Australian Government
Department of Health
Therapeutic Goods Administration

# Regulation of products with tradition of use at the Food/Cosmetic-Medicine interfaces

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ICFA Presentation

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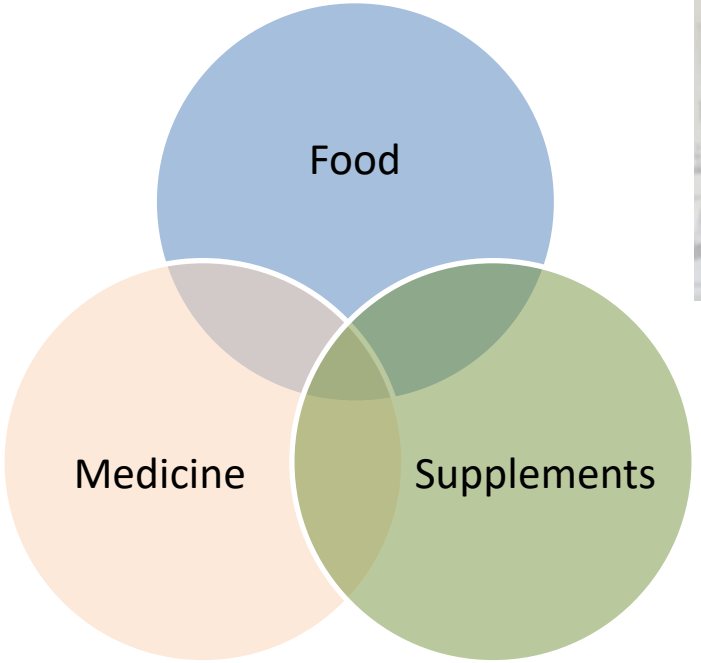
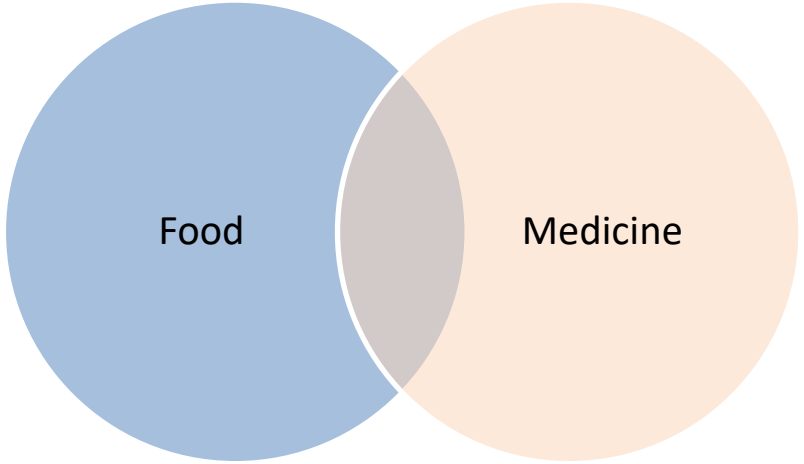
TGA Health Safety Regulation

# What is the Food-Medicine Interface?

## International markets




## Australia



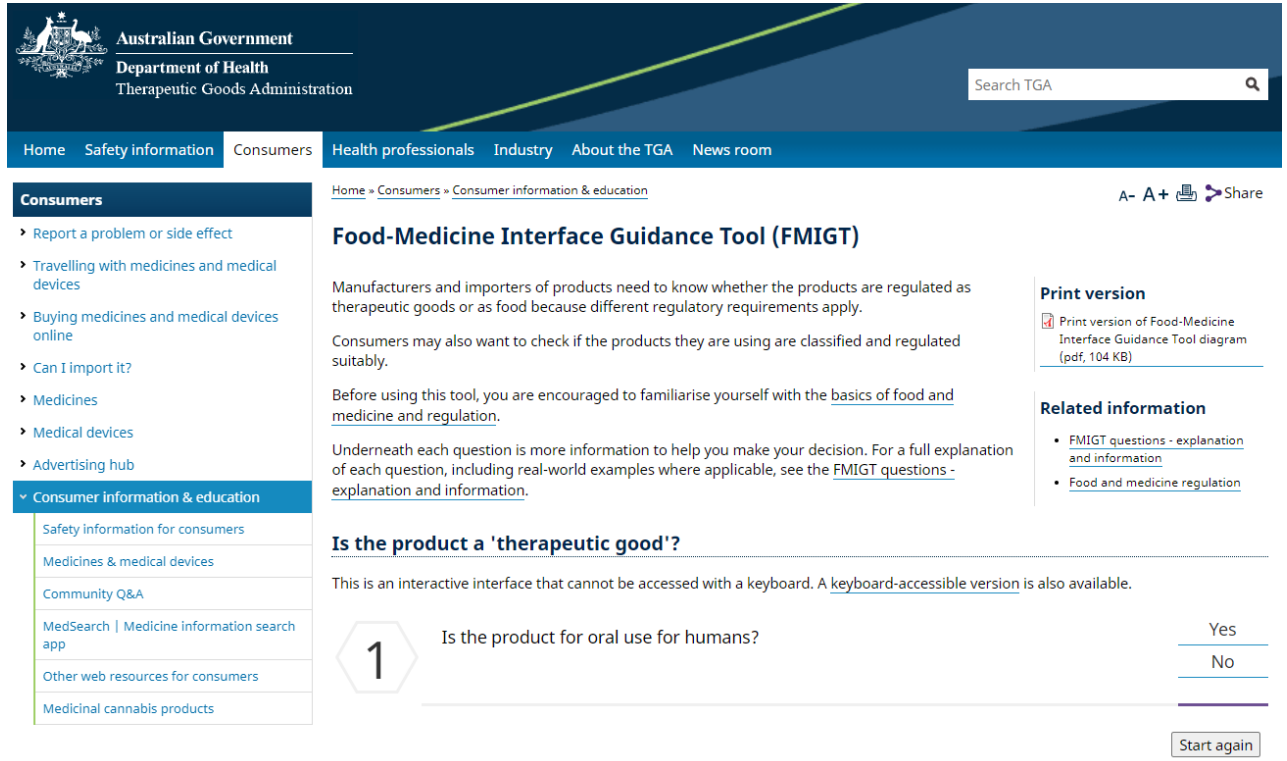
# Determining how a product is regulated?

**Therapeutic Good**

- Declared Good
- No Food Standard
- Not Traditional Food
- Therapeutic Use

**Food**

- Food Standard
- Tradition of use as food
- Excluded Good




Useful links:

- Food-Medicine Interface Guidance Tool (FMIGT)
- Food-Medicine Interface Guidance Tool questions - explanation and information

# Why does it matter?

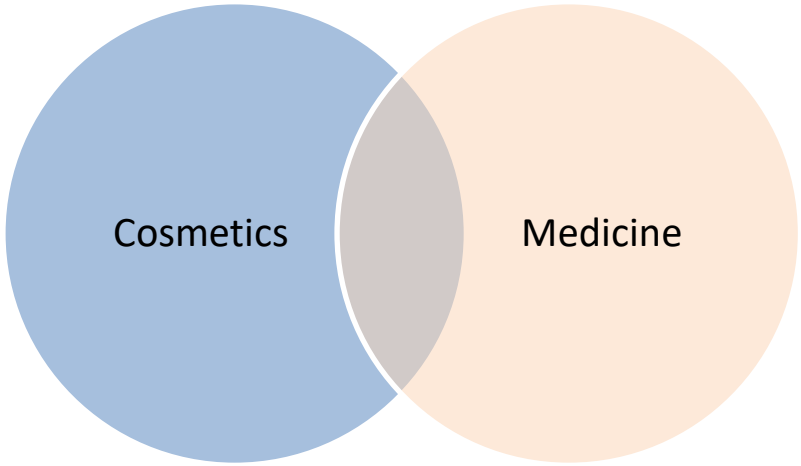
## Therapeutic Goods

- Regulated by the Therapeutic Goods Administration (TGA) – Federal level
- *Therapeutic Goods Act 1989*

## Foods

- Regulated by State/Territory jurisdictions
- *Food Standards Australia New Zealand Act 1991*

# The Cosmetic-Medicine Interface and regulation




Cosmetic Regulation:

- Australian Industrial Chemical Introduction Scheme (AICIS)
- Australian Competition and Consumer Commission (ACCC)

Cosmetics making therapeutic claims are therapeutic goods **unless:**

- The product is declared to NOT be a therapeutic good

# Cosmetic-Medicine Interface examples

- Sunscreens:
  - Primary sunscreens are therapeutic goods
  - Secondary sunscreens ***may*** be excluded goods, see Therapeutic Goods (Excluded Goods) Determination 2018
- Moisturisers
  - ***may*** be excluded goods, see Therapeutic Goods (Excluded Goods) Determination 2018
- Creams, oils, ointments
  - Dependent on claims and ingredients
- Oral use cosmetics
  - Are declared therapeutic goods, see Therapeutic Goods (Declared Goods) Order 2019


# Regulation of medicines

Key requirements:

- Unless ***exempt,*** must be included on the Australian Register of Therapeutic Goods (ARTG)
- Must be manufactured in accordance with the principles of good manufacturing practice (GMP)
- Other requirements depend on the type of medicine and their level of risk:
  - Higher risk – Registered medicines
  - Lower risk – Listed medicines


Overview of the regulation of listed medicines and registered complementary medicines

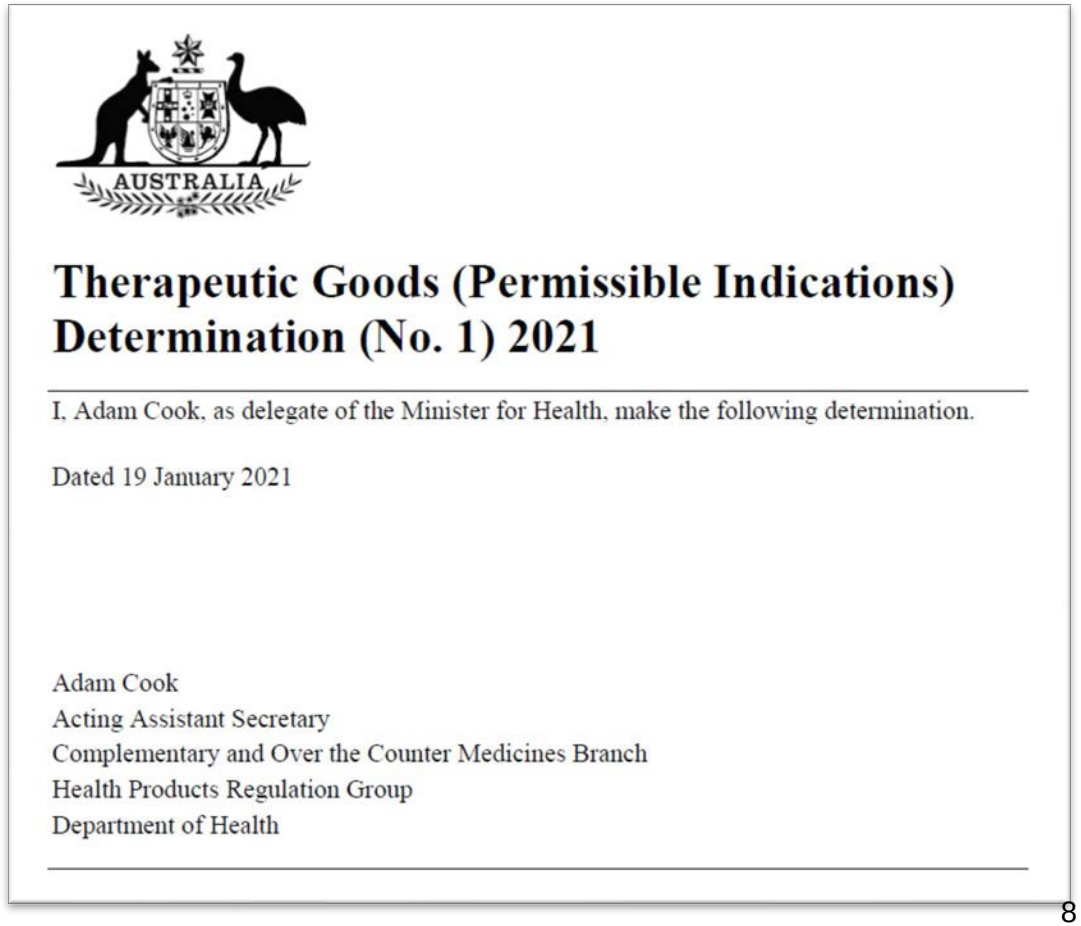
# Types of medicines

| Attribute | **Listed** | Assessed listed | Registered |
|---|---|---|---|
| ARTG number | AUST L | AUST L(A) | AUST R |
| Pre-market efficacy assessment | No | Yes | Yes |
| Ingredients | From a list of pre-approved ingredients only | From a list of pre-approved ingredients only | Ingredients are assessed pre-market |
| Indications (conditions the medicine says it will treat) | From a list of pre-approved conditions only | Conditions are assessed pre-market | Conditions are assessed pre-market |
| Available off-the-shelf | Yes | Yes | Some |
| Need for a prescription from a health professional | No | No | Some |

# Listed medicines - Permitted indications

Therapeutic Goods (Permissible Indications) Determination (No. 1) 2021

- Subsection 26BF of the *Therapeutic Goods Act 1989*
- Contains the list of pre-approved permitted indications
  - Sponsors can only choose from this list when listing their medicine on the ARTG
- Outlines 'requirements' relating to the use of indications
  - General rules for how permitted indications can be used on medicine labels and in advertising



AUSTRALIA

**Therapeutic Goods (Permissible Indications) Determination (No. 1) 2021**

I, Adam Cook, as delegate of the Minister for Health, make the following determination.

Dated 19 January 2021

Adam Cook
Acting Assistant Secretary
Complementary and Over the Counter Medicines Branch
Health Products Regulation Group
Department of Health

# Permitted Indications - Why are they low risk?

Permitted indications are pre-approved by the TGA.

Permitted indications can only refer to:

- **health enhancement** e.g. '*Promote healthy digestion'*
- **health maintenance** e.g. '*Maintain healthy joints'*
- prevention of **dietary deficiency** e.g. '*Prevent dietary calcium deficiency*'
- **a non serious form** of a disease or ailment etc. e.g.*'Relieve symptoms of common cold'*

Permitted indications must be consistent with a treatment paradigm

Using permitted indications

*This fact sheet provides guidance on how to select and use permitted indications for your listed medicine.*

**Selecting indications in the Electronic Listing Facility (ELF)**

When entering your medicine into ELF, you will be able search through the list of permitted indications using a key word, body part / system or evidence type (for example, tradition of use).

**How to select evidence qualifiers to align with evidence you hold**

You may select optional evidence qualifiers to make a permitted indication more specific and align with the evidence you hold for your medicine. If a qualifier is included on the medicine label, it must be included in the ARTG entry and vice versa. The evidence qualifiers include:

| | |
|---|---|
| Traditional context | This is a mandatory qualifier for indications supported by evidence of a tradition of use, for example: 'Traditionally used in Western herbal medicine'. |
| Population | This is an optional qualifier and specifies the target population, for example: 'in healthy individuals'. |
| Traditional Chinese Medicine pattern | This is an optional qualifier for TCMs and specifies the underlying pattern that causes rise to the symptoms included in the indication, for example: 'Qi Deficiency pattern'. |
| Time of use | This is an optional qualifier and indicates the time of use, for example: 'after exercise'. |

Using permitted indications

# Traditional use - Where does it fit?

Traditional medicines include a diverse range of health practices, approaches, knowledge and beliefs incorporating medicines of plant, animal and/or mineral origin.

- **Finished products** available to consumers are regulated as Listed Medicines
- Permitted indications are available with tradition of use qualifiers from recognised paradigms
- Recognised paradigms include:
  - Traditional Chinese Medicines
  - Traditional Ayurvedic Medicine
  - Traditional Australian indigenous medicine
- Currently, there are 13 listed medicines with indications including Traditional Australian indigenous medicine paradigm qualifiers

# How can new indications be added to the Determination?


- Who?
  - Any person may submit an application
- How?
  - Through the 'Indication and Qualifier application' form via the TGA Business Services website
- Is there a cost?
  - Yes there is an application fee
- What is required?
  - Completion of the form, payment of the fee, certifying that it meets the criteria in the Permitted indication assessment tool

# Listed medicines - Permitted ingredients

[Therapeutic Goods (Permissible Ingredients) Determination (No. 3) 2021 (legislation.gov.au)]

- Subsection 26BB(1) of the *Therapeutic Goods Act 1989*
- Covers pre-approved ingredients, low risk ingredients
  - Currently there are 5291 ingredients

- The determination already includes some Australian native plant ingredients such as:
  - Kakadu plum (*Terminalia ferdinandiana*)
  - Mountain pepper berry (*Tasmannia lanceolata*)
  - Tea Tree Oil (Melaleuca oil)

AUSTRALIA

**Therapeutic Goods (Permissible Ingredients) Determination (No. 3) 2021**

I, Cheryl McRae, as delegate of the Minister for Health and Aged Care, make the following determination.

Dated 18 October 2021

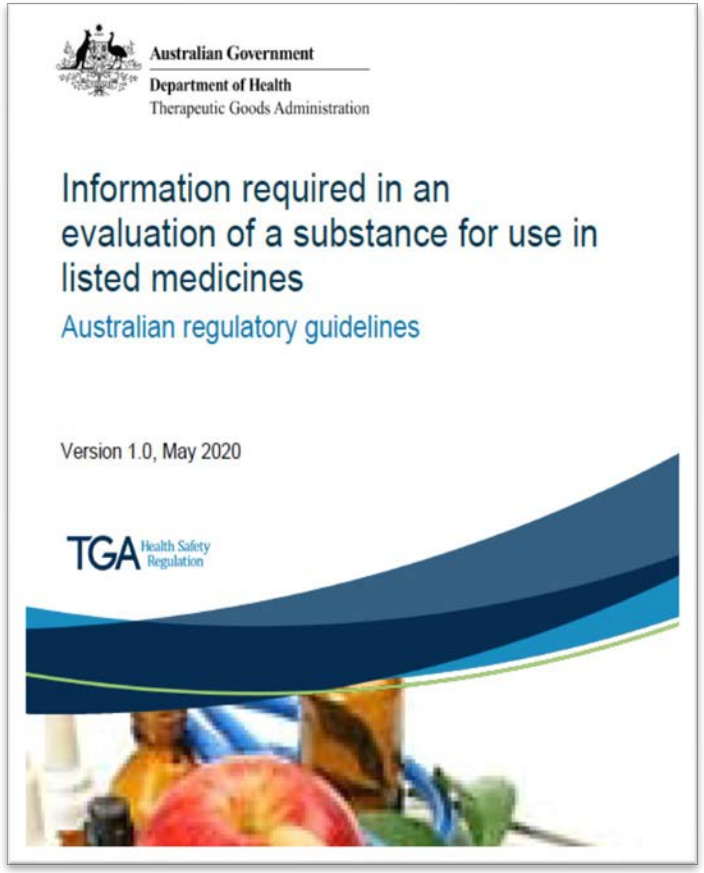
Cheryl McRae
Assistant Secretary
Complementary and Over the Counter Medicines Branch
Health Products Regulation Group
Department of Health

# How can new ingredients be added to the Determination?


- Who?
  - Any person may submit an application
- How?
  - Through the Application for evaluation of a new listed medicine substance' form
- Is there a cost?
  - Yes there is an application and an evaluation fee
- What is required?
  - Completion of the form, payment of the fee, submission of required information

Applications for new substances in listed medicines

# Data requirements



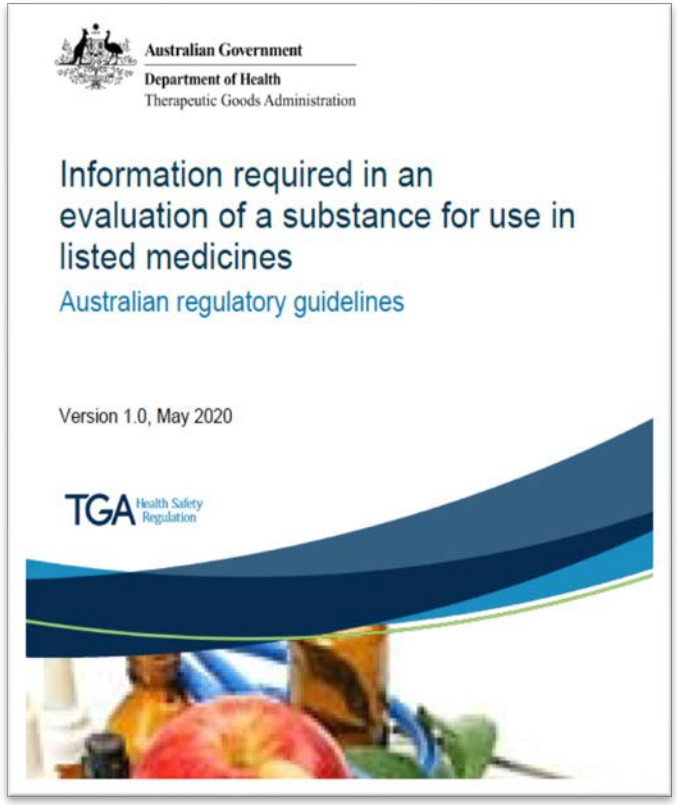

**Key requirements for traditional ingredients include:**

- Establish quality and safety data
  - Requirements:

| Quality | Safety |
|---|---|
| Definition | Literature search |
| Chemical identity | Traditional use – is the proposed substance the same as that used traditionally?<br>- same plant part, preparation, dosage, dosage form, route of administration and typical schedule of administration |
| General properties | |
| Manufacturing details | |
| Characterisation | Biological activity |
| Assay | Clinical trials |
| Incidental constituents | Adverse reactions |

Information required in an evaluation of a substance for use in listed medicines: guidance for sponsors

# Data requirements (continued)




**Key requirements for traditional ingredients include:**

- The population and culture in which this tradition occurred must be identified.
  - In some cases, evidence of traditional use, for example: aboriginal bush remedies, would require robust anthropological research data.
- Consideration must be given to account for differences between traditional vs modern methodologies that may produce considerably different compositional profiles
- Reference an existing pharmacopeial monograph entry OR develop a compositional guideline

Information required in an evaluation of a substance for use in listed medicines: guidance for sponsors

# Cost of new ARTG listings and indications

| Type of fee | Amount | Legislation |
|---|---|---|
| Listed Medicine application fee | $1,170 | Therapeutic Goods (Charges) Regulations 2018 Item 7(1)(c)(i) and Item 7(2)(c)(i) |
| Listed Medicine annual charge | $870 | *Therapeutic Goods Regulations 1990*, Schedule 9 Part 2 Item 3(b) |
| Application for a new indication | $1,090 | *Therapeutic Goods Regulations 1990*, Schedule 9 Part 2 Item 7C |

# New substance applications (new ingredients)

| Application Category | Application fee | Evaluation fee | Legislation |
|---|---|---|---|
| IN1 | $1,120 | $15,100 | Schedule 9, Part 4, Items 28 & 29 |
| IN2 | $1,120 | $15,100 | Schedule 9, Part 4, Items 30 & 31 |
| IN3 | $2,970 | $24,600 | Schedule 9, Part 4, Items 32 & 33 |
| IN4 | $2,970 | $24,600 | Schedule 9, Part 4, Items 34 & 35 |

For information on application types, see Applications for new substances in listed medicines.

**Exclusive use post-approval:**
Opt-in system, allows applicant to have exclusive use of the ingredient (in Listed Medicines) for 2 years

# Useful resources

TGA Small-Medium Enterprise (SME) assist resources:

- Regulation essentials
- Overview of supplying therapeutic goods in Australia
- Understanding ingredient requirements
- Useful resources for business and researchers

Other TGA information/resources:

- TGA Business services - how to use the site
- Listed complementary medicines
- Australian Regulatory Guidelines for Listed Medicines and Registered Complementary Medicines
- General guidance for listed medicines
- Evidence guidelines
- What evidence do you need to support your traditional indication?

Permitted indications resources:

- Permitted indications for listed medicines guidance: Applying for new indications
- FAQs on issues raised by industry in relation to permitted indications
- Outcomes of the consultation on the draft list of permitted indications

Permitted ingredients resources:

- Introduction to the Permissible Ingredients Determination
- Introduction to the Poisons Standard
- User guide: Evaluation of substances for use in listed medicines and assessed listed medicines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