Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Administration

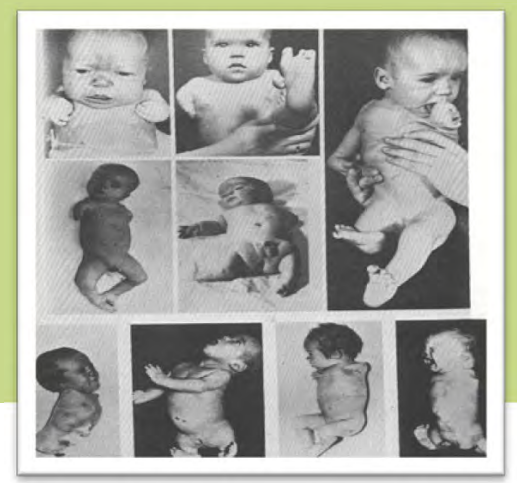
An introduction to the work of Australia's regulator of therapeutic goods

Overview

- Why do we need regulation?
- Who is Australia's regulator?
- How the TGA operates
- Who works at the TGA
- Therapeutic goods
- Australian Register of Therapeutic Goods
- TGA's mission
- The benefit versus risk approach
- Activities conducted before and after a product is released to the market
- Australia New Zealand Therapeutic Products Agency
- Other education modules

Why do we need regulation?

Australian doctor William McBride alerted the world to the **dangers** of **thalidomide** in the 1960s which triggered the need for an **Australian regulator of therapeutic goods.**



"In recent months I have observed that the incidence of multiple severe abnormalities in babies delivered of women who were given the drug thalidomide ('Distival') during pregnancy, as an anti-emetic or as a sedative, to be almost 20%."

Who is Australia's regulator?

- The Therapeutic Goods Administration was established in 1990 to "**safeguard** and **enhance** the health of the Australian community through **effective** and **timely regulation** of therapeutic goods"
- It provides a national system of controls relating to the **quality, safety, efficacy** and timely availability of therapeutic goods used in, or exported from, Australia

TGA – how we operate

- We are part of the **Australian Government Department of Health**
- Every decision the TGA makes is based on the ***Therapeutic Goods Act 1989***
- **Main offices in Canberra** – satellite offices in Sydney, Melbourne, Adelaide and Brisbane
- **Operations are primarily cost recovered (98%)** industry pays fees for making applications and annual charges for products they are responsible for

Who works at the TGA?

Approximately 750 staff made up of:

- Biomedical scientists
- Engineers
- Physiotherapists
- Medical officers
- Pharmacists
- Nurses
- Toxicologists
- Lawyers
- Nutritionists
- Dieticians
- Scientists
- Administrative staff

Under the *Therapeutic Goods Act 1989*, therapeutic goods are defined as:

Products for use in humans in connection with

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury
- influencing, inhibiting or modifying a physiological process
- testing the susceptibility of people to a disease or ailment
- influencing, controlling or preventing conception
- testing for pregnancy
- replacing or modifying parts of the anatomy

Types of therapeutic goods

Medicines and blood products

- prescription medicines
- over the counter medicines
- complementary medicines
- blood, blood components and plasma derivatives

Medical devices

- implants (artificial hips, breast implants)
- in-vitro diagnostics (pregnancy tests, blood glucose monitors)
- low risk medical devices (bandages, tongue depressors, condoms)

Biologicals

- human stem cells
- tissue-based products (skin and bone)
- cell-based products

Australian Register of Therapeutic Goods

All goods must be entered in the ARTG before they can be supplied in, imported to, or exported from Australia

Registered medicines

- higher risk medicines that are registered on the ARTG
- evaluated for quality, safety and efficacy
- Product Information is approved by the TGA

- **All** prescription medicines
- **Most** over-the-counter medicines
- **Some** complementary medicines

Listed medicines

- lower risk medicines that are listed on the ARTG
- contain pre-approved, low risk ingredients
- can only make limited claims and cannot imply that they will be useful in the treatment or prevention of serious illnesses

- **Some** over-the-counter medicines
- **Most** complementary medicines

Medical devices

- higher risk devices are evaluated for quality, safety and performance
- lower risk devices are not evaluated for performance

Devices are classified according to their level of risk, ranging from Class I (lower risk) such as urine collection bottles to Class III (higher risk) such as antibiotic bone cements

TGA's mission

Health
Safety
Regulation

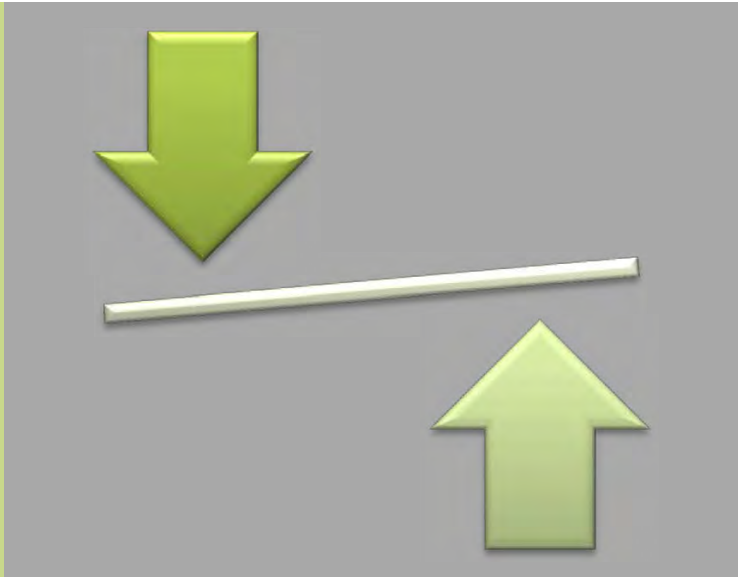
To safeguard and enhance the health of the Australian community through the effective and timely regulation of therapeutic goods.

How do we fulfil this mission?

1. Good Manufacturing Practice or Manufacturing Principles: licensing Australian manufacturers and verifying compliance of overseas manufacturers (see the TGA education module on GMP)
2. Premarket assessments: assessing therapeutic goods for quality and safety (the extent of the assessment depends on the type of product and level of associated risk), and for higher risk products also for efficacy or performance
3. Postmarket assessments: monitoring of therapeutic goods and enforcement of standards (see the TGA education module on postmarket monitoring)

The benefit versus risk approach

- No therapeutic good is **risk free**
- The work of the TGA is based on **applying scientific and clinical expertise** to **decision making**
- We ensure that the **benefits outweigh any risks** associated with the use of medicines, medical devices and other therapeutic goods



Premarket assessment

The level of assessment is based on how much risk the product poses

Low risk

Products such as complementary medicines and low risk medical devices are assessed for **quality** and **safety**

High risk

Products such as prescription medicines are assessed for **quality**, **safety** and **efficacy**

High risk medical devices are assessed for **quality, safety** and **performance**

For both categories there are manufacturing standards that must be met

Postmarket activities

Monitoring/Alerts

- **Monitors claims** made in advertisements for therapeutic goods and issues fines and sanctions if they can not be supported
- **Issues alerts**

Databases

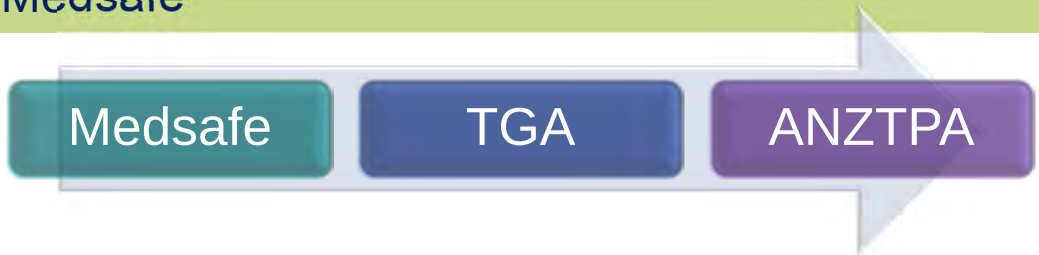
- **Records** reports of **adverse events** by consumers, health professionals and industry
- **Records recall actions**

Manufacturing

- **Further inspections of manufacturers** of therapeutic goods

Australia New Zealand Therapeutic Products Agency

- The Australian and New Zealand Governments have agreed to proceed with a **joint scheme** for regulation of therapeutic goods by 2016
- The creation of a joint regulatory scheme across both countries will safeguard public health and safety, while encouraging **economic integration** and benefitting industry in both countries
- The Australia New Zealand Therapeutic Products Agency will **absorb the current regulators;** Australia's Therapeutic Goods Administration and New Zealand's Medsafe



Other education modules include:

- Medicines
- Biologicals
- Medical devices
- Postmarket monitoring
- Good Manufacturing Practice