



# Overview of the Regulation of Complementary Medicines in Australia

**Dr David R. Briggs**

**Director**

**Office of Complementary Medicines**

**Therapeutic Goods Administration**

**CANBERRA ACT**

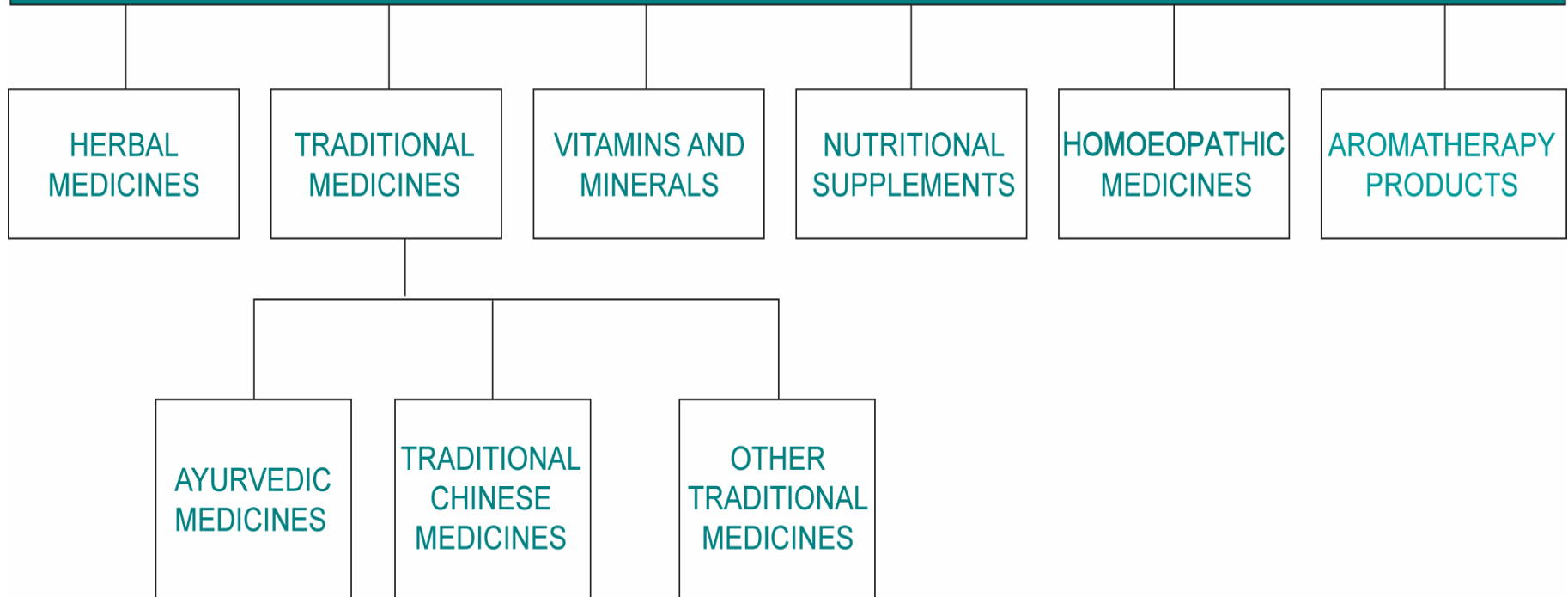


## Aims

- Outline the regulatory framework for complementary medicines in Australia
- Provide an overview of the functions of the Office of Complementary Medicines (OCM)
- Demonstrate the different approach applied to complementary medicines for standards of quality, safety and efficacy (“Separateness Within” the TGA)



## COMPLEMENTARY MEDICINES





# THE REGULATORY FRAMEWORK FOR COMPLEMENTARY MEDICINES IN AUSTRALIA

- Two-tiered regulatory system based on risk.  
Complementary medicines may be regulated as:
  - **Listed** medicines, or
  - **Registered** medicines (non-prescription; prescription)
- Listing or Registration proceeds in response to an Application made to the TGA
- Objective to ensure quality, safety and efficacy



# THE OFFICE OF COMPLEMENTARY MEDICINES

- **regulates complementary medicines**
- **supports and receives advice from the Complementary Medicines Evaluation Committee (CMEC)**
- **advises the Minister, DoHA and TGA on regulation of complementary medicines and associated matters**
- **consults and liaises with stakeholders to foster cooperation and confidence in regulation**



# THE OFFICE OF COMPLEMENTARY MEDICINES

The OCM regulates manufactured complementary medicines

- **evaluates new complementary medicine substances and products**
- **undertakes post-market reviews**
- **maintains and supports the Electronic Listing System**



# THE REGULATORY FRAMEWORK FOR COMPLEMENTARY MEDICINES IN AUSTRALIA

The OCM does not regulate dispensed or extemporaneously compounded complementary medicines

- **healthcare practitioners, such as pharmacists, naturopaths and homoeopaths, may prepare certain medicines for individual patients that do not need to be assessed or evaluated by the TGA for quality, safety or efficacy**



# THE REGULATORY FRAMEWORK FOR COMPLEMENTARY MEDICINES IN AUSTRALIA

The OCM does not regulate complementary  
healthcare practitioners

- **statutory regulation is a State/Territory responsibility**
- **self regulation through professional associations**
- **co-regulation**



# THE REGULATORY FRAMEWORK FOR COMPLEMENTARY MEDICINES IN AUSTRALIA

**Key elements of the TGA's regulatory processes to ensure quality, safety and efficacy of medicines include:**

- 1. Licensing and audit of manufacturers**
- 2. Pre-market assessment of products**
- 3. Post-market regulatory activity**



## Registered medicines - Higher Risk

Medicines that are assessed to be of higher risk on the medicines risk continuum, are individually evaluated for quality, safety and efficacy.

- products are included in the ARTG as Registered medicines
- identified on the label by AUST R followed by a unique number



## Listed medicines - Low Risk

- Listed medicines are not individually evaluated by the TGA before they are released onto the market
- Listed medicines may be supplied following application to the TGA by the sponsor of the product
- Sponsor certifies that the product meets the requirements for Listed medicines
- TGA validates that certain key requirements comply with legislation
- Identified on the label by AUST L followed by a unique number



# Post-market regulatory activity

- **Risk-based approach includes:**
  - targeted and random desk-based audits of Listed products;
  - monitoring of adverse reactions;
  - targeted and random laboratory testing of products and ingredients;
  - targeted and random surveillance in the market place;
  - an effective, responsive and timely recalls procedure;
  - audit of Good Manufacturing Practice (GMP); and
  - effective controls for the advertising of therapeutic goods.



## EXPERT ADVICE: THE COMPLEMENTARY MEDICINES EVALUATION COMMITTEE (CMEC)

8 -12 members appointed by the Minister with  
experience in:

- complementary medicine practice
- consumer representation
- general medical practice
- governmental regulation
- nutrition or nutritional medicine
- pharmacognosy
- pharmacology
- herbal medicine
- toxicology
- naturopathy



## EXPERT ADVICE: EXPERT ADVISERS TO CMEC

Up to 8 expert advisers may be appointed by the Minister to advise CMEC. Expertise may include:

- traditional Chinese medicine
- Ayurvedic medicine
- regulatory affairs
- consumer representation
- formulating, designing or manufacturing complementary medicines
- homoeopathy
- aromatherapy



# COMPLEMENTARY MEDICINES GUIDELINES

Developed in consultation with the

- **Complementary Healthcare Council of Australia (CHC)**
- **Australian Self-Medication Industry (ASMI)**
- **other stakeholders**
- Australian Regulatory Guidelines for Complementary Medicines (**ARGCM**)
- Adjunct guidance documents



## COMPLEMENTARY MEDICINES GUIDELINES

Guidelines recognise that compared with other medicines, most complementary medicines

- **low risk**
- **have a tradition/ history of use**
- **active components often not known**
- **composition may be complex and variable**
- **Evidence to support indications and claims may be based on scientific and/or traditional evidence**



# “Separateness Within”

## SUMMARY

- Regulatory framework for medicines is based on risk
- Framework underpins a level playing field
- Low risk applicable to most complementary medicines is recognised
- The nature of complementary medicines is recognised
- The OCM seeks and receives advice from expert committees, expert advisers and from industry, academia and consumers through consultation