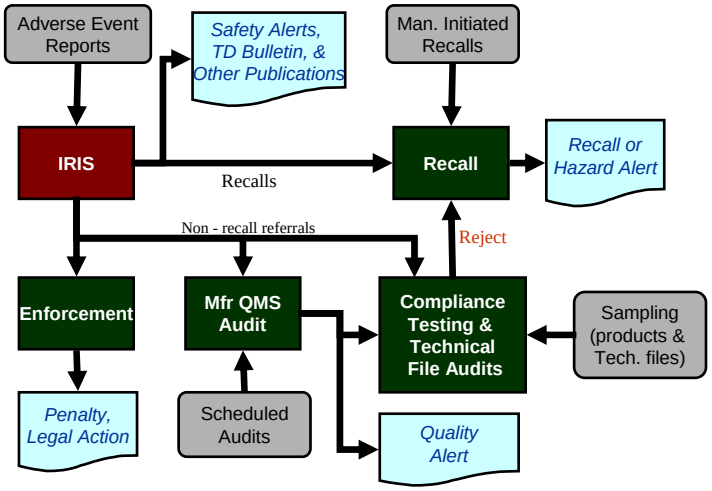
Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

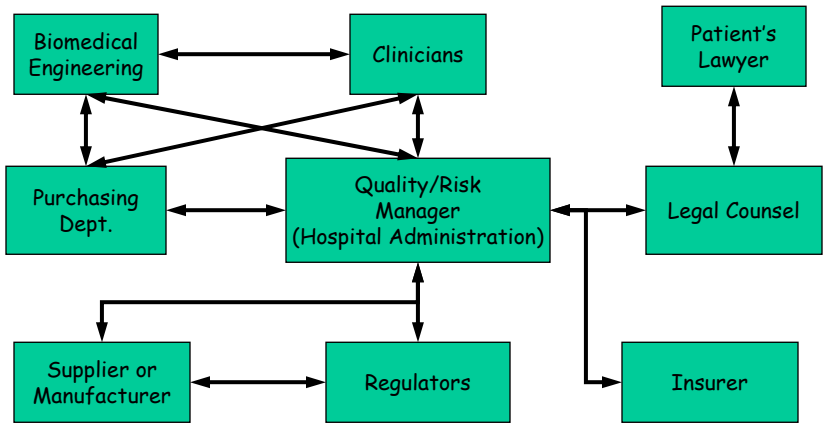
Sponsor/manufacturer reporting (mandatory)

- Timeframes
  - 'near adverse' event – 30 days
  - Death or serious injury – 10 days
  - Serious public health threat – 48 hours
- Penalties for non-compliance

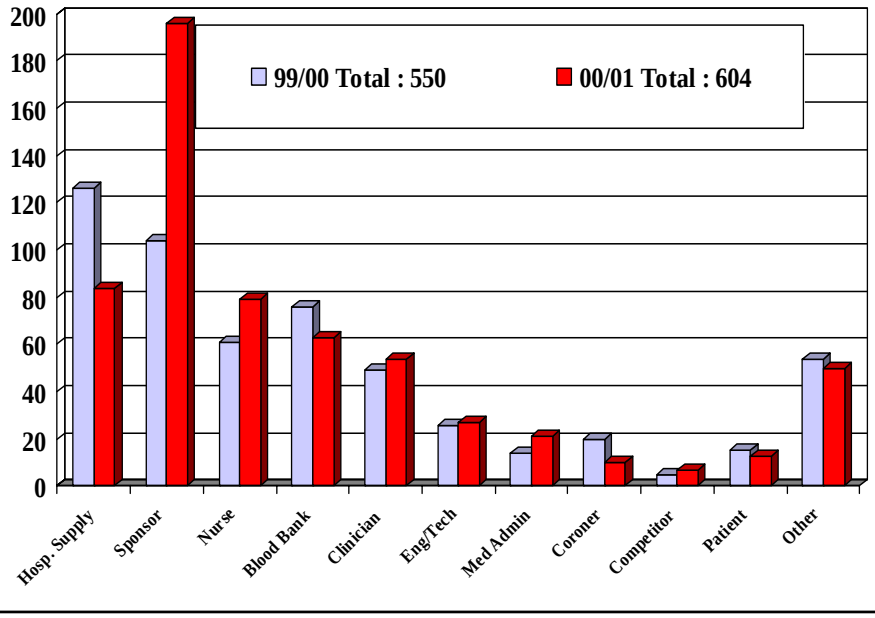
Agency's Post-Market Surveillance Systems



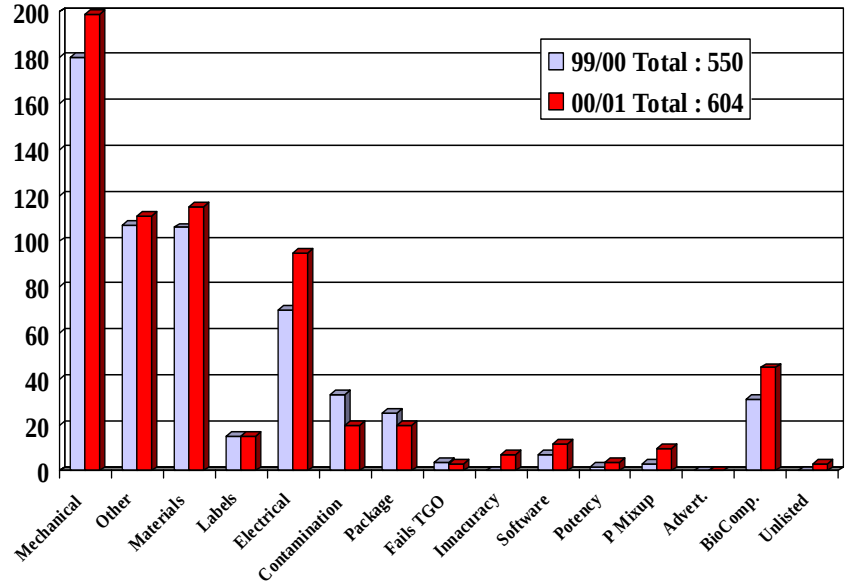
Lines of Communication



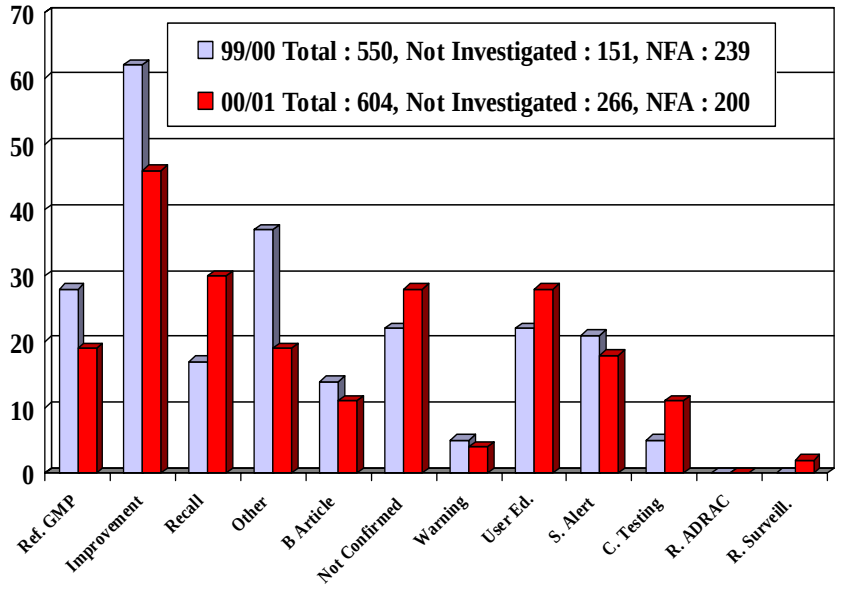
Source of Reports



Type of Reports Received



Result of Investigations



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

In summary – the key elements

- 14 Essential Principles for safety and performance
- 22 Rules of Classification based on Risk to user and/or patient
- Quality Systems – eg - ISO 13485
- Independent Assessment and on-going surveillance of Quality Systems
- Postmarket Surveillance

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Assessments

- All medical devices must comply with the Essential Principles regardless of Class
- All manufacturers must apply a conformity assessment procedure
- Many of the procedures require an independent assessment of a product or a Quality Management System

- Where possible, evidence of assessment in another regulatory jurisdiction, with a similar regulatory framework, will reduce the time for market approval


Break for
Questions ??
James Nedock / The Monitor