Overview

• The Complementary Medicines regulatory framework
• Traditional Chinese Medicines within the regulatory framework
• The future of Complementary Medicine regulation
The challenge

Managing industry innovation with consumer safety

- Timely market access
- High quality medicines that are safe and affordable
- Consistent, effective transparent regulation
- Efficacious with truthful advertising
- Minimal regulatory burden
- Effective and transparent regulation of all medicines
- International work sharing

Industry

Consumer

Overview of the Complementary Medicines regulatory framework
Therapeutic Goods Administration

- Established in 1989
- Part of the Department of Health
- Safeguard health of Australian public
- Regulates therapeutic goods (medicines and medical devices)
What is a Complementary Medicine?

- Traditional Medicines
- Herbal Medicines
- Aromatherapy Products
- Homoeopathic Medicines
- Vitamins and Minerals
- Nutritional Supplements

Overview of the Complementary Medicines regulatory framework
Why do we regulate complementary medicines?

- Safeguard the health of the Australian public
- Safe, high quality medicines
- Manage adverse events
What the TGA does not regulate

- Practitioners
- Cosmetics
- Health insurance
- Veterinary medicines
- Extemporaneously compounded complementary medicines
- Food products
Regulatory Framework for Complementary Medicines

- Therapeutic Goods Act 1989 (the Act)
- Therapeutic Goods Regulations 1990
- Poisons standard

Overview of the Complementary Medicines regulatory framework
A risk-based approach to regulation

Australian Register of Therapeutic Goods (ARTG)

AUST L
Listed medicines
- Low level indications
- Low risk ingredients
- No premarket evaluation of product

AUST R
Registered medicines
 Premarket evaluation of:
- quality
- safety
- efficacy

Lower risk

Higher risk

Overview of the Complementary Medicines regulatory framework
Overview of the Complementary Medicines regulatory framework
Listed Medicines Regulatory Framework

No premarket evaluation

- Pre-approved ingredients
- Good manufacturing practice (GMP)
- Low level therapeutic claims

Medicine listed on the ARTG

Post-market compliance
Applying for a listed medicine

- Electronic application:
  - Electronic Listing Facility (ELF)
- Easy access to market:
  - Supply within 48 hours of applying
Pre-approved ingredients

- Low risk
- Some restrictions:
  - Limits
  - Route of administration
  - Plant parts, type of preparation
  - Labels
  - Container type
We are often asked why the TGA does not allow some TCM?

- Potential reasons:
  - Legislative restriction
  - Negative outcome from previous evaluation
  - No previous application
  - Risk based approach
  - Something that has been used traditionally doesn’t always mean it is safe
  - Safety concerns require further scientific data to show absence of the concern
  - We can consider internationally recognised safety reports (e.g. from Health Canada, EFSA)
Good Manufacturing Practice (GMP)

- Pre-approved ingredients
- GMP
- Low level therapeutic claims

• Licence or clearance
Evidence for Listed Medicines

- Sponsor: evidence for all indications and claims
- Complementary medicines indications:
  - Traditional
  - Scientific
  - Cross-paradigm
- Evidence Guidelines
Listed Medicines Compliance Framework

- Pre-approved ingredients
- Good manufacturing practice (GMP)
- Low level therapeutic claims

Medicine listed on ARTG → Post-market Compliance review

- Fully compliant
- Non compliant

Cancelled from ARTG
TGA: Post market compliance

Risk based regulatory approach includes:

• desk-based audits of listed medicines – ‘compliance reviews’
• laboratory testing of products and ingredients
• monitoring of adverse reactions
• recalls
• audit of manufacturing sites
• controls for advertising
Post market compliance at our Branch

Risk based regulatory approach includes:

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Registered Complementary Medicines Regulatory Framework

- If the medicine cannot be listed then it may need to be Registered
Traditional Indications – Evidence

“Tradition of use”

• Evidence to show use for its intended purpose for at least 3 generations (75 years)
• Only refer to terms within that paradigm

Sources of evidence include:

• National formularies
• Materia medica
• Monographs
• Official pharmacopoeias e.g. Pharmacopoeia of the People’s Republic of China
Scientific Indications - Evidence

Scientific evidence:
• Quantifiable data

Sources of evidence include:
• Clinical studies
• Peer-reviewed published articles
• Pharmacopoeias
• Systematic reviews
Traditional Chinese Medicines within the regulatory framework

- Adulteration
- Aristolochic acids
- Homeopathic ingredients
Traditional Chinese Medicines within the regulatory framework

- Adulteration
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Akebia, Asarum, Bragantia, Clematis, Cocculus, Diploclisia, Menispernum, Saussurea, Sinomenium, Stephania, Vladimiria.

Products containing **Mu Tong** and **Fang Ji** as ingredients also at risk of containing the Aristolochia species.
Traditional Chinese Medicines within the regulatory framework

- Adulteration
- Aristolochic acids
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Outcomes of the Medicines and Medical Devices Review (MMDR)

• 58 recommendations altogether
• 19 recommendations for complementary medicines
• Included in the Government's 2016-17 budget statements
• Watch this space
• Department of Health [website](#) for more information
Guidance material

- Australian Regulatory Guidelines for Complementary Medicines (ARGCM)
- Evidence Guidelines

twitter.com/tgagovau
TGA.gov.au
Contact us

Complementary and OTC Medicines Branch

- complementary.medicines@tga.gov.au
- 1800 020 653 (freecall within Australia)
- 02 6232 8634

Report a perceived breach or questionable practices


Reporting adverse effects
