

## General Session

Medsafe, Medical Industry Association of New Zealand  
and Australian Therapeutic Goods Administration

**MEDSAFE**  
NEW ZEALAND MEDICINES  
AND MEDICAL DEVICES  
SAFETY AUTHORITY

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## General Session

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## General Session

- An Update on the Trans-Tasman Agency & Regulatory Scheme
- General WAND Issues
- Elements of the proposed Regulatory Framework for Medical Devices under the Joint Agency
- Proposed Assessment Process and Product Licensing under the Proposed Joint Agency. MRA / EU and Canada
- WAND moves onwards –the move towards the Joint Agency

## Current Requirements - Definition of a Medical Device

- Current Definition:

See Medicines Act 1981

- A medical device is defined as any device, instrument, apparatus used on one or more human beings for a therapeutic purpose.
- A therapeutic purpose is defined and means:
  - treating or preventing disease
  - Effecting contraception
  - Altering the shape, structure size, weight of the human body
  - Interfering with the physiological function of the body

## Under current legislation .....

- the following products are not Medical Devices
  - Surgical scrubs
  - Disinfectants used in hospitals
  - Lubricants used on devices
  - Devices containing radioactive materials

## Products which are Medicines in New Zealand but Devices Overseas

- Pregnancy Test Kits
- Contact Lens Solutions
- Dermal Fillers applied by injection
- IUDs containing copper
- Haemodialysis concentrates
- Bone Cement containing an antibiotic

## Examples of products which are classified as Medical Devices in New Zealand

- Medicated Stents
- Wound dressings containing silver (not systemically absorbed)
- Wound gels containing no active ingredient (provide an environment for healing)

## Legislation

- Medicines (Database of Medical Devices) Regulations 2003  
(see [www.legislation.govt.nz](http://www.legislation.govt.nz))
  - Definitions
  - Defines classifications
  - WAND requirements
  - Exempt medical devices

## Web Assisted Notification of Devices Database (WAND)

- A sponsor is required to make only one entry on WAND if a group of devices have the same:
  - Manufacturer and
  - Global Medical Device Nomenclature (GMDN term) and
  - the same Classification (Class)

## Devices excluded from the WAND database

- In-vitro diagnostic devices
- A device used in a clinical trial
- A device obtained by a health professional for use on a specific patient
- A device imported for personal use
- A radioactive device
- Disinfectants used in hospitals

## Who needs to record information on WAND?

- New Zealand sponsor importing a medical device from Australia or any other country
- A company manufacturing a device in New Zealand or a company that organises the manufacture of a device in New Zealand
- An organisation or company purchasing a device in New Zealand is not required to record the information on WAND

## Who needs to record information on WAND?

New Zealand manufacturer includes an organisation that carries out the following and distributes the device outside their organisation:

- Manufacturing a device
- Sterilising a device
- modifying a device or relabelling a device
- producing a procedure pack, systems pack

## Information on how to access WAND

- Go to Medsafe website – [www.medsafe.govt.nz](http://www.medsafe.govt.nz)
- Go to WAND Medical Device
- Go to Application for Access Rights to WAND
- Complete Appendix 2 and 3 and submit to Becci Slyfield
- A master password and user id will be sent to the E-Business Administrator. This person should be a senior person employed within the company.
- Go to the User Management System on the WAND homepage
- Please note the master password and user id will only give you access to the User Management System. It will not work on WAND. Passwords used on the Australian TGA DEAL system do not operate on WAND.

## User Management System

- Enter your Master password and User ID
- Click on Master Account
- Click on New Account
- Fill-in the form with persons who will have access to WAND. Drafters can draft notifications. Submitters can both draft and submit notifications. Save and Close.
- Each person above will be emailed a user password and user id to access WAND.
- If somebody leaves, the person with the Master password and User id should go into the User Management System and deactivate that person's account.

## Accessing WAND

- Once you have been emailed a User id and Password go to the Medsafe website – [www.medsafe.govt.nz](http://www.medsafe.govt.nz)
- Go to WAND Medical Devices
- Go to “To Enter, Edit or View and Entry in WAND”
- Enter your User id and Password

## Loss of Password

- If you lose your master password and user id please contact Medsafe to get your password reset.
- If you lose your user password and user id please contact your E-Business Administrator to get your password reset.

## Other Changes

- If a company has information notified on the WAND database and changes its name or merges with another company both companies should contact Medsafe and advise of the change
- Medsafe may be able to arrange to change the information on the WAND database rather than the new company having to resubmit all the information again

## Kits, Procedure and System Packs on the WAND database

- Procedure packs contain components which are packed and include at least one component which is a medical device.
- Procedure packs are intended to be used in medical treatment or surgical procedures.

## What is a Procedure Pack?

- Emergency Kit, first aid (previously called First Aid Kit)
- Surgical procedure kit
- Surgical procedure kit, single use
- Surgical procedure kit, laparoscopic, single use, non-medicated

## Systems Packs

Systems packs can be any bulk combination of equipment. Examples include:

- Diagnostic imaging Equipment
- Anaesthetic Delivery Equipment
- Cardiac/IC Monitoring Equipment
- Video Endoscopy Equipment

## Procedure Packs Containing a Medicine and Devices

- If the pack contains a pharmacy only or prescription medicine, consent must be obtained from Medsafe before the pack can be marketed.
- If the pack contains a device(s) and a general sale medicine(s) and the medicine is in the form in which consent has been granted this pack must be notified on WAND as a procedure pack.

## What is not a Procedure Pack?

The following are not procedure packs:

- Package of orthopaedic screws and plates
- Heart valves of different sizes
- Stents of different sizes

## Notes on Procedure Packs

- If any **organisation including** a District Health Board purchases components locally and produces a procedure pack for use in their **organisation**, this procedure pack does not **need to be notified** on the WAND database.
- If any **organisation including** a District Health Board purchases components locally and produces a procedure pack which is sold /distributed to other **organisations** or to the public, this is considered an assembling (manufacturing) operation and this pack must be notified on the WAND database.

## Notes on Procedure Packs

- If any **organisation including** a District Health Board purchases devices from overseas and produces a procedure pack this must be notified on the WAND database.
- If any **organisation including** a District Health Board purchases a procedure pack assembled in New Zealand then either the organisation or the New Zealand manufacturer must **take responsibility for the product and notify the pack on** the WAND database.

## Where from Here?

- WAND database – notification system (initial requirements to be able to market a device in New Zealand after the start up of the Joint Agency)
- DEAL Database – Australian Approval System
- Remaining information today will be based on the proposed Joint Agency
- Remember draft Rules will be published for consultation