Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Regulation of Complementary Medicines in Australia

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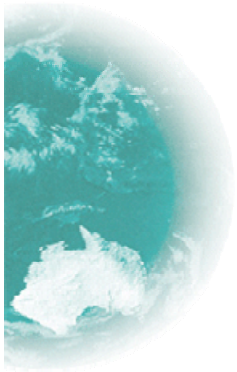

Overview

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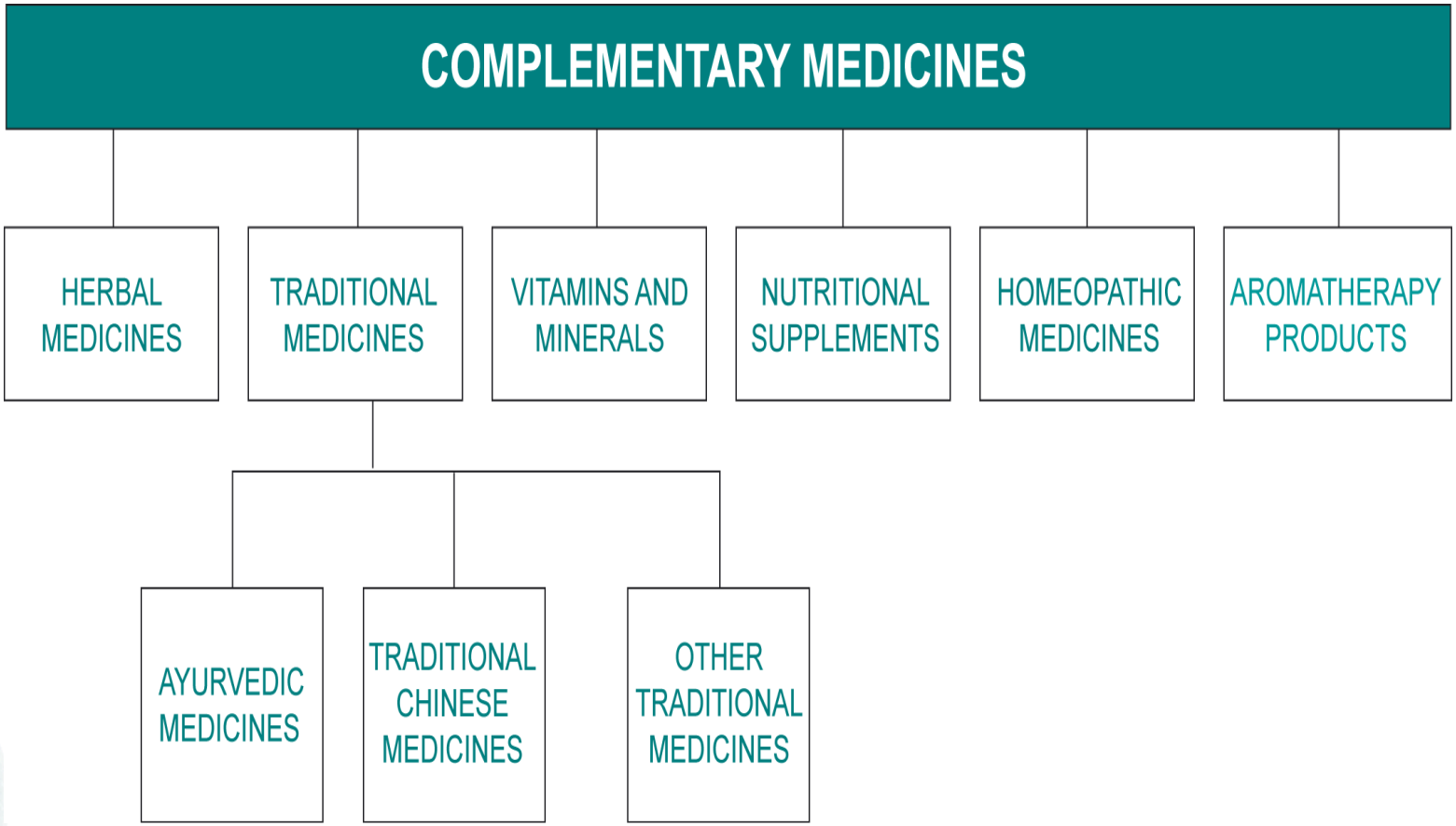
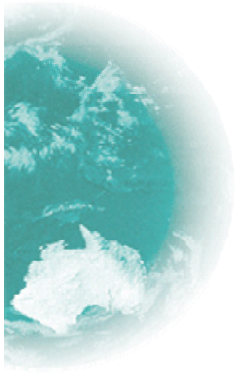

COMPLEMENTARY MEDICINES
HERBAL MEDICINES
TRADITIONAL MEDICINES
VITAMINS AND MINERALS
NUTRITIONAL SUPPLEMENTS
HOMEOPATHIC MEDICINES
AROMATHERAPY PRODUCTS
AYURVEDIC MEDICINES
TRADITIONAL CHINESE MEDICINES
OTHER TRADITIONAL MEDICINES

Office of Complementary Medicines

Regulates manufactured complementary medicines:

- evaluates new complementary medicine substances and products;
- undertakes ‘post-market’ reviews and ingredient safety reviews;
- maintains and supports the Electronic Listing Facility (ELF) for Listed medicines.

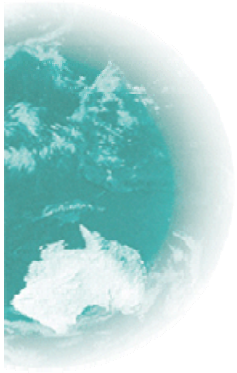


Regulatory Framework for Complementary Medicines

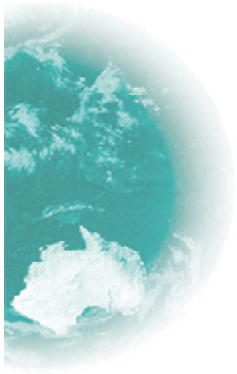
- Medicines, including complementary medicines are regulated under the *Therapeutic Goods Act 1989* (the Act).
- Regulatory framework aims to ensure quality, safety and efficacy.

Australian Regulatory Guidelines for Complementary Medicines (ARGCM)

- Detail the regulatory processes for complementary medicines.
  - Indicate requirements to support quality, safety and efficacy of Registered and Listed complementary medicines
  - http://www.tga.gov.au/docs/html/argcm.htm

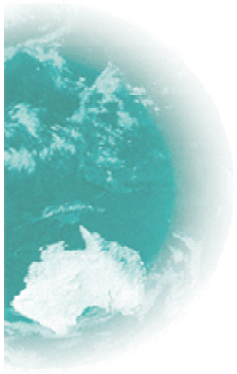


Licensing and Approval of Manufacturers

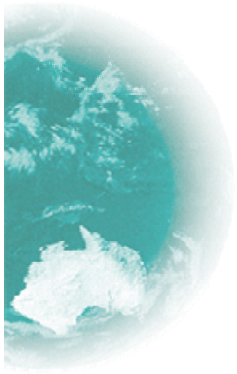


Manufacturer Requirements

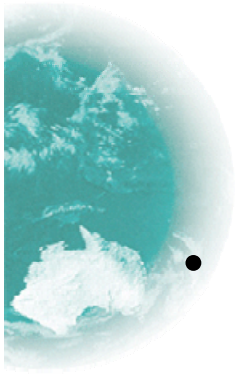
- Each manufacturer of medicinal products for human use must hold a licence or be approved by the TGA.
- Licensed and approved manufacturers are required to comply with Good Manufacturing Practice (GMP).



Pre-Market Assessment Processes



- Australia has a two-tiered regulatory system which is based on **risk**.
- Complementary medicines may be regulated as:
  - **Listed** (low risk) medicines, or
  - **Registered** (higher risk) medicines
- Assessment of risk is based on factors such as:
  - Ingredients, including significance of side effects & potential for misuse
  - Dosage form
  - Indications and claims
  - Significance of side effects and potential for misuse
- Most, but not all Complementary medicines are Listed.



Listed Medicines – Lower Risk

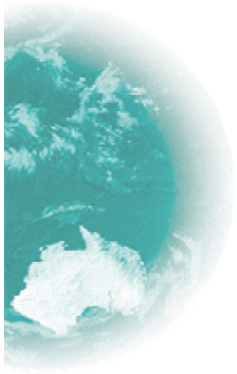
- May only contain ingredients that have been approved by the TGA as being of low risk.
- May only make certain indications/claims.
- Sponsor must hold evidence to support all indications/claims.
- General sales medicine – i.e. access not restricted.
- Identified on the label by ‘AUST L’ followed by a number.

Listed Medicines – Ingredients

- Pre-approved substances that are of low risk.
- May be subject to restrictions including:
  - dosage limits
  - route of administration
  - restriction on plant parts, components, type of preparation extraction solvent, etc
  - label advisory statements
  - container type
- Approximately 2,500 substances are ‘Listable’: http://www.tga.gov.au/docs/html/listsubs.htm

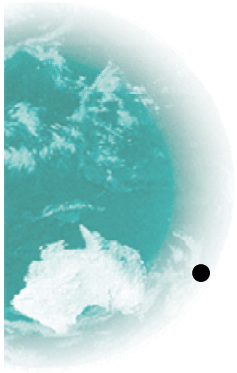
Listed Medicines – Indications

- Generally NOT permitted to claim they can treat, manage, cure or prevent a disease, disorder, or condition or refer to a serious form of a disease.
- May make claims related to health maintenance, health enhancement, reduction of risk of a disease, disorder or condition, symptomatic relief.



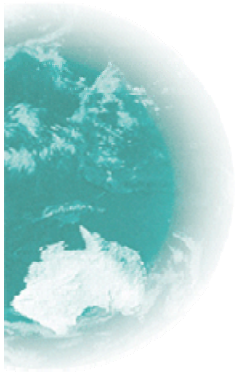
Listed Medicines – Process

- Listed medicines are not individually evaluated by the TGA before market access.
- Sponsor applies to the TGA via the Electronic Listing Facility (ELF) and must legally certify that the product meets all legal requirements.
- ELF electronically validates that the application complies with the legislative requirements for Listed medicines.
- Product is automatically Listed on ARTG.



Listed Medicines – Sponsor Certification

- Includes the following:
  - The medicine is safe for the purposes for which it is to be used;
  - Each step in manufacture has been carried out by the holder of a licence to carry out that step;
  - The medicine complies with all quality or safety criteria;
  - The applicant holds evidence to support all indications and claims.

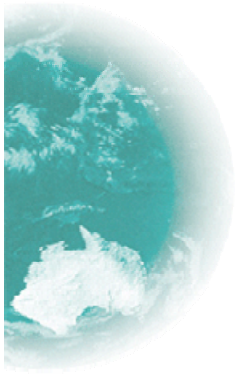


Evaluation of New Listable Substances

Quality

- Nature or character of a substance
- Distinguishing characteristics
- Constituents of safety and/or therapeutic significance, e.g. impurities and incidental constituents
- Biological, chemical and physical variations

Safety

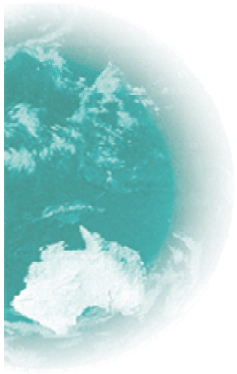


- History and patterns of previous human use
- Biological activity
- Toxicology
- Clinical trials
- Reports of adverse reactions

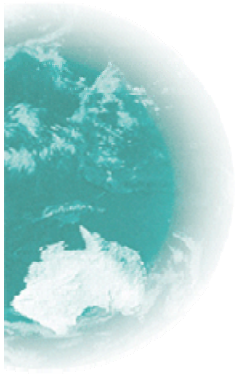
Registered Medicines – Higher Risk

Registered medicines are individually evaluated for quality, safety and efficacy.

- may have restrictions on access, e.g. Pharmacist Only.
- may make higher level claims than Listed medicines.
- identified on the label by 'AUST R' followed by a number.

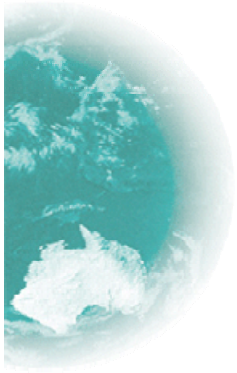


Post-Market Regulatory Activities



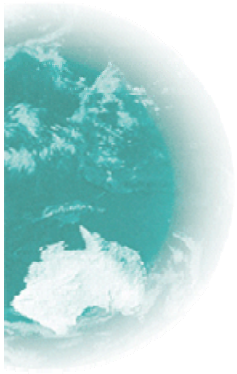
Review of Listed Medicines

- As Listed medicines are included on the ARTG through an on-line system, there is limited pre-market oversight.
- The majority of regulatory activity in relation to Listed medicines is conducted once the product is on the market.



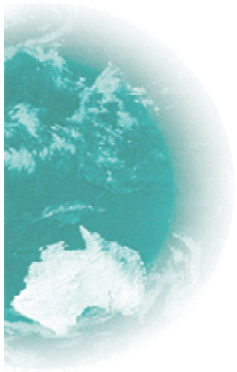
Risk-based regulatory approach includes:

- random and targeted desk-based audits of Listed products;
- random and targeted laboratory testing of products and ingredients;
- random and targeted surveillance in the market place;
- monitoring of adverse reactions;
- a responsive and timely recalls procedure; and
- controls for advertising.



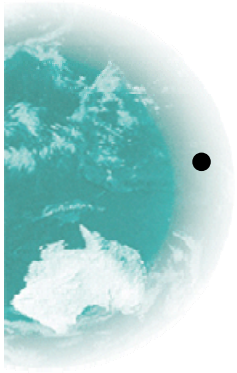
Review of Listed Medicines

- Random – a certain proportion of newly Listed medicines are automatically selected by ELF.
- Targeted – in response to concerns regarding quality, safety or efficacy from:
  - Results from random sample review;
  - Safety reviews;
  - GMP Audits; and
  - Adverse reaction reports
  - Other medicine problem reports.



Summary

- Australia has a risk-based system for regulating complementary medicines.
- Guidelines have been developed that detail regulatory requirements and processes.
- Complementary medicines must be manufactured under the same code of GMP as other medicines.
- Post-market regulatory activities are important to help assure quality, safety and effectiveness.



Questions?