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Department of Health and Ageing

Therapeutic Goods Administration

Australian Regulatory Guidelines for Complementary Medicines

Part IV: General Guidance

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TGA Health Safety
Regulation



About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. The TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.

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Version history

Version	Description of change	Author	Effective date
V4.0	The ARGCM was amended to take into account the TGA restructure of July 2010. Some editorial changes were made, such as corrections of typographic errors.	Office of Complementary Medicines	March 2011
V4.1	Version 4.0 was transferred into the new TGA template. The content remained the same, but page numbers changed. This version was also labelled 'Version 4.0'	Office of Parliamentary and Strategic Support	May 2011
V4.2	A version history table was added. The version was labelled as 'Version 4.2'. Changes were also made to capitalisation of titles.	Office of Parliamentary and Strategic Support	August 2011

Contents

1. Overview	9
2. Homoeopathic preparations and mother tinctures	10
2.1. Notes on homoeopathic preparations	10
2.1.1. Homoeopathic potency	10
2.1.2. What is a Listable homoeopathic preparation?	11
2.1.3. Which homoeopathic preparations do not need to be included in the ARTG?	11
2.1.4. Specific labelling requirements for homoeopathic preparations	11
2.1.5. Guidance on claims	11
2.1.6. Poisons scheduling	11
2.1.7. Manufacture	12
2.2. Criteria for Listing	12
3. Traditional herbal medicines	13
3.1. Traditional use	14
3.2. Quality	14
3.3. Stability testing	15
3.4. Safety	15
3.5. Efficacy	16
3.6. Multi-ingredient products	16
3.7. Supporting material	17
4. Aromatherapy	18
4.1. Essential oil products making therapeutic claims	18
4.2. Essential oils for use as starting materials	19
4.2.1. Essential oils supplied solely as starting materials to practitioners	19
4.2.2. Essential oils used in the manufacture of therapeutic goods	19
5. Practitioner products	20
5.1. Dispensed and extemporaneously compounded medicines	20
5.2. Pre-packaged (manufactured) medicines	20
5.3. 'For Practitioner Dispensing Only' products	21
5.3.1. Purpose statements on 'For Practitioner Dispensing Only' product labels	21

5.4. Legal constraints	22
6. Exempt / Excluded goods	23
6.1. Excluded	23
6.2. Exempt	23
6.3. Further information	23
7. Proprietary ingredients	24
7.1. New classification system for proprietary ingredients lodged with the TGA for use in Listed medicines	24
7.2. Data requirements for proprietary ingredients	25
7.3. Specific requirements for proprietary ingredients in Listed medicines	25
7.3.1. Type 1a: Colours	25
7.3.2. Type 1b: Flavours, fragrances and inks	25
7.3.3. Type 2: Active intermediate formulations (active pre-mixes)	26
7.3.4. Type 3: Vehicles (cream and ointment bases, capsule shells)	26
7.3.5. Type 4: Pre-formulated mixes of preservatives	26
7.4. Labelling associated with proprietary ingredients	27
8. Interface issues	28
8.1. Medicine / Device interface	28
8.1.1. Regulatory system for medical devices	28
8.2. Cosmetic / Medicine interface	29
8.2.1. Composition	29
8.2.2. Proposed use	29
8.2.3. Legislation	30
8.3. Medicine / Food interface	30
8.3.1. Food Standards Australia New Zealand (FSANZ)	30
8.3.2. Differentiation between therapeutic goods and foods	31
8.3.3. Food / Medicines interface group	32
8.4. Complementary / Pharmaceutical medicine interface: route of evaluation	33
8.4.1. OCM to OTC or <i>vice versa</i>	33
8.4.2. Prescription to OTC or OCM	33
8.4.3. OCM to Prescription	34
8.4.4. Excipients	34

8.4.5.	Currently registered non-prescription transdermal patches_____	34
8.4.6.	Administrative details_____	35
9.	Australian native and endangered species in therapeutic goods	36
9.1.	Background_____	36
9.2.	The role of the Therapeutic Goods Administration_____	37
9.3.	More information_____	37
10.	Other legislation	38
11.	Certificates of analysis – product	39
12.	Product Specifications	40
13.	Enforcement procedures	42
13.1.	Listed medicines_____	42
13.2.	Post market monitoring_____	42
13.3.	Listing Compliance Section (LCS) of the OCM_____	43
13.4.	Regulatory action_____	43
14.	Review of decisions	44
14.1.	Appeal mechanisms (Section 60 appeals)_____	44
14.2.	The Administrative Appeals Tribunal (AAT)_____	45
14.3.	Federal Court_____	45
15.	Genetically Modified Organisms	46
15.1.	Definitions_____	46
15.2.	TGA assessment of GMOs and GM Products_____	46
15.3.	Gene technology legislation_____	47
15.3.1.	Public record_____	47
15.3.2.	Exchange of advice on GMOs or GM products_____	48
15.4.	Labelling_____	48
15.5.	More information_____	49
16.	Medicines for export	50
16.1.	Medicines already approved for supply in Australia_____	50
16.2.	‘Solely for Export’ medicines_____	50

17.	Naming of new substances and terminology	52
17.1.	What is Australian approved terminology? _____	52
17.2.	What are the different types of names for substances? _____	53
17.3.	Substances that do not have an approved name _____	54
17.3.1.	Application Forms _____	54
17.3.2.	Review of New AAN Requests _____	55
18.	Colourings permitted in medicines for oral use	57
19.	Herbal ingredients – quality	58
19.1.	Background _____	58
19.2.	Scope of the Guideline for herbal substances _____	58
19.3.	General concepts _____	59
19.3.1.	Characterisation _____	59
19.3.2.	Development considerations _____	59
19.3.3.	Pharmacopoeial tests and acceptance criteria _____	60
19.3.4.	Alternative non-pharmacopoeial tests _____	60
19.3.5.	Evolving technologies _____	60
19.3.6.	Reference standard _____	60
19.3.7.	Statistical concepts _____	60
19.4.	Compositional guideline _____	60
19.4.1.	Definition of compositional guideline _____	60
19.4.2.	Justification of specifications _____	61
19.4.3.	Universal tests / criteria _____	61
19.5.	Herbal preparations _____	63
20.	Ingredients of human or animal origin	66
20.1.	Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products _____	66
20.2.	Ingredients of human origin _____	67
21.	Glossary of terms used in the Australian Regulatory Guidelines for Complementary Medicines	68
21.1.	Notes _____	68
21.2.	Glossary _____	68

22. Abbreviations and acronyms used in the Australian Regulatory Guidelines for Complementary Medicines 93

23. Hyperlink references contained in the Australian Regulatory Guidelines for Complementary Medicines 98

23.1.	Therapeutic Goods Act 1989 _____	99
23.2.	Therapeutic Goods Regulations 1990 _____	99
23.3.	TGA guidance _____	99
23.4.	Other guidance _____	101
23.5.	Forms _____	102
23.6.	Therapeutic Goods Orders _____	103
23.7.	Other legislation _____	103
23.8.	E-mail contacts _____	104
23.9	Other regulatory agencies _____	104
23.10.	Miscellaneous _____	104

1. Overview

The purpose of this Part of the Guidelines is to provide guidance to sponsors on specific complementary medicine modalities such as homoeopathy, traditional herbal medicine and aromatherapy. This part also provides information on exempt medicines, combination complementary / pharmaceutical medicines and the food / medicine interface.

The regulatory requirements for the Registration and Listing of complementary medicines are discussed in Parts I and II of the Guidelines. The regulatory requirements for the evaluation of complementary medicine substances are discussed in Part III.

Detailed guidance is provided in the following sections:

- [Section 2.](#) – Homoeopathic Preparations and Mother Tinctures
- [Section 3.](#) – Traditional Herbal Medicines
- [Section 4.](#) – Aromatherapy
- [Section 5.](#) – Practitioner Products
- [Section 6.](#) – Exempt / Excluded Goods
- [Section 7.](#) – Proprietary Ingredients
- [Section 8.](#) – Interface Issues
- [Section 9.](#) – Australian Native and Endangered Species in Therapeutic Goods
- [Section 10.](#) – Other Legislation
- [Section 11.](#) – Certificates of Analysis – Product
- [Section 12.](#) – Product Specifications
- [Section 13.](#) – Enforcement Procedures
- [Section 14.](#) – Review of Decisions
- [Section 15.](#) – Genetically Modified Organisms
- [Section 16.](#) – Medicines for Export
- [Section 17.](#) – Naming of New Substances and Terminology
- [Section 18.](#) – Colourings Permitted in Medicines for Oral Use
- [Section 19.](#) – Herbal Ingredients - Quality
- [Section 20.](#) – Ingredients of Human or Animal Origin
- [Section 21.](#) – Glossary of Terms Used in the ARGCM
- [Section 22.](#) – Abbreviations and Acronyms Used in the ARGCM
- [Section 23.](#) – Hyperlink References Contained in the ARGCM.

2. Homoeopathic preparations and mother tinctures

This section is divided into the following subsections:

2.1. [Notes on homoeopathic preparations](#)

2.2. [Criteria for Listing](#)

In Australia, products containing homoeopathic medicines are regulated under the [Therapeutic Goods Act 1989](#) (the Act). Homoeopathic medicines are considered to be low-risk medicines. Where a homoeopathic preparation meets certain conditions it may not need to be included in the Australian Register for Therapeutic Goods (ARTG) and, in some cases, may not need to be manufactured under good manufacturing practice (GMP).

The current definition for 'homoeopathic preparation' included in the [Therapeutic Goods Regulations 1990](#) (the Regulations) is based upon the central tenet of homoeopathy – *similia similibus curentur* or 'let like cure like', and the principles of homoeopathic pharmacy – serial dilution and succussion of a stock.

Consistent with the definition, the dilution of an ingredient *does not* make it a homoeopathic preparation. A homoeopathic preparation must also be 'formulated for use on the principle that it is capable of producing in a healthy person symptoms similar to those which it is administered to alleviate'; in other words, it should comply with the principle of 'like cures like'.

A homoeopathic medicine should be adequately described to ensure that it is clearly differentiated from those medicines not consistent with the homoeopathic paradigm.

2.1. Notes on homoeopathic preparations

2.1.1. Homoeopathic potency

Homoeopathic potency is defined in *Therapeutic Goods Order No. 69 – General Requirements for Labels for Medicines* ([TGO 69](#)):

Homoeopathic potency means the dilution factor expressed as:

- a. 'nX', where each dilution is a decimal or ten fold dilution and 'n' is the number of dilutions such that the total dilution is 10^n ; or
- b. 'nC', where each dilution is a centesimal or hundred fold dilution and 'n' is the number of dilutions such that the total dilution is 100^n .

2.1.2. What is a Listable homoeopathic preparation?

To be Listed as a homoeopathic preparation, a product must be a 'homoeopathic preparation' as defined in [Regulation 2 of the Therapeutic Goods Regulations](#) 1990 (the Regulations); i.e. it must be a preparation:

- formulated for use on the principle that it is capable of producing in a healthy person symptoms similar to those which it is administered to alleviate;
- prepared according to the practices of homoeopathic pharmacy using the methods of:
 - serial dilution and succussion of a mother tincture in water, ethanol, aqueous ethanol or glycerol; **OR**
 - serial trituration in lactose.

2.1.3. Which homoeopathic preparations do not need to be included in the ARTG?

Where an ingredient meets the definition of 'homoeopathic preparation', and meets the conditions set out under Schedule 5, Item 8 of the Regulations, it may not need to be included in the ARTG. This *does not* apply where the homoeopathic preparation is part of a product containing other ingredients requiring inclusion in the ARTG.

Homoeopathic preparations are exempt from the need to be Listed or Registered if:

- all components are more dilute than a one-thousand-fold dilution of the mother tincture;

the indications for use are permitted indications under clause 4 of the [Therapeutic Goods Advertising Code](#) (TGAC);

- the product is not of a kind that needs to be sterile; and / or

the preparation contains no ingredients of human origin, or animal-sourced material which is a Category A or Category B substance (see [ARGCM Part V – Minimising the Risk of Transmissible Spongiform Encephalopathies \(TSEs\)](#)).

Homoeopathic medicines prepared by practitioners specifically for an individual patient do not need to be entered in the ARTG.

2.1.4. Specific labelling requirements for homoeopathic preparations

The labelling standard, *Therapeutic Goods Order No. 69 – General Requirements for Labels for Medicines* ([TGO 69](#)) includes some special requirements for homoeopathic preparations.

2.1.5. Guidance on claims

The presence of claimed indications for use that are outside those permitted in Clause 4 of the TGAC does not make a homoeopathic preparation Registrable; it may still be Listed in the ARTG. However, the label on the container and on the primary pack of such products must include a statement that the indications have not been 'approved' by the TGA. Such a statement would be: 'Homoeopathic product without approved therapeutic indications'.

The TGAC requirements apply in the usual way to homoeopathic products, which may not be displayed and advertised to the general public for purposes outside those permitted by the TGAC and Regulations, **whether or not** those indications are Listed in the ARTG.

2.1.6. Poisons scheduling

Some homoeopathic preparations prepared from scheduled poisons are exempted from the requirements of the [Standard for the Uniform Scheduling of Medicines and Poisons](#) (SUSMP) by the provisions of SUSMP Appendix G, which covers products containing certain poisons at very low (specified) concentrations.

Appendix C of the SUSMP lists hazardous substances that are generally prohibited as product ingredients. However, it is accepted that this prohibition does not apply to homoeopathic preparations in which the ingredient is a dilution of 10^{12} or greater of the mother tincture.

2.1.7. Manufacture

Concentrated homoeopathic preparations (less than or equal to a one-thousand-fold dilution of the mother tincture) must be manufactured by a licensed manufacturer. Those more dilute than a one-thousand-fold dilution of the mother tincture are exempt from this requirement provided they are not preparations of a kind required to be sterile.

If imported products are of a type whose manufacturer in Australia would need to be licensed, evidence of an acceptable standard of overseas manufacture must be provided and cleared before lodgement of the Listing application. An explanation of how this evidence can be obtained is given in the document *Guidelines on Standard of Overseas Manufacturers*.

2.2. Criteria for Listing

Homoeopathic preparations and mother tinctures are Listable if they:

- are a mother tincture or a homoeopathic dilution of one-thousand-fold or less; **OR** (irrespective of potency) have indications for use outside those permitted for public advertising under Clause 4 of the [TGAC](#), or are derived from substances of human origin or animal-sourced material that are Category A or Category B substances;
- contain an ingredient which is at a dilution of one-thousand-fold or less (of the mother tincture) and any part of the manufacture occurring in Australia is carried out by a licensed manufacturer;
- contain an ingredient which is at a dilution of one-thousand-fold or less (of the mother tincture), and are manufactured overseas, and evidence has been provided to demonstrate that the overseas manufacture is of a standard equivalent to that required in Australia;
- are NOT subject to the conditions of a schedule (or applicable Appendix) to the SUSMP, **OR** if the product is subject to the conditions of a schedule (or applicable Appendix) to the SUSMP, the ingredient that causes the product to be scheduled is present at a dilution greater than one-thousand-fold;
- do NOT contain substances that are prohibited imports under the *Customs Act 1901* [refer [Customs \(Prohibited Imports\) Regulations](#)];
- are NOT for supply as a pharmaceutical benefit under the Pharmaceutical Benefits Scheme (PBS); and
- are NOT a preparation of a kind that needs to be sterile (such as eye drops, eye ointments, injections, irrigation solutions and implants).

Listed homoeopathic preparations and mother tinctures which are Listed must:

- be labelled in compliance with the general requirements for labels for medicinal products as current and in force (currently [TGO 69 and 69C](#)), and any other applicable official standards;
- comply with advertising requirements set out in [Schedule 2](#) of the Regulations; and
- comply with any quality or safety criteria prescribed in the Regulations.

3. Traditional herbal medicines

This section is divided into the following subsections:

- 3.1. [Traditional use](#)
- 3.2. [Quality](#)
- 3.3. [Stability testing](#)
- 3.4. [Safety](#)
- 3.5. [Efficacy](#)
- 3.6. [Multi-ingredient products](#)
- 3.7. [Supporting material](#)

herbal substance means all or part of a plant or substance (other than a pure chemical or a substance of bacterial origin):

- a. that is obtained only by drying, crushing, distilling, extracting, expressing, comminuting, mixing with an inert diluent substance or another herbal substance or mixing with water, ethanol, glycerol or aqueous ethanol; and
- b. that is not subjected to any other treatment or process other than a treatment or process that is necessary for its presentation in a pharmaceutical form.

Herbal medicines are those therapeutic goods which are, or contain as the major active ingredient(s), herbal substances as defined in [Regulation 2 – Interpretation](#) of the Therapeutic Goods Regulations 1990 (the Regulations).



The following guidance is intended to provide assistance for sponsors preparing Registration applications for traditional herbal medicines.

An 'ingredient' refers to a herbal substance in the formulation, and a 'component' is a chemical constituent of an ingredient.

There are special characteristics of herbal products which necessitate the provision of additional information for their Registration for therapeutic use. This does not imply that the principles of evaluation differ but that allowance is made for different product characteristics which include that:

- usage is wholly or partly based on a traditional use rather than efficacy established by formal clinical studies;

- active components of the herbs may not have been isolated, characterised or quantified; and
- efficacy is claimed to result from the summation of pharmacological activity of an undefined blend of active components from one or more species of herb.

3.1. Traditional use

A 'traditional medical system' means a formalised set of practices, historically evolved from deliberate behaviour to enhance health and not explicitly derived from the conceptual framework of modern medicine.

A 'traditional use' means the use of a herb or herbal mixture by practitioners of a traditional medical system where:

- the use is well established and widely acknowledged, i.e. the use represents the accumulated experience of many practitioners over an extended period;
- the effective preparation, dosage, method of use and indications are well established; and
- the botanical identity of the herbal substance(s) is clearly established.



This subsection of the Guidelines does not apply directly to traditional medicines with ingredients of animal and mineral origin. However, many of the same principles do apply, and sponsors of such products are advised to follow these guidelines wherever possible.



This subsection does not apply to active component(s) of a herb which have been identified and either isolated or synthesised as chemical component(s) of a medicine (e.g. atropine).

3.2. Quality

Each herbal ingredient in the formulation should be characterised by giving its Australian Approved Name (AAN) (refer to Section 3 *Herbal Substances* in the Therapeutic Goods Administration [\(TGA\) Approved Terminology for Medicines](#)). Sponsors should ensure that they state the part of the plant used and its form, i.e. whether it is a fresh or dried material, together with details of any processing it undergoes before use in the manufacture of the product. Where appropriate it may be necessary to state the country or region of origin of the ingredient, or give other details such as time of harvesting and stage of growth, which are pertinent to the quality of the ingredient.

If a herb is not included in the [Herbal Substances AAN List](#), you should propose a botanical name for it, using the [application form](#) included in the introduction to the List.

If the herb is processed to produce a galenical form, the extraction and any concentration processes should be described or a reference cited, indicating whether the extract or additives, such as calcium phosphate in dry extracts, are present in the final product formulation.

Starting material specifications should be provided or a reference cited for each starting material. Where a pharmacopoeial reference does not apply to an ingredient, the specification should give details of the test methods and test specifications. Appropriate testing techniques are required in accordance with the [Guide to Good Manufacturing Practice for Medicinal Product - Annexes](#), Annex 7 – *Manufacture of Herbal Medicinal Products*. These would need to cover identity and, where appropriate, adulteration and contamination, both chemical and microbiological. Where a herbal ingredient is standardised in terms of a component(s) and the statement of activity on the label is based on this standardisation, you should provide evidence of how the standardisation is achieved.

Data on the nature or chemistry of the active component should be provided. This may include citation of pharmacopoeial monographs, photocopies from authoritative references, or your own data.

A brief description of the manufacturing process should also be provided.

The finished product specifications should be provided, defining the physical, chemical and microbiological characteristics of the product and detailing quality-control test methods and test specifications.

3.3. Stability testing

Refer to [ARGCM Part I](#), and ARGCM Part I, Appendix 3 – *Stability of the Finished Product* for detailed information on stability testing. In addition, further advice for sponsors is provided in the document *Questions & Answers on the Stability Testing of Listed Complementary Medicines*, which is published on the TGA website at <http://www.tga.gov.au/industry/cm-stability-testing-qa.htm>.

Where the active components of a traditional medicine cannot be quantified, you should state the basis for establishing the shelf life, taking into account the physical and microbiological stability of the product and its chemical stability based on chromatographic profile. Physical characteristics could include colour or odour changes, and precipitation.

3.4. Safety

Traditional use is not a substitute for safety assessment. As herbal components are isolated and studied, and as the methodology of toxicological studies improves, much more information on the safety of herbs is becoming available. However, long-term and safe therapeutic use of a herb or formula will be taken into account in evaluating the safety of a product.

Safety is dependent upon the formulation of the product overall, its intended therapeutic purpose, dosage, method (or route) of administration, duration of use, the patient group (such as children, the elderly, and pregnant and lactating women) and use under circumstances where it may interfere with critical medication. It is important where traditional use or a history of use is being used to support safety, that the details of use (e.g. duration, dose etc.) be consistent with the proposed use.

The applicant should provide details of any toxicological studies and traditional records of harmful effects that are reasonably available to establish the safety profile of the herbal ingredients and the product formulation. Details should be provided where the product is contraindicated for use in particular patient groups.

Information on the pharmacological activity of ingredients and their components should be provided where available.

Where the data documenting a tradition of use is insufficient, or there are suspicions of effects that are difficult or impossible to detect with population or clinical studies, the safety evaluation (unless otherwise justified) will need to be supported with other studies (e.g. by single and repeat-dose toxicity, immunotoxicity, reproduction, genotoxicity and carcinogenicity studies).

3.5. Efficacy

Traditional use will be taken into account in establishing efficacy; see the guidance document [Guidelines for Levels and Kinds of Evidence to Support Indications and Claims Levels of Evidence](#).

Supporting evidence can constitute or include material from suitable herbal reference books, provided that the information has not been superseded by more recent research and study. In many instances, the documentation associated with traditional use may not be sufficient in itself to support efficacy for Registration purposes. Such data would need to be supplemented with clinical evidence of efficacy.

Where claims for a herb, prepared with a non-traditional method of harvesting and / or processing, are based on the traditional use of that herb, evidence should be provided to establish that the preparations are medicinally equivalent. If the preparations are medicinally equivalent, clinical evidence of the efficacy of the 'new' preparation may not be required.

Preparations would be considered 'medicinally equivalent' if the preparations, when used in the recommended doses, have or would be reasonably likely to have, a comparable therapeutic effect on the body.

To establish this, it should be shown that the preparations contain a similar range and concentration of constituents, including any known active constituents.

For non-traditional use of herbs, therapeutic claims will need to be supported by clinical evidence of efficacy from published or in-house, controlled clinical trials.

Where non-herbal ingredients are included in a product, a rationale for their inclusion should be provided.

3.6. Multi-ingredient products

Many herbal products consist of a combination of herbal ingredients, with the assumption that the ingredients contribute an undefined range and balance of pharmacologically active components to their overall therapeutic use.

Traditional formulations will normally be accepted unless current adverse evidence exists.

New formulations will be assessed to ensure that the evidence provided in the application demonstrates that:

- each herbal ingredient and any claimed active component(s) contribute toward the intended therapeutic purpose (see the guidance document [Guidelines for Levels and Kinds of Evidence to Support Indications and Claims Levels of Evidence](#))
- the ingredients are chemically, pharmacologically and therapeutically compatible and are in appropriate, effective dosages

- no component adversely affects the safety of the product to the point where the risk / benefit ratio is unacceptable.

The logic of the formulation in terms of the duration of effect of the active components in the body in relation, for instance, to the dosage regime, should be considered.

The rationality of multi-ingredient products should be considered very carefully. Sponsors are therefore advised to consider the validity and need for multi-ingredient formulations.

3.7. Supporting material

All supporting material included in the application should be presented in a form suitable for consideration by the Office of Complementary Medicines (OCM). Where many supporting documents are attached, a table of contents should be included. Documents should be annotated, giving, as appropriate, full details of the author, title, publisher, place of publication, and volume and page numbers.

Where supporting material is provided you should also provide a brief summary of each document stating its relevance to the application.

Abbreviations that are not defined in the introduction to the Herb List, should be defined where the abbreviation is first used.

Where supporting materials are in a language other than English, an accurate English translation must be provided. Where a document concerns a proposed AAN, the translation into English must be authenticated.

Sponsors should check that their application is complete. If the application is not complete or is otherwise deficient, a final decision will be postponed until the information needed is supplied.

4. Aromatherapy

This section is divided into the following subsections:

- 4.1. [Essential oil products making therapeutic claims](#)
- 4.2. [Essential oils for use as starting materials](#)

4.1. Essential oil products making therapeutic claims

Products which contain essential oils must be Listed or Registered in the Australian Register of Therapeutic Goods (ARTG) if they are intended for therapeutic use¹ (e.g. therapeutic claims are made about the product such as: 'relief of pre-menstrual symptoms' or 'relief of sleeplessness').

In addition to the requirements of the [Therapeutic Goods Act 1989](#) (the Act) and the [Therapeutic Goods Regulations 1990](#) (the Regulations) for Listed / Registered medicines, sponsors of products containing essential oil(s), which are considered to be therapeutic goods,² must also comply with standards such as the British Pharmacopoeia (BP), the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), Therapeutic Goods Order No. 69 – [General Requirements for Labels for Medicines](#) (TGO 69) and [TGO 80 Child Resistant Packaging Requirements for Medicines](#) where required.

Many essential oils are included in schedules to the SUSMP, but they are not subject to the conditions of that schedule:

- a. when packed in containers having a nominal capacity of 15 mL or less, fitted with a restricted flow insert, and labelled with the warnings:
KEEP OUT OF REACH OF CHILDREN; and NOT TO BE TAKEN;
- b. when packed in containers having a nominal capacity of 25 mL or less, fitted with a restricted flow insert and child-resistant closure, and labelled with the warnings:
KEEP OUT OF REACH OF CHILDREN; and NOT TO BE TAKEN; or
- c. in preparations containing 25 per cent or less of essential oil.

Note: Complementary medicines containing essential oils must be Registered if they:

- contain an ingredient or component that is subject to the conditions of a Schedule (or relevant appendix) to the SUSMP; and / or
- contain an ingredient or component that has been identified as not suitable for use in Listed medicines (see [Schedule 4, Part 4, Division 1 of the Regulations](#)); and / or
- have indications inappropriate for Listed medicines.

¹ Therapeutic use is defined in Chapter 1, Section 3 of the Act.

² Therapeutic goods are also defined in Chapter 1, Section 3 of the Act.

4.2. Essential oils for use as starting materials

4.2.1. Essential oils supplied solely as starting materials to practitioners

Essential oils that are supplied *solely* as starting materials to practitioners, are generally exempt from the requirement to be included in the ARTG before supply. This means that these oils can be supplied only for the purpose of being subsequently dispensed or extemporaneously compounded for a particular person, for therapeutic application to that person.

4.2.2. Essential oils used in the manufacture of therapeutic goods

The production of essential oils that are to be used as starting materials in the manufacture of therapeutic goods are exempt from the requirement to be manufactured under conditions of good manufacturing practice (GMP). For example, the manufacturer of the 'bulk' essential oil (e.g. the farmer extracting lavender oil from lavender plants) does not need to be licensed for GMP.

However, the manufacturer of the finished dosage form and those who undertake steps in the manufacture (after the initial production of the oil as a starting material), such as those who are responsible for filling, blending, labelling, release for supply, testing etc.) are currently required to hold an appropriate GMP licence.

5. Practitioner products

This section is divided into the following subsections:

- 5.1. [Dispensed and extemporaneously compounded medicines](#)
- 5.2. [Pre-packaged \(manufactured\) medicines](#)
- 5.3. [‘For Practitioner Dispensing Only’ products](#)
- 5.4. [Legal constraints](#)

5.1. Dispensed and extemporaneously compounded medicines

Certain medicines do not need to be included in the Australian Register of Therapeutic Goods (ARTG). This includes medicines that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person. This allows complementary healthcare practitioners, such as pharmacists, herbalists and homoeopaths, to prepare medicines for individual patients that do not need to be assessed or evaluated by the Therapeutic Goods Administration (TGA) for quality, safety or efficacy.



Note: The exemption applies to medicines prepared for individual patients, either following consultations with that particular patient, or to fill a prescription for that particular patient. The exemption does not cover situations where the practitioner makes up medicines in advance, in anticipation of patients who may come onto the premises and ask for that medicine.

Access to some medicinal ingredients is restricted by State and Territory drug and poisons legislation. For example, ingredients included in Schedule 4 of the [Standard for the Uniform Scheduling of Medicines and Poisons](#) (SUSMP) are available only on prescription from a medical practitioner registered under a law of a State or Territory. Depending on the level of access control, some ingredients are not available for dispensing or extemporaneous compounding by complementary healthcare practitioners, such as herbalists, nutritionists, naturopaths, practitioners of traditional Chinese medicine or homoeopathic practitioners.

5.2. Pre-packaged (manufactured) medicines

Most herbal ingredients are not subject to restricted access and may be used for preparing medicines that are dispensed or extemporaneously compounded. However, some ingredients used by practitioners in dispensing or extemporaneous compounding of medicines for patients are subject to TGA legislation. For example, ingredients that are either pre-packaged for other therapeutic purposes, or formulated as a dosage form (such as medicines ‘For Practitioner Dispensing Only’ – see subsection 5.3 below), are subject to TGA assessment for quality, safety and efficacy as appropriate, and are to be included on the ARTG.

5.3. 'For Practitioner Dispensing Only' products

'For Practitioner Dispensing Only' products are complementary medicines that are supplied in a dispensing pack to a (registered) complementary healthcare practitioner with the words 'For Practitioner Dispensing Only' included on the label. These medicines must meet the same standards required for other Listed or Registered complementary medicines.

The difference between 'For Practitioner Dispensing Only' products and other Listed or Registered complementary medicines is that the former do not need to include a statement of their purpose on the label. Other medicines must include therapeutic indications and claims on the label.

The regulation of complementary medicines 'For Practitioner Dispensing Only' is specifically addressed in the Therapeutic Goods Order (TGO) No. 69 – [General Requirements for Labels for Medicines](#).

These regulatory requirements are summarised below.

TGO 69 advises that 'complementary healthcare practitioner' means a person described in paragraph 4(1)(c) of the Regulations. Paragraph 4(1)(c) of the Regulations has been replaced with Section 42AA (1)(c) of the Act, but the definition remains the same:

complementary healthcare practitioner means:

'herbalists, homoeopathic practitioners, chiropractors, naturopaths, nutritionists, practitioners of traditional Chinese medicine, podiatrists or osteopaths [who are] registered under a law of a State or Territory.'

Non-registered practitioners are therefore not 'complementary healthcare practitioners' for the purpose of being supplied with 'dispensing packs' 'For Practitioner Dispensing Only'.

5.3.1. Purpose statements on 'For Practitioner Dispensing Only' product labels

Subsection (m) of Section 3(2) TGO 69 advises that, as long as goods are supplied in a dispensing pack to a (registered) complementary healthcare practitioner and the words 'For Practitioner Dispensing Only' are included on the label, the product does not require a statement of the purpose or purposes for which it is intended that the goods be used. Other information such as an AUST L number, as detailed in TGO 69, must be included on the label.

dispensing pack is defined in TGO69 as follows:

'in relation to complementary healthcare, [dispensing pack] means a pack which is to be supplied solely to complementary healthcare practitioners for supply to a person after affixing an instruction label following a consultation with that person.'

Products available in dispensing packs and labelled 'For Practitioner Dispensing Only' are intended for supply to a person after consultation with that person. An instruction label must be affixed to the product, before supply to the person. All advisory statements appropriate for the ingredient must be included on the label.

Note that medicinal products covered by Schedules 4 and 8 of the SUSMP, which require a prescription before being supplied, are also exempt from the label requirement to include a statement of the purpose for which it is intended that the product be used.

5.4. Legal constraints

Certain diseases may be diagnosed and / or treated only by Registered medical practitioners. Complementary healthcare practitioners should make enquiries to State and Territory Health authorities when considering therapeutic applications for complementary medicines.

Historical document

6. Exempt / Excluded goods

This section is divided into the following subsections:

- 6.1. [Excluded](#)
- 6.2. [Exempt](#)
- 6.3. [Further information](#)

All medicines manufactured for supply in Australia must be Listed or Registered in the Australian Register of Therapeutic Goods (ARTG) unless they are exempt or excluded.

6.1. Excluded

Some products may be unintentionally covered by the definition of a 'therapeutic good'. They are therefore specifically excluded under [Section 7](#) of the *Therapeutic Goods Act 1989* (the Act).

None of the requirements of the Act apply to excluded products.

6.2. Exempt

Some medicines do not need to be Registered or Listed in the ARTG as a result of a specific exemption or determination. Section 18 of the Act and [Schedules 5](#) and 5A of the Therapeutic Goods Regulations 1990 (the Regulations) indicate the goods that are exempt from the need to be included in the ARTG. These include, for example, medicines (other than those used for gene therapy) that are dispensed or extemporaneously compounded for a particular person for therapeutic application to that person; certain homoeopathic preparations; and certain shampoos for the treatment / prevention of dandruff.

While exempt from inclusion in the ARTG, it is important to note that all other applicable requirements under the Act and the Regulations (e.g. standards and advertising or labelling) must be complied with.

Some medicines or persons are exempt from the manufacturing requirements set out in Part 4 of the Act. The criteria for these exemptions are indicated in Section 34 of the Act, together with Schedule 7 of the Regulations (exempt medicines) and Schedule 8 of the Regulations (exempt persons). An example of a person exempt from licensing to manufacture is a pharmacist in their place of practice (including a private hospital).

6.3. Further information

The *Summary Classification of Medicines* is a quick guide to whether a medicine is Listed, Registered, exempt, or excluded. This document is available on the Therapeutic Goods Administration (TGA) website at <<http://www.tga.gov.au/industry/basics-medicines-classification.htm>>.

7. Proprietary ingredients

This section is divided into the following subsections:

- 7.1. [New classification system for proprietary ingredients lodged with the TGA for use in Listed medicines](#)
- 7.2. [Data requirements for proprietary ingredients](#)
- 7.3. [Specific requirements for proprietary ingredients in Listed medicines](#)
- 7.4. [Labelling associated with proprietary ingredients](#)

The term 'proprietary ingredient' (PI) means a confidential formulation usually containing two or more ingredients and about which information is not in the public domain. PIs include fragrances, flavours, colouring ingredients, trans-dermal patch adhesives and printing inks. However, where a pre-mix of active ingredients is used in a PI formulation, the active ingredients must be disclosed. A single ingredient is not usually acceptable as a PI formulation.

Before a PI is included in a product, the sponsor should ensure that:

- formulation and / or processing details have already been disclosed to the Therapeutic Goods Administration (TGA) (in which case the sponsor should give the ingredient's Australian Register of Therapeutic Goods (ARTG) number in the application form) **OR**
- they have asked the manufacturer of the proprietary ingredient to provide the TGA with details of the formulation on a [Notification of a Proprietary Ingredient form](#), and have obtained the ARTG PI number to include in the application form.

Sponsors should be aware that there is no evaluation of the PI formulation in terms of safety or efficacy. However, the individual ingredients of the PI are assessed for safety. For colouring PIs, the colour must be one that is approved for ingestion if the ingredient is to be used in an oral product.

7.1. New classification system for proprietary ingredients lodged with the TGA for use in Listed medicines

New PIs for use in Listed medicines lodged with the TGA are to be categorised into one or other of five types based on the risk profile of ingredients within them:

- | | |
|-----------------|---|
| Type 1a: | Colours – low risk, often long history of use, generally small quantities in finished products. |
| Type 1b: | Fragrances, flavours and printing inks – low risk, often long history of use, generally very small quantities in finished products. |
| Type 2: | Active intermediate formulations (active pre-mixes) – relatively high risk as they contain therapeutically active substances. |
| Type 3: | Vehicles and coating materials (such as cream, ointment bases and capsule shells) – low risk, often long history of use. |

Type 4: Pre-formulated mixes of preservatives – medium risk, as some individuals are sensitive to some preservatives.

7.2. Data requirements for proprietary ingredients

The following information is required when a new PI for use in Listed medicines is lodged with the TGA:

1. The type of PI should be identified;
2. All ingredients should have approved names consistent with the Australian Approved Terminology for Medicines (i.e. AAN, ABN, AHN, AHS or PRV); and
3. Quantitative composition (as a concentration of the total PI) should be provided for all ingredients.

The only exceptions to 2 and 3 above will be for Type 1b PIs, i.e. fragrances, flavours and printing inks, where the declaration of quantitative composition and use of Australian Approved Terminology is not mandatory.

7.3. Specific requirements for proprietary ingredients in Listed medicines

7.3.1. Type 1a: Colours

Only those PIs that are colours currently approved for pharmaceutical ingestion will be allowed in Listed medicines. PIs that are colours require:

- classification of the PI type;
- all ingredients to be in approved names consistent with the Australian Approved Terminology for Medicines (i.e. AAN, ABN, AHN or PRV); and
- quantitative composition (concentration) for all ingredients.

7.3.2. Type 1b: Flavours, fragrances and inks

Type 1b:	Maximum concentration allowed in the final product
Flavours	5%
Fragrances	1%
Inks	0.1%

PIs that are flavours will be allowed in Listed medicines up to a maximum concentration of 5 per cent in the final product. Incorporation beyond this level will require further assessment by the TGA. Requirements for PIs that are flavours:

- Classification of the PI type is the only mandatory requirement. The qualitative formulation of the PI is required, but it is not necessary that this be in Australian Approved Terminology format, although that is preferred if possible.

PIs that are fragrances will be allowed in Listed medicines up to a maximum concentration of 1 per cent in the final product. Incorporation beyond this level will require further assessment by the TGA. Requirements for PIs that are fragrances:

- Classification of the PI type is the only mandatory requirement. The qualitative formulation of the PI is required, but it is not necessary that this be in Australian Approved Terminology format, although that is preferred if possible.

PIs that are Inks will be allowed in Listed medicines up to a maximum concentration of 0.1 per cent in the final product. Incorporation beyond this level will require further assessment by the TGA.

Requirements for PIs that are inks:

- Classification of the PI type is the only mandatory requirement. The qualitative formulation of the PI is required, but it is not necessary that this be in Australian Approved Terminology format, although it is preferred if possible.

7.3.3. Type 2: Active intermediate formulations (active pre-mixes)

PIs that are classified as active pre-mixes must contain at least one active ingredient. PIs that are active pre-mixes require:

- classification of the PI type;
- all ingredients to be expressed using approved names consistent with the Australian Approved Terminology for Medicines (i.e. AAN, ABN, AHN or PRV);
- quantitative composition (concentration) for all ingredients; and
- that the active ingredient be a permitted Listable ingredient as allowed by [Schedule 4 of the Regulations](#).

7.3.4. Type 3: Vehicles (cream and ointment bases, capsule shells)

PIs that are vehicles require:

- classification of the PI type;
- all ingredients to be expressed using approved names consistent with the Australian Approved Terminology for Medicines (i.e. AAN, ABN, AHN or PRV); and
- quantitative composition (concentration) for all ingredients.

7.3.5. Type 4: Pre-formulated mixes of preservatives

PIs that are classified as preservatives must contain only Listable ingredients which are permitted for the proposed route of administration of the finished product. PIs that are preservatives require:

- classification of the PI;
- all ingredients to be expressed using approved names consistent with the Australian Approved Terminology for Medicines (ie. AAN, ABN, AHN or PRV); and

- quantitative composition (concentration) for all ingredients.

Note that for types 1a, 2, 3 and 4 PIs to be eligible for inclusion in Listed medicines, all ingredients within the PIs must be eligible for inclusion in Listed medicines.

7.4. Labelling associated with proprietary ingredients

Where appropriate, proprietary ingredients may be described as 'natural', 'nature-identical' or 'artificial'.

If the label includes a negative disclosure statement (e.g. 'sugar free'), sponsors should also ensure that the substance referred to in the negative disclosure statement is not contained in any PI in the product formulation.

8. Interface issues

This section is divided into the following subsections:

- 8.1. [Medicine / Device interface](#)
- 8.2. [Cosmetic / Medicine interface](#)
- 8.3. [Medicine / Food interface](#)
- 8.4. [Complementary / Pharmaceutical medicine interface: route of evaluation](#)

8.1. Medicine / Device interface

A 'medical device' is defined in the *Therapeutic Goods Act 1989* (the Act) as:

- any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is – or is to be – supplied, to be used for humans for the purpose of one or more of the following:
 - diagnosis, prevention, monitoring, treatment or alleviation of disease;
 - diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or handicap;
 - investigation, replacement or modification of the anatomy, or of a physiological process; and / or
 - control of conception;
 and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means; **OR**
- is an accessory to such an instrument, apparatus, appliance, material or other article.

Medical devices include a wide range of products such as medical gloves, bandages, syringes, condoms, contact lenses, X-ray equipment, heart-rate monitors, surgical lasers, pacemakers, dialysis equipment, baby incubators and heart valves.

8.1.1. Regulatory system for medical devices



A new regulatory system for medical devices in Australia was introduced in Australia on 4 October 2002. This new system was established under the Act as amended by the [Therapeutic Goods Amendment \(Medical Devices\) Bill 2002](#) and the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#).

Following the amendments to the Act, an additional part was created in the ARTG for medical devices. The new part is for medical devices included in the Register. The parts of the ARTG for goods known as Registered and Listed goods remain.

Therapeutic goods, which are currently Registered or Listed in the ARTG, cannot be transferred to the new part. An application will be required to have a medical device included in the ARTG.

Sponsors are encouraged to use the [Devices Electronic Application Lodgement system](#) (DEAL) for these applications.

The guidance document, the [Australian Regulatory Guidelines for Medical Devices](#) (ARGMD), has been developed to help explain the new regulatory system for medical devices.

8.1.1.1. Transition period

The Act as amended by the [Therapeutic Goods Amendment \(Medical Devices\) Act 2002](#), has made provision for the following transition periods for certain therapeutic goods, as follows:

- Medical devices that are currently Registered or Listed goods in the Australian Register of Therapeutic Goods (ARTG) can remain Registered or Listed until 4 October 2007. However, any Registered or Listed therapeutic devices in the ARTG after that date will be automatically cancelled. During the transition period, an application can be made to include those goods in the ARTG. If the application for inclusion is successful the Registration or Listing will then be cancelled; **OR**
- Medical devices that are exempt goods will remain exempt until 4 October 2004. After that time, those goods, if they no longer satisfy the definition of exempt goods, will have to become medical devices included in the ARTG so that they can be supplied in Australia; **OR**
- Applications for entry in the ARTG for Listable therapeutic devices manufactured in Australia that do not currently require a manufacturing licence from the TGA will still be accepted until 4 October 2004.

8.2. Cosmetic / Medicine interface

This subsection is intended to provide guidance in relation to the cosmetic / therapeutic interface in respect of product claims; however, it is not an exclusive or exhaustive listing. The industry association representing the manufacturers and distributors of cosmetics – the Cosmetic, Toiletry and Fragrance Association of Australia (CTFAA) – has a Code of Conduct which also provides guidance on the cosmetic / therapeutic interface is **ACCORD Australasia Limited** (<http://www.accord.asn.au>).

Products are determined to be either ‘cosmetics’ or ‘therapeutic goods’ on the basis of two factors:

- the composition of the product; and
- the proposed use of the product.

8.2.1. Composition

The composition of a product does not necessarily determine its classification. However, it is quite possible that an ingredient, or the concentration of an ingredient, may make the product unsuitable for classification as a cosmetic.

8.2.2. Proposed use

According to the definitions of the terms ‘therapeutic goods’ and ‘cosmetic products’ in the legislation, the key consideration for the classification of a product is its proposed use. The claims made in package inserts, in advertisements, and especially in product labels, indicate to the consumer the intended use of the product. It is also important to consider the context in which the

product is marketed. Claims that indicate the product is a therapeutic good (medicine) cannot be made for a product marketed as a cosmetic.

8.2.3. Legislation

The TGA administers the [Act](#) and the Therapeutic Goods Regulations 1990 (the Regulations). Products subject to this legislation are 'therapeutic goods', i.e. products intended for 'therapeutic use' which includes 'modifying a physiological process'. Normally, cosmetic products do not come within the ambit of this legislation. However, if a product claims to modify a physiological process (or treat or prevent disease) then it falls within the ambit of the legislation and requires inclusion in the ARTG before supply of the goods.

Specific legislation concerning cosmetic products is the [Trade Practices \(Consumer Product Information Standards\) \(Cosmetics\) Regulations](#) administered by the Treasury. The scope of the legislation is limited to requirements concerning ingredient labelling information. 'Cosmetic product', as defined in the information standard, means a substance or preparation intended for placement in contact with any external part of the human body, including the mucous membrane of the oral cavity, and the teeth, with a view to achieving one or more of the following:

- altering the odours of the body;
- changing its appearance;
- cleansing it;
- maintaining it in good condition;
- perfuming it; and / or
- protecting it.

8.3. Medicine / Food interface

This subsection is intended to provide general guidance on the interface between foods and therapeutic goods.

The sale and supply of 'therapeutic goods' is regulated by the Act and its associated Regulations and Therapeutic Goods Orders. Some provisions, such as the scheduling of substances and the safe storage of therapeutic goods, are covered by State or Territory legislation.

The sale and supply of 'food' is regulated by State and Territory food legislation with the import of food regulated by Commonwealth legislation. These sets of legislation uniformly adopts the [Australia New Zealand Food Standards Code](#) (the Code), but apply additional requirements and restraints over and above those stipulated in the Code.

8.3.1. Food Standards Australia New Zealand (FSANZ)

Food Standards Australia New Zealand ([FSANZ](#)) is a statutory authority operating under the [Food Standards Australia New Zealand Act 1991](#) (the FSANZ Act).

FSANZ works in partnership with the Australian, State and Territory governments and the New Zealand Government, to protect the health and safety of the people in Australia and New Zealand by maintaining a safe food supply.

The TGA works closely with the FSANZ, particularly with respect to products at the food / medicine interface.

8.3.2. Differentiation between therapeutic goods and foods

The differentiation between food and medicines is defined through the Act FSANZ Act. Where necessary, both Acts enable the regulators to declare a product as either a 'therapeutic good' or a 'food', to maintain clarity at the food / medicine interface.

Key considerations in determining when a substance or product is considered a food or therapeutic good include:

- the composition or nature of the substance or product;
- the presentation of the substance or product, including any representations in labels or advertising; and
- the intended use or purpose for the substance³ or product, including any tradition of use.

8.3.2.1. Therapeutic goods

Therapeutic goods are those products that are represented in any way to be, or likely to be taken to be, for therapeutic use or for use as an ingredient in the manufacture of a therapeutic good. 'Therapeutic use' is defined in the therapeutic goods legislation. However, a therapeutic good does not include:

- goods declared not to be therapeutic goods⁴;
- goods for which there is a prescribed standard in the Code (need to include recent amendments in therapeutic goods legislation that reduces the impact of this exclusion); and / or
- goods which, in Australia or New Zealand, have a tradition of use as foods in the form in which they are presented.

8.3.2.2. Foods

Foods include:

- any substance used for human consumption, including live animals and plants;
- any substance used as an ingredient or additive in a food referred to in (a);
- any substance used in preparing a substance referred to in (a);
- chewing gum or an ingredient or additive in chewing gum; and
- any substance or thing declared to be a food.

In considering whether a substance or product is a food or a therapeutic good, it should be noted that food labels and advertising must not:

- include a claim for therapeutic or prophylactic action;
- include the word 'health' as a part of the name of the food;
- contain any advice of a medical nature from any person; and

³ The use of a substance in a therapeutic good does not preclude its use as a food, e.g. garlic (subject to the provisions of the Code).

⁴ There is power in the Act to declare goods to be, or not to be, therapeutic goods (Section 7).

- include the name of, or a reference to, any disease or physiological condition.

A review of health claims on food is currently being undertaken. In order to preserve the integrity of Australia's food / medicine interface, the review will attempt to ensure a 'level playing field' for the regulation of claims on either side of the interface.

8.3.3. Food / Medicines interface group

From time to time, sponsors and regulators of medicine or food products need access to a mechanism that can provide clarification as to the regulatory status of products which fall at or near what is known as the 'food / medicines interface'. For this reason, the Foods / Medicines Interface Group was established to provide advice to sponsors, food manufacturers, TGA surveillance staff and food enforcement officers on the compliance of certain products with food or medicines legislation.

The Interface Group comprises members from FSANZ, the TGA and the Australian Quarantine Inspection Service (AQIS). The group meets on an as-needed basis to discuss, case-by-case, specific products forwarded to it and to make suggestions as to whether a product is more appropriately regulated as a food or a medicine. The advice provided by the group often consists of suggestions about labelling or compositional changes that may be needed to make the regulatory status of the particular product clearer.

In providing its advice for a particular product, the group takes into consideration a number of factors including:

- the presentation of the product;
- whether or not the product is likely to be consumed as a therapeutic good or as a food;
- the composition and ingredients;
- the physical form, i.e. liquid, capsule, powder, bar or other food form;
- the suggested directions for use and / or prescribed dosage regime;
- the labelling;
- any claims made;
- the way the product is marketed and / or promoted; and
- if it is covered by a food standard in the Code.

The advice provided by the Interface Group is always subject to the legislative framework in which products are considered. Changes to the legislation for both foods and therapeutic goods over time, such as the changes to therapeutic legislation in relation to Section 7⁵ declarations, are taken into account by the Interface Group when considering particular products.

The advice of the Interface Group should not be considered as 'decisions', because the group has no statutory power to make decisions. The advice given is the group's best understanding of the regulatory frameworks for foods and medicines and its interpretation of those frameworks as they apply to particular products.

Sponsors of complementary medicines seeking advice of this nature may contact the Office of Complementary Medicines (OCM) in the Therapeutic Goods Administration (TGA) or, if the product is more likely to be a food, then sponsors should contact FSANZ, by telephone, on its advice line 1300 652 166.

⁵ More information on Section 7 of the Act can be found in the ARGCM Part V – Policy.

8.4. Complementary / Pharmaceutical medicine interface: route of evaluation

Medicines are evaluated by one or other or all of three regulatory units. Complementary medicines are evaluated by the OCM, prescription and over-the-counter (OTC) medicines by the Office of Medicines Authorisation (OMA). The criteria for deciding which of these units evaluates a particular medicine are set out in Schedule 10 to the Regulations.

In some circumstances, it may be more appropriate for a particular medicine to be evaluated by a different unit to the one specified in Schedule 10. The Regulations allow for the transfer of applications between the regulatory units. Once transferred, the applications are dealt with according to the requirements (e.g. fees and data requirements) of the new area. A decision to transfer an application to a different regulatory unit may be taken at the initiative of the TGA delegate. In such cases, the sponsor will be advised before the transfer takes place and be given the opportunity to comment.

Where a sponsor wishes to have an application dealt with by an evaluation unit other than the one specified in Schedule 10 to the Regulations, they will need to provide a justification to the TGA to establish that this is appropriate. The justification can be provided separately in advance of an application or as part of the application itself. If the justification is accepted, the application for that product or substance will then be dealt with by the new evaluation unit in the same way as other products / substances regulated by that unit (e.g. application and evaluation fees and data requirements will be those of the new evaluation unit).

If the justification is refused, any subsequent application for that product will be dealt with according to Schedule 10 to the Regulations. Details of a procedure for appeals are included later, under '[Administrative Details](#)'. The information required in a justification will vary depending on the current and proposed route of evaluation.

8.4.1. OCM to OTC or *vice versa*

In general, products containing active ingredients that would normally be evaluated as OTC medicines (e.g. paracetamol) in combination with active ingredients that would normally be evaluated as complementary (e.g. herbal substances, vitamins, minerals) will be evaluated *via* the OTC route. Where a sponsor wishes to propose a different route, a justification must be provided.

8.4.2. Prescription to OTC or OCM

Products containing new active substances (i.e. those that are not included in any medicine currently authorised for sale in Australia) are evaluated by the OMA. Exceptions to this general rule are complementary medicines substances (evaluated by OCM). Where a justification for evaluation of a product or substance *via* the OCM route is proposed, the primary factors to be taken into account include:

- the safety of the active substance;
- the need for professional counselling before use;
- the nature of the ailments or symptoms to be treated (can they be easily recognised by the consumer, do they require medical diagnosis or management?);
- the abuse potential of the product or substance;
- the incidence of adverse effects and contraindications;

- the risk of masking serious disease; and
- the risk / benefit profile of the product (e.g. therapeutic index).

Other factors that may be taken into account include whether or not:

- the product would be in a lower schedule (or unscheduled) in the *Standards for the Uniform Scheduling of Medicines and Poisons* (SUSMP), if presented in a different form (e.g. different pack size, different strength, different indications, different route of administration);
- products containing the substance are available without prescription in other countries with comparable regulatory regimes to Australia;
- the product contains a substance that has a closely related chemical structure and similar therapeutic action to other substances that are in a less-restrictive schedule (or are unscheduled); and
- the substance appears to meet the criteria for Listing.

8.4.3. OCM to Prescription

In some circumstances, sponsors may prefer to have an application evaluated by the OMA rather than the OCM (e.g. where a product range includes strengths that are prescription as well as Listable). A justification should be submitted, but minimal supporting data will be required in such cases.

8.4.4. Excipients

Excipients are usually evaluated *via* the same route as the products in which they are to be used (e.g. a new excipient that is to be used in a complementary medicine will be evaluated by the OCM). In general, the evaluation criteria for new excipients are common across all areas of the TGA. Information on data requirements is available from the evaluation area applicable.

8.4.5. Currently registered non-prescription transdermal patches

Under Schedule 10 to the [Regulations](#), transdermal systems are routinely evaluated by the OMA, even if they are non-prescription products. Notwithstanding this, evaluation of a particular application *via* the OCM route will be accepted when it involves a change or changes that do not result in a new delivery system or influence the characteristics of the currently approved delivery system. Changes in formulation, membrane or other specific factor(s) that control release of the active ingredient frequently result in what could be considered a new delivery system.

Acceptable changes (i.e. to be considered by the OCM route), therefore include applications involving clinical data, toxicological data, and only those pharmaceutical chemistry changes that do not create a new transdermal system or influence the characteristics of the currently approved system. Examples of changes that will be accepted for evaluation *via* the OCM route are:

- labelling changes;
- sponsor changes;
- Consumer Medicine Information (CMI);
- Product Information (PI);

- packaging changes, other than immediate packaging; and
- product detail changes not involving a change to the delivery system.

Changes other than those specified will require a justification if an alternative evaluation area is desired. Such changes would include, for example:

- product detail changes involving the delivery system;
- quality control changes – finished-product specifications which do not result in a new transdermal system;
- quality control changes – starting material specifications which do not result in a new transdermal system; and
- manufacturing changes – finished product.

8.4.6. Administrative details

A form ([‘Justification for a particular route of evaluation’](#)) is provided to assist sponsors in submitting the required information. The justification request should be submitted to the evaluation unit specified in Schedule 10 to the Regulations (e.g. a ‘prescription only medicine’ (Schedule 4 to the SUSMP) justification request should be submitted to the OMA) with a copy sent to the proposed evaluation unit. There is no fee for this.

A decision will be made by the TGA within 20 working days (four weeks) of receipt of the justification request. The decision will be made by the relinquishing area following discussion with the proposed receiving area.

The sponsor will be advised of the decision by the relinquishing area. If the initial decision is to refuse the justification request, the reasons for refusal will be given.

Following the initial decision, if the sponsor and the TGA cannot come to a mutually acceptable position, the sponsor may ask the TGA National Manager to undertake an independent internal review. This review will be completed within 20 working days of the receipt of the request and may involve consultation with the chairs of the relevant evaluation committees.

9. Australian native and endangered species in therapeutic goods

This section is divided into the following subsections:

- 9.1. [Background](#)
- 9.2. [The role of the Therapeutic Goods Administration](#)
- 9.3. [More information](#)

This section provides guidance to sponsors on their responsibilities regarding the use of ingredients that may be regulated under the [Environment Protection and Biodiversity Conservation Act 1999](#) as either native species and / or identified under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

9.1. Background

Australia's unique plants and animals are known throughout the world and are a part of our natural heritage. The Australian Government recognises the value of our native species and the need to ensure their continued survival. Regulation of international movement (exports and imports) of wildlife and wildlife products is acknowledged internationally as an important element of effective nature conservation. In addition to protecting native species, the Australian Government reinforces the efforts of other countries to protect their wildlife by regulating trade in those species identified under CITES (<http://www.cites.org>). These controls, as well as contributing to the international cooperative conservation effort, also complement the wildlife conservation efforts of Australian States and Territories.

For all wildlife except cetaceans (whales, dolphins etc.), international movement of wildlife and wildlife products is regulated under Part 13A of the [Environment Protection and Biodiversity Conservation Act 1999](#). Sections 232A and 232B of Part 13 of this Act cover cetaceans. The *Environment Protection and Biodiversity Conservation Act 1999* regulates the:

- export of Australian native species other than those identified as exempt;
- export and import of all species that are recognised internationally as endangered or likely to become so if trade is not strictly regulated;
- importation of species identified by other CITES member countries as requiring international cooperation to regulate their trade; and
- importation of live plants and animals that, if they became established in Australia, could adversely affect native species or their habitats.

Commercial export of regulated wildlife and wildlife products may occur only where the specimens have been derived from an approved source (a captive breeding program, an artificial propagation program, an aquaculture program, a wildlife trade management operation, or a wildlife management plan).

The importation of CITES listed specimens for commercial purposes must be from an approved commercial import program or approved captive source, and is subject to specific conditions (303CH) described in the particular appendix on which the specimen is listed. Specific conditions (303CH) also apply to the commercial export of CITES-listed species.

9.2. The role of the Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) does not have the legislative power to reject Listing or Registration applications on the grounds that they contain a substance derived from a species that is subject to State or Australian Government environmental regulation. This may result in the situation where therapeutic goods that are Listed or Registered on the Australian Register of Therapeutic Goods (ARTG) may be seized at Customs if they are exported or imported. Therefore, it is the responsibility of sponsors of therapeutic goods containing substances that are derived from Australian native or endangered species to:

- be aware that controls on the trade of these goods may exist
- take appropriate steps to avoid action by enforcers of the Commonwealth Department of Sustainability, Environment, Water, Population and Communities or by Customs officers.

While the TGA does not play a role in the administration or enforcement of Environment Protection and Biodiversity Conservation legislation, the TGA is obligated to take reasonable steps to prevent the illegal trade of endangered and Australian native species. In order to meet these obligations, the TGA will release to the Commonwealth Department of Sustainability, Environment, Water, Population and Communities information about therapeutic goods that contain substances derived from endangered or Australian native species.

While the TGA will continue to treat commercial-in-confidence information in accordance with legislated requirements, Section 61(6) of the [Therapeutic Goods Act 1989](#) allows the release of therapeutic goods information. Regulation 46 of the [Therapeutic Goods Regulations 1990](#) (the Regulations) describes the kinds of therapeutic goods information that the Secretary may release. As described in Regulations this information may include:

- the name of the therapeutic goods;
- the name and address of the sponsor of the goods;
- the names and quantities of therapeutically active substances in the goods; and
- the presence or absence of any specific excipient in the goods.

9.3. More information

For further information on how to comply with Regulations controlling the trade of Australian native or endangered species, and products derived from them, *within Australia*, sponsors should contact the Environmental Protection Authority in their State.

For further information on how to comply with Regulations controlling the import / export of Australian native or endangered species, and products derived from them, sponsors should contact the Commonwealth Department of Sustainability, Environment, Water, Population and Communities (telephone: 02 6274 1111; fax: 02 6274 1666, website: (<<http://www.environment.gov.au>>).

10. Other legislation

Sponsors developing therapeutic goods for supply in Australia should be aware of the requirements applicable under other Commonwealth, State and Territory legislation such as those concerning:

- trade practices;
- weights and measures;
- deceptive packaging;
- Customs (Prohibited Imports) Regulations;
- Quarantine;
- State / Territory therapeutic goods legislation;
- State / Territory drugs and poisons scheduling;
- Advertising; and
- genetically modified organisms or genetically modified products.



Listing of a product in the Australian Register of Therapeutic Goods (ARTG) does not absolve it or its sponsor from the provisions of other relevant legislation.

11. Certificates of analysis – product

A certificate of analysis (used for 'release for supply' purposes) is a document certified as a truthful statement of the tests and test results for an individual, manufactured batch of a particular product.

The certificate should identify at least:

- the primary manufacturer;
- the product;
- the date of the certificate and the date of the testing;
- the batch of the product;
- the tests and the test results;
- the acceptable test specifications; these are the test limit or the range of results for each test with which the batch must comply before release for supply; and
- the signature of the appropriate company official.

The range of tests applied to a product is at the discretion of the manufacturer and will depend on a number of factors including the type(s) of active ingredients and the pharmaceutical dosage form. Reference should be made to standard pharmacopoeial texts for guidance on tests and test methods. Some products are also subject to requirements under Therapeutic Goods Orders.

For example, a herbal tablet formulation should include tests for at least:

- identity tests for the presence of actives;
- disintegration time;
- uniformity of weight;
- assay of actives (if possible); and
- tests for contaminants (if the starting materials are not tested for these individually) such as microbiological contaminants, heavy metals and foreign matter.

Sponsors should also make reference to the guidance document [Quantified By Input](#). This guidance describes the criteria under which a manufacturer is not required to analyse an ingredient in a finished product. It also details the wording that should be used on a certificate of analysis, where an actual ingredient has been 'quantified by input'.

On occasions, a certificate of analysis may not be available for a manufactured batch at the time of lodging an application for Listing. In such cases, a statement of the intended tests and test specifications for an acceptable batch should be available.

12. Product Specifications

The product specification is a description of the product formulation, and the tests to be applied to batches of the product.

The statement should contain (or make reference to):

- name of product;
- dosage form;
- product code;
- date of specification;
- revision or version number;
- name and signature of the appropriate company official;
- description of physical appearance;
- detail of physical tests performed (and limits) including total weight, weight variation, tests and limits, disintegration tests and limits;
- stage of manufacture;
- packaging type and closure;
- recommended storage conditions;
- recommended shelf-life; and
- details of the full formulation including all active and all excipient ingredients (including coatings and capsule shell ingredients).

For every ingredient:

- give the Australian Approved Name (AAN);
- state the quality standard and / or grade;
- state any overages used;
- state the nominal (label claim) amount:
 - Clearly identify whether the amount of substance is expressed in terms of the salt / complex, or base. If the label claim is not in the same terms, the amount in terms of the label statement should also be stated; and
 - If the ingredient is herbal, the [TGA Approved Terminology for Medicines](#) (Chapter 1, Section 3 – *Herbal Substances*) offers useful guidance. Include, for example, the botanical species, plant part and, if an extract, state the amount of the extract, the strength of the extract, and the equivalent amount of dried plant. The extracting solvent and diluting medium should also be described.
 - Guidance on the identification of herbal materials and extracts is provided in the document titled *Questions & Answers for the Identification of Herbal Materials and Extracts*, available at <http://www.tga.gov.au/industry/cm-identification-herbal-extracts.htm> on the TGA website; and

- If direct compression (DC) tableting materials are used, then, as with herbal extracts, describe the amount of DC material used, its equivalence to active substance, and describe the diluent.

For each active ingredient state:

- what is analysed in each batch;
- what is analysed on rotation, and the frequency (see the guidance document [Quantified by Input](#));
- what is not analysed at all, and how the ingredient's presence is verified in such cases;
- describe briefly the analytical procedure (HPLC, AA, TLC) applied to each ingredient in the final product;
- unless covered in a separate document, the release limits – upper and lower; and
- unless covered in a separate document, the expiry limits – upper and lower.

If declarations are to be made about the absence of any substances in the product, then Proprietary Ingredients, such as colourings and flavours and ingredient diluents, should be checked to ensure the accuracy of such declarations.

13. Enforcement procedures

This section is divided into the following subsections:

- 13.1. [Listed medicines](#)
- 13.2. [Post market monitoring](#)
- 13.3. [Listing Compliance Section \(LCS\) of the OCM](#)
- 13.4. [Regulatory action](#)

13.1. Listed medicines

Under the Listing process, medicines will be Listed in the Australian Register of Therapeutic Goods (ARTG) on the basis of their sponsor's provision of information and a declaration that the product is eligible for Listing and complies with all Listing requirements.

The [Therapeutic Goods Act 1989](#) (the Act) provides for the immediate cancellation of a product's Listing if the application is found to have been falsely certified and the product to be ineligible for Listing. Recall of any distributed goods will be required in such cases and whenever public safety is at risk as a result of product non-compliance. Major or repeated offences against the Act and the Therapeutic Goods Regulations 1990 (the Regulations) may lead to prosecution by the Therapeutic Goods Administration (TGA).

13.2. Post market monitoring

The regulation of complementary medicines in Australia through the TGA's Listed medicine system allows for early market access for low-risk complementary medicines. In facilitating early market access, there is reliance on a comprehensive risk-based system for the post market monitoring.

The objectives of the TGA's post-market program covering complementary medicines are to:

- provide assurance of the safety of complementary medicines through a risk-based program of post market monitoring and surveillance;
- provide consumer confidence in the safety and quality of complementary medicines; and
- ensure industry compliance with regulatory standards and guidelines for complementary medicines.

The measures required to meet the objectives include:

- targeted and random desk-based audits of Listed medicines;
- monitoring of suspected adverse reactions;
- targeted and random laboratory testing of medicines and ingredients;
- targeted and random surveillance in the market place;

- an effective, responsive and timely recalls procedure;
- audit of good manufacturing practice (GMP); and
- an effective co-regulatory approach to control advertising.

These measures provide timely identification and appropriate regulatory responses to problems associated with the formulation, manufacture, labelling and advertising of medicines.

13.3. Listing Compliance Section (LCS) of the OCM

The Office of Complementary Medicines' (OCM) Listing Compliance Section (LCS) has five areas of activity:

- monitoring of complementary medicines Listed on the ARTG through the Electronic Listing Facility Version 3 (ELF 3);
- investigation of medicines for which a potential problem has been identified;
- reviewing evidence supporting indications and claims made for Listed complementary medicines;
- regulatory action; and
- administration and business processes.

The LCS carries out the regulatory actions associated with ELF 3 monitoring, medicine investigation and evidence reviews. Typically, these actions include:

- Section 28 notices (additional conditions);
- Section 29D notices (suspension)
- Section 30 notices (cancellations and proposals to cancel);
- Section 30EA (recalls); and
- Section 31 notices (request for information).

13.4. Regulatory action

Where a post-Listing review reveals minor technical errors that do not have significant safety implications, applicants will be advised that the product is subject to cancellation, but that the TGA will consider a submission setting out proposed corrective action.

Depending on the individual circumstances, this action may include recovery of distributed stock, relabelling before further distribution, over-labelling to an appropriate level or correction within a stated period, and lodgement of appropriate variation applications.

Where a submission is not received, the matter will be dealt with through the standard cancellation and prosecution powers under the Act.

Any cancellation by the TGA is subject to appeal to the Minister of Health and Ageing and subsequently to the Administrative Appeals Tribunal (AAT).

14. Review of decisions

This section is divided into the following subsections:

- 14.1. [Appeal mechanisms \(Section 60 appeals\)](#)
- 14.2. [The Administrative Appeals Tribunal \(AAT\)](#)
- 14.3. [Federal Court](#)

All decisions made by the Therapeutic Goods Administration (TGA) are subject to appeal. This includes decisions to request information ([Section 31 of the Therapeutic Goods Act 1989](#)), to impose conditions of Registration or Listing ([Section 28](#)) or to cancel products from the Australian Register of Therapeutic Goods (ARTG) ([Section 30](#)).

If there is disagreement with a decision made by the delegate of the Secretary, a review may be sought. Several procedures are available (see Section 60 of the Act).

14.1. Appeal mechanisms (Section 60 appeals)

Decisions by the Secretary of the Department of Health and Ageing, or a delegate of the Secretary, that are subject to review following a request for reconsideration may be appealed under Section 60 of the Act. Examples include:

- a refusal to Register or List goods on the ARTG;
- the variation or addition of conditions applying to a Registration or Listing;
- cancellation of a Registration or a Listing; and
- revocation or suspension of a manufacturing licence.

If a decision can be appealed, details of the appeal rights will usually accompany the decision. Appeals must be lodged within 90 days of decisions.

The appeal letter should be sent to:

The Parliamentary Secretary to the Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

and should be clearly marked Appeal under *Section 60 of the Therapeutic Goods Act 1989*.

It would assist early consideration of the request for reconsideration if a copy of the letter were sent to the TGA National Manager.

The Minister, or the Minister's delegate for this purpose, may confirm or revoke the initial decision or substitute a new decision. If a sponsor has not received a response from the Minister or the Minister's delegate within 60 calendar days of receipt of the appeal, the first decision is deemed to be upheld.

If a sponsor wishes to appeal, but is unable to do so before the 90-day deadline, then the sponsor should contact the TGA to request an extension of time. This is given only in exceptional

circumstances. Written details of the reason for the inability to lodge the appeal in the specified time should be provided.

14.2. The Administrative Appeals Tribunal (AAT)

If not satisfied with the outcome of a Section 60 appeal, an application may be made to the Administrative Appeals Tribunal (AAT) for review. Applications to the AAT must be made within 28 calendar days of the Minister's decision regarding a Section 60 appeal.

The AAT may affirm the decision, vary it or set it aside, substitute a new decision, or refer the decision back to the original decision maker.

14.3. Federal Court

Whereas the AAT provides a merit review process, affected parties may appeal at any time to the Federal Court, on the grounds of the legality of a decision.

15. Genetically Modified Organisms

This section is divided into the following subsections:

- 15.1. [Definitions](#)
- 15.2. [TGA assessment of GMOs and GM products](#)
- 15.3. [Gene technology legislation](#)
- 15.4. [Labelling](#)
- 15.5. [More information](#)

15.1. Definitions

Section 10 of the [Gene Technology Act 2000](#) (the GT Act) defines a genetically modified organism (GMO) as:

- an organism that has been modified by gene technology; **OR**
- an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology.

Further, a genetically modified product (GM product) is defined in Section 10 of the GT Act as a thing (other than a GMO) derived or produced from a GMO.

GMOs have parts of their genetic material (DNA) altered in a way that does not occur naturally by mating and / or natural recombination; i.e. they are deliberately modified using *modern methods of biotechnology (such as recombinant DNA, molecular and / or cell-biology)* to exhibit one or more traits that do not exist in / are new to the species.

Plants grown using techniques such as hybridisation and selective cultivation are not considered to be GMOs.

The decision as to what is a GMO or GM product made available for supply under the [Therapeutic Goods Act 1989](#) is decided in the first instance by the Therapeutic Goods Administration (TGA), based on the definition of a GM product under the gene technology legislation.

15.2. TGA assessment of GMOs and GM Products

The Therapeutic Goods Administration (TGA) will assess the safety, quality and, where relevant, efficacy of an application relating to a GMO or GM product by the same means as any other application relating to a therapeutic good. Sponsors of therapeutic goods containing GMOs or GM products should therefore provide the same information with the same detail to allow evaluation of safety, quality (and efficacy) as stipulated in the other parts of the Guidelines.

15.3. Gene technology legislation

The GT Act, which came into force on 21 June 2001, introduced a national scheme for the regulation of GMOs in Australia, in order to protect the health and safety of Australians and the Australian environment. The GT Act establishes a statutory officer, the Gene Technology Regulator (the GT Regulator), to administer the legislation and make decisions under the legislation.

The legislation requires all dealings with GMOs (that are not exempt or notifiable low-risk dealings (see below)) to be licensed by the GT Regulator. Dealings with GMOs may be entered on the GMO Register once they have been licensed for a certain period of time.

The Gene Technology Regulations also set out categories of dealings with GMOs that are very low risk and which may proceed provided that certain conditions spelt out in the regulations are observed (notifiable low-risk dealings).

This will include requirements that the specified dealings be undertaken only in contained facilities, overseen by Institutional Biosafety Committees (IBCs) and notified to the GT Regulator. These will be similar to class licences, and the conditions under which such dealings will operate will be clearly set out in the Regulations.

Where the GT Regulator is confident that a certain dealing involves a very low risk, the class of dealing with the GMO will be recorded in the Regulations as exempt (e.g. contained research involving a very well understood process for creating and studying a GMO).

This will mean that no licence is required, provided that the activity remains within the specified parameters. There will be no exemptions for any release of a GMO into the environment (e.g. field trials and commercial releases).

The GT Act does not allow dealings that involve the intentional release of a GMO into the environment to be prescribed as a notifiable low-risk dealing.

The regulatory scheme requires the GT Regulator to take action in respect of GM products assessed by the TGA in two instances:

- to maintain a public record of GMOs and GM products; and
- to promote an exchange of advice on issues relating to GMOs or GM products.

15.3.1. Public record

Section 138 of the GT Act requires the GT Regulator to maintain a public record of GMOs and GM products that are available for supply in Australia. This requirement applies to therapeutic goods. Information supplied to the TGA in relation to GM ingredients in therapeutic goods will be made available to the GT Regulator and placed on the public record unless sponsors apply to have data regarded as confidential commercial information (see below).

The Gene Technology Regulations prescribe the particular information to go on the Record in relation to GMOs or GM products. The following information is required:

- the name of the organisation producing the GMO or GM product (i.e. the manufacturer of the product, rather than the supplier)
- a description of the GMO or GM product with reference to:
 - the [Therapeutic Goods Act 1989](#) (the Act), e.g. Listed medicine, vaccine; and
 - its common name as a product, or type or class of product, e.g. insulin
- information about the GMO or GM product, including:

- the common name and the scientific name of the parent organism involved;
- details of the introduced trait in the GM product;
- the identity of the introduced gene responsible for conferring the introduced trait; and
- whether the product contains viable GMOs.
- the date on which a decision under therapeutic goods legislation that enables supply of the GMO or GM product in Australia takes effect; and
- details of any conditions attached to that permission.

Where a GM product is approved by the TGA, the information set out above, including that provided by the sponsor, will be made publicly available on the Record of GMOs and GM Product dealings. An application for the information to be treated as commercial-in-confidence may be submitted to the GT Regulator under Section 184 of the GT Act. The GT Regulator will provide the sponsor with a reasonable time in which to make such an application. However, the responsibility for such an application lies with the sponsor not the TGA or the GT Regulator.

15.3.2. Exchange of advice on GMOs or GM products

The GT Regulator does not directly regulate the use of GM products in Australia. However, the gene technology legislation prescribes a licensing system for dealings with live, viable GMOs. After the TGA has assessed an application relating to a GMO or GM product, Section 30C of the Act requires the TGA to inform the GT Regulator that:

- an application has been made relating to a GMO or GM product; and
- advice is sought from the GT Regulator about the application.

Where the TGA is required to seek the advice of the GT Regulator in relation to a GM product application, the TGA will write directly to the Regulator asking for such advice. The GT Regulator may accept the advice of the TGA in relation to the health and safety aspects of an application relating to a GMO or GM product. However, the GT Regulator may also provide advice to the TGA on other aspects of the application, including matters relating to the environmental release of GMOs or GM products. The TGA must take this advice into account in assessing the application relating to a GMO or GM product.

15.4. Labelling

Therapeutic goods legislation does not require a declaration on the product label that the therapeutic good is or is not derived from a GMO. However, applicants should establish and maintain documentation about GMOs or substances derived from GMOs, so that they are in a position to:

- provide definitive information to consumers should it be requested;
- comply with any other legislation that requires this information to be declared; and
- be prepared in case future legislative changes to therapeutic goods legislation make the declaration of this information mandatory.

Sponsors should make reference to the other legislation that applies to therapeutic goods in relation to GMOs.

15.5. More information

Sponsors intending to apply to the TGA to use a GMO as a medicinal product (including use in a clinical trial) are advised to also consult the Office of the Gene Technology Regulator (OGTR) to determine their obligations under the GT Act. Further information can be obtained from the OGTR website at <<http://www.ogtr.gov.au>>

Historical document

16. Medicines for export

This section is divided into the following subsections:

16.1. [Medicines already approved for supply in Australia](#)

16.2. [‘Solely for Export’ medicines](#)

The export of medicines from Australia, including prescription, over-the-counter (OTC) and complementary medicines, is regulated by the Therapeutic Goods Administration (TGA) in order to protect health and safety by ensuring that exported medicines are of a similar quality and safety standard to those supplied domestically.

The TGA:

- requires that medicines exported from Australia comply with necessary quality and safety standards;
- approves the supply of medicinal products for export;
- issues export certificates (including certificates issued under the World Health Organization (WHO) Certification Scheme); and
- communicates with other regulatory authorities to maintain awareness of any potential quality and safety issues.

16.1. Medicines already approved for supply in Australia

Medicines, including complementary medicines, approved for supply in Australia are automatically approved also for export by the sponsor or their agent, subject to other applicable export legislation.

If a product has to include specific warning statements on its label in order to be eligible for Listing in the Australian Register of Therapeutic Goods (ARTG) for domestic supply, and it is also to be exported, these warning statements must remain on the label in order for the Australian Listing approval to extend to the exported product. Warning statements may be omitted only where the product is separately listed solely for export.

16.2. ‘Solely for Export’ medicines

Medicines intended solely for export, including products that would be regarded as complementary medicines in Australia, must be Listed (not Registered) on the ARTG before export. Broadly, they must:

- be safe for their intended purpose of use;
- be manufactured under conditions of good manufacturing practice (GMP);
- meet any standards applicable under [Section 10 of the Therapeutic Goods Act 1989 \(the Act\)](#); and
- not be of an unacceptable presentation.

Efficacy requirements are similar to those applying to other Listed products on the ARTG, and sponsors must hold evidence in support of claims made on 'solely for export' products.

Advisory statements on 'solely for export' products are often associated with the types of indications permitted for the product within the regulatory framework of the country of destination. It is the sponsor's responsibility to ensure that any advisory statements needed are included on the product label as required by the importing countries.

The export regulatory framework aims to provide necessary protection to the international community in terms of the safety and quality of products, while acknowledging that there are often valid reasons why products manufactured and listed exclusively for export are not able to be supplied on the Australian market. The export only products are required to go through a quality and safety assessment prior to listing them on the ARTG.

As part of the TGA's commitment to supporting a strengthened understanding in the importing country of the regulatory status of the product in Australia, the TGA may include a clarification statement on the export certificate for 'export only' medicines. In addition to simply certifying that the product is not listed for supply in the exporting country domestic use (as is required under the WHO Certification Scheme), I may include clarification statements for example:

- "This product has the same formulation as another product on the Australian market which is supplied in a different container or packaging (include AUST L / R number)."
- "The product approved for supply in Australia has been reformulated to exclude excipients not approved in the importing country."
- "This product has been developed exclusively for the importing country and as such, Listing / Registration for the Australian market is not required."

In the extremely small number of instances (approximately five per year) where an application is received by the TGA for a product that contains a therapeutic substance not previously evaluated in Australia, any evidence that the applicant can provide to demonstrate that the substance / product is approved in the country of destination, or that the importing country has no objection to the TGA Listing the product for export to that country, is generally considered sufficient to gain export approval.

Sponsors should also be aware of the following documents pertinent to the export of medicines available on the TGA website:

Therapeutic Goods Administration (TGA) Policy for the Export of Medicines from Australia

<http://www.tga.gov.au/industry/export-medicines-policy.htm>

Exporting Medicines from Australia – Operational Guidelines

<http://www.tga.gov.au/industry/export-medicines-guidelines.htm>

Application for Listing of Export Only Medicines under Section 26 of the Therapeutic Goods Act 1989

<http://www.tga.gov.au/about/ebs.htm>

17. Naming of new substances and terminology

This section is divided into the following subsections:

- 17.1. [What is Australian approved terminology?](#)
- 17.2. [What are the different types of names for substances?](#)
- 17.3. [Substances that do not have an approved name](#)

17.1. What is Australian approved terminology?

The Therapeutic Goods Administration (TGA) has developed and maintains lists of Australian approved terminology for medicines to ensure accuracy and consistency in the information available to consumers and compiled in the Australian Register of Therapeutic Goods (ARTG). These lists are published in the [TGA Approved Terminology for Medicines](#) and the terms prescribed in this publication are considered Australian approved terminology. The lists outline the terminology names for ingredients (active and excipient), containers, dosage forms, routes of administration and units of expression and proportion.

Australian approved terminology has been developed by the TGA because there is currently no single internationally agreed list or primary reference available that comprehensively covers all substances or terms used, or likely to be used, in therapeutic goods in Australia.

Australian approved terminology should be used:

- when submitting applications for Registration or Listing of medicines;
- in product formulation records included in the ARTG;

on labels, in accordance with the requirements of [Therapeutic Goods Order No. 69 – General requirements for labels for medicines](#) (TGO 69); and

- in product information, consumer medicine information (CMI) and other promotional literature where use of approved terminology is required.

Consistency in naming assists the retrieval of information from the ARTG and the ability of health professionals and the public to compare similar goods.

The list of Australian Approved Names (AAN) for ingredients in the *TGA Approved Terminology for Medicines* has been divided into three sections for ease of reference:

- chemical substances;
- biological substances - covering substances of biological origin (other than antibiotics) which are not derived from plants; and
- herbal substances – covering substances of plant origin including fungi and blue-green algae.

The list gives AANs for substances and cites the authority or reference that uses or defines the name (e.g. Merck Index). It is intended that the name, together with the reference, will define the molecular species in the case of a single substance; the composition of the substance in the case of a mixture; or the characteristics of a variable material.

Use of a reference will depend on common usage and / or the value of the monograph in describing the name.

Complete details relating to the terminology for medicines is provided in the [TGA Approved Terminology for Medicines](#).

Sponsors and other users of the list should note the following:

- Inclusion of a name in the *TGA Approved Terminology for Medicines* does not imply any recommendation for the use of the substance. This document is the source of an approved name only and it does not mean that the ingredient has been approved for use in Listed medicines;
- The citation of an authority or reference for a name in the list does not imply that the standard specified by that authority is applicable to the substance used in a particular medicine; and
- The list of substances included in the *TGA Approved Terminology for Medicines* is not a list of ingredients found in products currently included in the ARTG.

17.2. What are the different types of names for substances?

AAN – Australian Approved Chemical Substance Name

AANs are allocated to chemical substances. When an application is received for a chemical substance that is to be used as an excipient in topical products, the excipient may be allocated a PRV⁶ status until it has been evaluated for safety. However, that a chemical substance has an 'AAN' does not necessarily mean that use of the substance in therapeutic goods has been approved.

ABN – Australian (Approved) Biological Substance Name

ABNs are allocated to biological substances. In addition to the name of the organism, the part, preparation and / or biological descriptor may be required to fully name a biological substance.

AHN – Australian (Approved) Herbal Name

AHNs are allocated to herbs and are in the Latin binomial format. The name of the species, the part and the preparation (including solvents and ratio if applicable) are used to fully name a herbal ingredient.

AHS – Australian (Approved) Herbal Substance

AHS names are allocated to herbal ingredients (e.g. olive oil) that are fully characterised in a monograph of an accepted pharmacopoeia.⁷ While this is the exception to the rule, in the case of AHSs, the substance must comply with the monograph that is the source of the substance name.

HCN – (Australian Approved) Herbal Component Name

⁶ PRV indicates 'provisional' status. This means that the ingredient may be included in topical Listed medicines subject to the provision of certain assurances in relation to safety (refer to [ARGCM Part III](#)).

⁷ Where possible, substance AHSs refer to a monograph in the most recent edition of the British Pharmacopoeia (BP), European Pharmacopoeia (PH Eur) or the United States Pharmacopoeia (USP) and their supplements. Where there is no relevant monograph in the most recent edition of the BP, PH Eur or USP, an earlier edition of another suitable pharmacopoeial reference may be used.

HCNs are names for classes of constituents that are found in herbal ingredients. The need for a HCN most often arises when a herbal extract is standardised to a particular class of constituents, or where particular classes of constituents are restricted (e.g. hydroxyanthracene derivatives). Where a herbal extract is standardised to a single constituent, the single constituent should have an AAN (chemical name). A HCN is not a stand-alone name and should be used only when expressing a herbal substance.

AFN – Australian (Approved) Food Name

AFNs are allocated to substances (e.g. orange) that are food grade. In addition to the AFN, the full name of the food ingredient (e.g. orange juice) in the 'preparation' is usually required. When using the AFN for a substance, the ingredient can be used only as an excipient in therapeutic goods. If the substance is to be included as an active ingredient in a product, the name of the substance should be expressed in AHN format (e.g. *Citrus sinensis* fruit juice).

Label-AAN – Australian Approved Label Names

In the case where the name needed to describe a substance (the full AAN) is considered too long to be mandatory on labels, the TGA may approve an alternative name for use on labels only (a label-AAN). The full AAN would need to be a minimum of 40 characters before a label-AAN would be considered.

Label-AANs may also be approved for complementary medicine substances where the full AAN is considered unsuitable for use on labels because consumers may not understand the terminology used.

Labels may also include Greek symbols (e.g. α -tocopherol instead of the AAN alpha tocopherol). However, as the ARTG is unable to store these symbols, the full AAN must be included in product applications.

Where an ingredient used in a formulation is a hydrated form and the water of hydration information is included in the approved name, it is acceptable to include the approved name (and quantity) of the anhydrous form on product labels.

17.3. Substances that do not have an approved name

17.3.1. Application Forms

When submitting an application for evaluation of a complementary medicine substance, including a new substance in a Registrable complementary medicine, that does not currently have an AAN, sponsors will need to submit a proposal for a new AAN with their application.

The seven different application forms are available on the TGA website, as follows:

- [Application Form for Proposing a Chemical Name](#) (AAN or ADN and chemical PRV)
- [Application Form for Proposing a Biological Name](#) (ABN and biological PRV) or Term
- [Application Form for Proposing a Botanical Name for a Herb](#) (AHN and herbal PRV)
- [Application Form for Proposing a Herbal Substance Name](#) (AHS and herbal substance PRV)
- [Application Form for Proposing a Herbal Component Name](#) (HCN)
- [Application Form for Proposing a Plant Food Name](#) (AFN)

- [Application Form for Proposing Approved Names\(s\) be Added to a Label-AAN Group](#) (all name types).

Specific details of what should be provided with a proposal for a new name are included in each of the application forms. Proposed Label-AANs for the substance should be included on the application form. A proposal for a Label-AAN should be accompanied by a justification for its use and references in support of its use.

Applications are likely to be processed without delay if:

- the ingredient name form (the latest edition of the *TGA Approved Terminology for Medicines*) is received correctly completed;
- the ingredient is defined by a monograph in one (or more) of the references included in the [TGA Approved Terminology for Medicines](#) 1999 edition (pages 11-12 for chemical ingredient names and pages 162-163 for biological ingredient names);
- copies of the relevant monograph(s) are attached to the proposal form;
- the monograph defines the name with sufficient precision to enable the committee(s) (see below) to have confidence that the ingredient so named can be identified.



Note: Copies of product labels are not required to process an AAN application.

Completed forms should be sent to:

AAN Committee / ABN Committee / Herbal Ingredient Naming Committee
 c/- Non-Prescription Medicines Branch, Office of Scientific Services
 Market Authorisation Group
 Therapeutic Goods Administration
 PO Box 100
 WODEN ACT 2606
 AUSTRALIA

17.3.2. Review of New AAN Requests

The TGA has established three committees to review applications for new AANs, in order to accurately identify substances and provide consistency in naming:

- Australian Approved Name (AAN) Committee;
- Australian Biological Name (AAN) Committee; and
- Herbal Ingredient Naming Committee (HINC).

The process for review of new AAN applications is summarised below:

1. Applications are checked to determine whether the form has been fully completed and references attached (applications which are not complete will be returned with a request for more information).
2. 'Complete' applications are referred to the appropriate committee for review (committee members have five working days in which to consider the application).
3. Committee members meet to review the application and make a decision.
4. If successful, sponsors will be notified by mail (and [TGA eBusiness Services](#) (eBS)) will be updated to include the new name).
5. If unsuccessful, sponsors will be notified by mail of the decision and a justification provided as to why the proposed name is unacceptable. (Sponsors may request that their application be considered again, if they believe that they have justification to support an alternative to the committee's decision.)

The AAN and ABN committees and the HINC attempt to consider and approve (or otherwise) proposals for new ingredient names within fifteen (working) days from their receipt by the Office of Scientific Services. However, these time frames are unlikely to be met if insufficient information is provided in the application.

18. Colourings permitted in medicines for oral use

A list of colourings permitted in complementary, over-the-counter and prescription medicines for oral use, and indicative data requirements for the evaluation of new colours (for inclusion in medicines for oral use), is located at <<http://www.tga.gov.au/industry/pm-argpm-guidance-22.htm>> on the Therapeutic Goods Administration website.

19. Herbal ingredients – quality

This section is divided into the following subsections:

- 19.1. [Background](#)
- 19.2. [Scope of the Guideline for herbal substances](#)
- 19.3. [General concepts](#)
- 19.4. [Compositional guideline](#)
- 19.5. [Herbal preparations](#)

The following information provides general principles on the setting and justification, to the extent possible, of a compositional guideline for herbal substances.

This information has been adapted from the European Medicines Agency (EMA) document entitled *Note for Guidance on Specifications: Test Procedures and Acceptance Criteria for Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products* ([CPMP/QWP/2820/00](#)).

19.1. Background

A compositional guideline is a list of tests, references to analytical and biological procedures, and appropriate acceptance criteria, which are numerical limits, ranges, or other criteria for the tests described. It establishes the set of criteria to which a herbal substance should conform to be considered acceptable for its intended use.

Compositional guidelines for herbal substances are one part of a total control strategy for herbal medicinal products designed to ensure product quality and consistency.

In the case of herbal medicinal products, compositional guideline requirements are generally applied to the herbal substance used in the manufacture of the product (includes raw herbal materials and herbal preparations). Compositional guideline requirements are primarily intended to define the quality of the herbal substance and should focus on those characteristics found to be useful in ensuring safety and quality.

19.2. Scope of the Guideline for herbal substances

The quality of herbal medicinal products is determined by the quality of the herbal substance, development, in-process controls, good manufacturing practice (GMP) controls, and process validation, and by compositional requirements applied to them throughout development and manufacture. This guideline addresses compositional guideline requirements, ie. those tests, procedures, and acceptance criteria used to assure the quality of the herbal substance at the time it is used in the production of the finished product. Compositional guidelines are an important component of quality assurance, but are not its only component. All of the considerations listed above are necessary to ensure consistent production of herbal medicinal products of high quality.

Guidance is provided about acceptance criteria which should be established for all herbal substances unless otherwise justified. This guideline should not be considered all encompassing. For example, sponsors should refer to the [CHC Code of Practice for Ensuring Raw Material Quality & Safety](#) (prepared by the Raw Material Suppliers Committee of the Complementary Healthcare Council of Australia) for general principles relating to the quality of raw materials for use in complementary medicines.

New analytical technology and modifications to existing technology are continuously being developed. Such technologies should be used when appropriate.

19.3. General concepts

The following concepts are important in the development and setting of compositional guidelines for herbal substances. They are not universally applicable, but each should be considered in particular circumstances. A brief definition of each concept and an indication of the circumstances under which it may be applicable are given.

19.3.1. Characterisation

Consistent quality of products of herbal origin can be assured only if the starting plant material is defined in a rigorous and detailed manner. Characterisation of a herbal substance (which includes a detailed evaluation of the botanical and phytochemical aspects of the plant and manufacture of a preparation where applicable) is therefore essential to allow establishment of compositional guidelines that are comprehensive and relevant to safety and quality.

Compositional guidelines should primarily be established and justified based on information from batches used in establishing safety (including clinical studies) or described in relevant bibliographic data.

Extensive characterisation is usually performed only in the development phase and where necessary following significant process changes.

Macroscopical / microscopical characterisation

This type of characterisation includes features that distinguish the active plant from potential adulterants and substitutes.

Phytochemical characterisation

This covers analytical research of constituents, including active constituents and compounds suitable as marker substances, and chromatographic fingerprinting.

Potential impurities / contaminants / degradation products

This includes aspects such as toxic elements, pesticides, fumigants etc.

Biological variation

This includes historical batch data and published information about biological variation.

19.3.2. Development considerations

The experience and data accumulated during the development of a new herbal substance should form the basis for the setting of compositional guidelines. For example, it may be possible to propose excluding or replacing certain tests on this basis.

Two examples are:

- reduced testing for pesticides residues where a plant is grown under strict organic cultivation without pesticides etc and potential contamination has been eliminated; and
- excluding or reducing tests for microbial limits in herbal extracts or tinctures depending on the ethanol content if justified by scientific evidence.

19.3.3. Pharmacopoeial tests and acceptance criteria

The British Pharmacopoeia (BP) contains important requirements pertaining to certain analytical procedures and acceptance criteria that are relevant to herbal substances. Wherever they are appropriate, pharmacopoeial methods should be used.

19.3.4. Alternative non-pharmacopoeial tests

Alternative tests may be used to measure an attribute if the tests control the quality of the herbal substance product to an extent that is comparable with or superior to the pharmacopoeial procedure. However, the pharmacopoeial procedure should still be used to demonstrate compliance with the compositional guideline (see [Subsection 19.4](#)).

19.3.5. Evolving technologies

New technology and modifications to existing technology are continuously being developed. Such technologies should be used when they are considered to offer additional assurance of quality.

19.3.6. Reference standard

A reference standard, or reference material, is a substance prepared for use as the standard in an assay, identification, or purity test. In the case of herbal substances, the reference standard may be a sample of the plant or a chemically defined substance, e.g. a known active constituent, a marker substance or a known impurity. The composition of reference standards intended for use in assays should be adequately controlled, and the authenticity or purity of a standard should be determined by validated procedures.

If the herbal substance is not described in the BP or other recognised monograph, an authenticated reference specimen (herbarium sample) of the whole plant or a part of the plant should be available to the manufacturer for authentication. (For more information on the requirements of reference standards, sponsors should refer to the Therapeutic Goods Administration (TGA) document – [Questions & Answers for the Identification of Herbal Materials and Extracts](#).)

19.3.7. Statistical concepts

When necessary, statistical analysis should be applied to quantitative data reported.

19.4. Compositional guideline

19.4.1. Definition of compositional guideline

A compositional guideline is defined as a list of tests, references to analytical or biological procedures, and appropriate acceptance criteria, which are numerical limits, ranges, or other criteria for the tests described. It establishes the set of criteria to which a herbal substance should

conform to be considered acceptable for its intended use. 'Conformance to the compositional guideline' means that the herbal substance when tested according to the Listed analytical procedures will meet the Listed acceptance criteria.

It is possible that a compositional guideline requirement may list in-process tests, periodic (skip) tests, and other tests that are not always conducted on a batch-by-batch basis.

19.4.2. Justification of specifications

Compositional guidelines for herbal materials (mainly whole, unfragmented or cut plants, parts of plants in an unprocessed state, usually in dry form but sometimes fresh) are linked to:

- botanical characteristics of the plant part;
- phytochemical characteristics of the plant part – known therapeutic or marker constituents, toxic constituents (identity, assay, limit tests);
- biological / geographical variation;
- cultivation / harvesting / drying conditions (microbial levels, aflatoxins, toxic elements etc.);
- pre / post-harvest chemical treatments (pesticides, fumigants); and
- profile and stability of the constituents.

Compositional guidelines for herbal preparations (obtained by subjecting herbal materials to certain treatments, such as extraction, distillation etc., consistent with definition of a herbal substance) are linked to:

- quality of herbal material (as above);
- method of preparation from the herbal material;
- drying conditions (e.g. microbial levels, residual solvents in extracts);
- profile and stability of the constituents;
- microbial stability; and
- batches used in establishing safety of the preparation.

Compositional guidelines should be based on data obtained from lots used to demonstrate consistency. Linking compositional guidelines to a manufacturing process is important, especially with regard to process-related constituents and process-related impurities.

Historical batch data should be taken into account where available.

Changes in the manufacturing process, and degradation products produced during storage, may result in a herbal substance that differs from that used to establish safety. The significance of these changes should be considered.

19.4.3. Universal tests / criteria

Herbal materials

Herbal materials are a diverse range of botanical materials including leaves, herbs, roots, flowers, seeds, bark etc. A comprehensive compositional guideline should be developed for each herbal material, even if the starting material for the manufacture of the finished product is a herbal preparation (e.g. an extract). In the case of fatty or essential oils used as active substances, a

compositional guideline requirement for the herbal material is recommended. The requirement should be established on the basis of recent scientific data.

The general monograph *Herbal Drugs* of the BP should be consulted for interpretation of the following guidelines.

The following tests and acceptance criteria are considered generally applicable to all herbal materials.

Definition: a qualitative statement of the botanical source, plant part used and its state (e.g. whole, reduced, powdered, fresh, dry). It may also be important to know the geographical source(s) and the conditions under which the herbal material is obtained.

Characters: a qualitative statement about the organoleptic character(s) where characteristic, and the macroscopic and microscopic botanical characters of the herbal material.

Identification: identification testing optimally should be able to discriminate between related species and / or potential adulterants / substitutes that are likely to be present. Identification tests should be specific for the herbal drug and are usually a combination of three or more of the following:

- macroscopical characters;
- microscopical characters;
- chromatographic procedures; and / or
- chemical reactions.

Tests:

- foreign matter;
- total ash;
- ash insoluble in hydrochloric acid⁸;
- water soluble extractive⁹; and / or
- extractable matter⁹.

Particle size: For some herbal materials intended for use in herbal teas or solid herbal medicinal products, particle size can have a significant effect on dissolution rates, bioavailability, and / or stability. In such instances, testing for particle size distribution should be carried out using an appropriate procedure, and limit criteria should be provided.

Water content: This test is important when the herbal materials are known to be hygroscopic. For non-pharmacopoeial herbal materials, criteria should be justified by data on the effects of moisture absorption. A 'loss on drying' procedure may be adequate; but in some cases (essential-oil containing plants), a detection procedure that is specific for water is required.

Incidental metals and non-metals: The need for tests and acceptance criteria for incidental metals and non-metals should be studied during development and based on knowledge of the plant species, its cultivation and the manufacturing process.

Acceptance criteria will ultimately depend on safety considerations. Where relevant, procedures and acceptance criteria for sulfated ash / residue on ignition should follow pharmacopoeial precedents; other impurities may be determined by other appropriate procedures, e.g. atomic absorption spectroscopy.

⁸ These tests might not all apply to herbal materials.

Microbial limits: There may be a need to specify the total count of aerobic micro-organisms, the total count of yeasts and moulds, and the absence of specific objectionable bacteria. The source of the herbal material should be taken into account when considering the inclusion of other possible pathogens (e.g. *Campylobacter* and *Listeria* species). Microbial counts should be determined using pharmacopoeial procedures or other validated procedures.

Microbial toxins: The potential for microbial toxin contamination should be fully considered. Where necessary, validated methods should be used to control potential microbial toxins.

Agricultural and veterinary chemicals etc.: The potential for residues of pesticides, fumigants etc. should be fully considered. Where necessary, validated methods should be used to control potential residues. In the case of pesticide residues, the method, acceptance criteria and guidance on the methodology of the BP should be followed.

Other appropriate tests: ⁹ (e.g. swelling index).

Assay: In the case of herbal materials with constituents of known therapeutic activity, the content of the constituents should be assayed. Where possible, a specific, stability-indicating procedure should be used to determine the content of active constituent in the herbal material. In cases where a non-specific assay is used, other supporting analytical procedures should also be used to achieve overall specificity. For example, where determination of essential oils is adopted to assay the herbal material, the combination of the assay and a suitable test for identification (e.g. fingerprint chromatography) can be used.

In the case of herbal materials where the constituents responsible for the therapeutic activity are unknown, appropriate marker substances may be assayed.

19.5. Herbal preparations

Herbal preparations are diverse in character, ranging from simple, comminuted or powdered plant materials, to extracts, tinctures, essential oils and fatty oils and exudates. A comprehensive compositional guideline based on recent scientific data should be developed for each herbal preparation. The general monograph *Herbal Drug Preparations* of the BP should be consulted for the interpretation of the following guidelines.

The following tests and acceptance criteria are considered generally applicable to all herbal preparations:

Definition: a statement of the botanical source, and the type of preparation (e.g. dry or liquid extract) and the ratio of the herbal material to the herbal preparation.

Characters: a qualitative statement about the organoleptic characters of the herbal preparation where characteristic.

Identification: Identification tests should be specific for the herbal preparation, and optimally should be discriminatory with regard to substitutes / adulterants that are likely to occur. Identification solely by chromatographic retention time, for example, is not regarded as being specific; however, a combination of chromatographic tests (e.g. high-performance liquid chromatography (HPLC) and thin-layer chromatography (TLC)-densitometry) or a combination of tests into a single procedure, such as HPLC / ultraviolet (UV)-diode array, HPLC / mass spectrometry (MS), or gas chromatography (GC) / MS may be acceptable.

Residual solvents: The BP monograph *Residual Solvents* can be referred to for detailed information.

⁹ These tests might not all apply to herbal materials.

Water content: This test is important when the herbal preparations are known to be hygroscopic. The acceptance criteria may be justified with data on the effects of hydration or moisture absorption. A 'loss on drying' procedure may be adequate, but in some cases (essential-oil-containing preparations), a detection procedure that is specific for water is required.

Incidental metals and non-metals: the need for inclusion of tests and acceptance criteria for incidental metals and non-metals should be studied during the development, and based on knowledge of the plant species, its cultivation and the manufacturing process. The potential for the manufacturing process to concentrate residues should be fully addressed. If the manufacturing process will reduce the burden or residue, the tests with the herbal material may be sufficient. Acceptance criteria will ultimately depend on safety considerations. Where relevant, procedures and acceptance criteria for sulfated ash / residue on ignition should follow pharmacopoeial precedents; other impurities may be determined by other appropriate procedures, e.g. atomic absorption spectroscopy.

Microbial limits: The source of the herbal material should be taken into account when considering the inclusion of other possible pathogens (e.g. *Campylobacter* and *Listeria* species).

Sterile Products

The official requirements for sterility tests in Australia are those specified in the current gazetted edition of the BP. This is the minimum standard with which manufacturers must comply. The sterility tests published in editions of the BP and Ph. Eur. prior to 1998 are not acceptable.

The [TGA Guidelines for Sterility Testing of Therapeutic Goods](#) provide guidance for sterility testing of sterile therapeutic goods supplied in Australia for human use. These guidelines, however, are not mandatory for industry.

Generally, products that are required to be sterile (e.g. for ophthalmic use) will require extremely stringent microbiological specifications together with detailed information on manufacturing steps that ensure sterility.

Non-Sterile Products

[Therapeutic Goods Order No. 77 – Microbiological Standards for Medicines](#) sets out the microbial limits that apply to non-sterile dosage forms.

All non-sterile dosage forms should include limits for microbial content in the finished product batch release and expiry specifications. Microbial specifications for solid oral or dry powder products may not be necessary if their absence can be justified in the application by establishing during product development that the product is at a very low risk of contamination and microbial growth is not supported. It is not a requirement that every batch of a product be tested at batch release. Once it has been demonstrated that the manufacturing processes do not permit contamination by excessive numbers of microorganisms, by testing a number of routine production batches to establish a product history, testing could be reduced to once every six to twelve months or on a selected basis (e.g. every tenth batch).

Products with significant water content (e.g. creams, gels and oral liquids) are likely to support microbial growth. Such products should include tests and limits for microbial content in both the batch release and expiry specifications.

For products containing antimicrobial preservatives, both the batch release and expiry specifications should include physico-chemical tests and limits for content of preservatives. Given that the effectiveness of many preservatives is pH dependent, the specifications for such products should usually include requirements for pH that will ensure preservative efficacy. The expiry limits for the preservative should be supported by preservative efficacy testing that is performed during stability testing.

Microbial toxins: The potential for microbial toxin contamination should be fully considered. Where necessary, validated methods should be used to control potential microbial toxins.

Agricultural and veterinary chemicals etc: the potential for residues of pesticides fumigants etc. should be fully considered. Where necessary, validated methods should be used to control potential residues. In the case of pesticide residues the method, acceptance criteria and guidance on the methodology of the BP should be applied.

Assay: In the case of herbal preparations with constituents of known therapeutic activity, the content of the active constituents should be assayed. Where possible, a specific, stability-indicating procedure should be included to determine the content of the active constituent in the herbal preparation. In cases where use of a non-specific assay is used, other supporting analytical procedures should also be used to achieve overall specificity.

For example, where a visible UV spectrophotometric assay is used e.g. with anthraquinone glycosides, a combination of the assay and a suitable test for identification (e.g. chromatographic fingerprint) can be used. In the case of herbal preparations where the constituents responsible for the therapeutic activity are unknown, appropriate marker substances may be assayed.

Guidance on validating analytical test methods can be found in [Analytical procedure validation for complementary medicines](#).

20. Ingredients of human or animal origin

This section is divided into the following subsections:

- 20.1. [Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products](#)
- 20.2. [Ingredients of human origin](#)

20.1. Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products

The purpose of this subsection is to provide further guidance to sponsors and manufacturers for minimising the risk of carrying transmissible spongiform encephalopathy (TSE) agents in therapeutic goods. These assessment practices are in accordance with guidance developed by the European Union (EU).

This document complements the guidance document developed in the EU by the Committee for Medicinal Products for Human Use (CHMP) *Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products* ([EMA/410/01 Rev 2](#)) and its subsequent revisions by the European Medicines Evaluation Agency (EMA). The CHMP guidance has been adopted by the TGA as the basis for managing TSE risks in therapeutic goods.

The Therapeutic Goods Administration (TGA) document *Supplementary Requirements for Therapeutic Goods for Minimising the Risk of Transmitting Transmissible Spongiform Encephalopathies (TSEs)* is available at <http://www.tga.gov.au/industry/tse-supplementary-requirements.htm> on the TGA website. The document focuses on ingredients of human and animal (particularly ruminant) origin that are currently classified in Category C of the CHMP Guidance; that is, those ingredients characterised as having no detectable infectivity according to current knowledge of TSE transmission. The supplementary requirements propose that Category C ingredients should be allowed for use in the preparation of active or excipient substances or as raw or source materials, or reagents in their production.

Sponsors must self-assess Category C materials according to the requirements. A questionnaire has been provided to aid sponsors in obtaining information from suppliers. The TSE questionnaire for sponsors can be downloaded from <http://www.tga.gov.au/industry/tse-sponsor-questionnaire.htm>.

This questionnaire has been designed by the TGA in consultation with Australian industry bodies to facilitate the collection of data to enable sponsors to self-certify their therapeutic goods against the TGA's *Supplementary Requirements for Therapeutic Goods for Minimising the Risk of Transmitting Transmissible Spongiform Encephalopathies (TSEs)*. The questionnaire should be sent to suppliers and manufacturers to obtain information about materials of ruminant origin used in the manufacture of raw materials, active ingredients, excipients, device components, reagents and finished products.

If the ingredients are sourced from countries with a high risk of TSE (as per appendix 3 of the TGA's TSE guidance document) or from countries with low-moderate risk of TSE where the material is not one of the following:

- hide-derived gelatine;
- bone-derived gelatin (excluding vertebrae);
- wool derivatives, tallow derivatives or milk; and
- derivatives (produced without the use of rennet / other ruminant materials)

then clearance for use of the ingredient will have to be obtained from the TGA.

Applications for clearance of ingredients of animal origin can be completed online (<<http://www.tga.gov.au/industry/cm-forms-animal-derived-ingredients.htm>>) and should be directed to:

Administrative Officer
Pathogen Safety Section
Biological Science Unit Blood and Tissues Unit
Office of Scientific Evaluation
Market Authorisation Group
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606.

Initial information should provide:

- the product's identification;
- the name of the ingredient(s) of animal origin;
- any pharmacopoeial reference applicable to the ingredient;
- the quantity of the ingredient per dose unit;
- the name of the animal species;
- the name of the body part; and
- the country of origin of the animal.

This information will enable the Office of Scientific Evaluation (OSE) to determine whether more information is required. If the screening demonstrates that the product could pose a risk of slow virus transmission, details of additional data requirements will be advised.

Any material of animal (ruminant) origin that is not highly processed (e.g. blood, enzymes) should be submitted to the OSE for pre-clearance.

20.2. Ingredients of human origin

If the material is of human origin, sponsors should first contact the Head of the OSE for details of data requirements.

21. Glossary of terms used in the Australian Regulatory Guidelines for Complementary Medicines

This document contains interpretations of terms commonly used by the Therapeutic Goods Administration (TGA) in regard to medicines and identifies terms which are defined in the [Therapeutic Goods Act 1989](#) and [Therapeutic Goods \(Charges\) Act 1989](#) and the [Therapeutic Goods Regulations 1990](#).

This glossary is not exhaustive and does not include many terms that are 'technically' specific to only some areas of TGA; in particular, it does not interpret terms, which are used exclusively for, or in connection with the manufacture of prescription medicines or therapeutic devices.

Terms which are defined in the Acts and their Regulations may be defined slightly differently (e.g. to expand or narrow a definition) in Therapeutic Goods Orders made under the Act. References should be made to the definitions in the relevant Order when determining the requirements of a standard such as those for the labelling of medicines.

This document includes terms used only in relation to medicines. It does not include terms related only to medical devices.

21.1. Notes

1. Defined in the *Therapeutic Goods Act 1989* in subsection 3(1) unless another Section of the Act is indicated
2. Defined in the *Therapeutic Goods Regulations 1990* in Regulation 2 unless another regulation number is indicated
3. Defined in the *Therapeutic Goods (MD) Regulations 2002* in Regulation 1.3 unless another regulation number is indicated
4. Defined in the *Therapeutic Goods (Charges) Regulations 1990* in Regulation 2 unless another regulation number is indicated

* Relates only to drug products – Medicine Regulations

21.2. Glossary

Acceptable country^{2*}

A country that the Minister has notified in the Gazette as an acceptable country for the purposes of this regulation. (*Regulation 16C*)

Act⁴

The *Therapeutic Goods Act 1989*.

Active ingredient^{1, 2*}

The therapeutically active component in a medicine's final formulation that is responsible for its physiological action.

Active pharmaceutical ingredient (API)

Therapeutically active component in the final formulation of therapeutic goods.

Active raw material

The unformulated active chemical substance, usually a powder or a liquid, in the form in which it is used to manufacture a dosage form, usually in combination with excipients.

Actual or potential tampering¹

- a. tampering with the therapeutic goods; **OR**
- b. causing the therapeutic goods to be tampered with; **OR**
- c. proposing to tamper with the therapeutic goods; **OR**
- d. proposing to cause the therapeutic goods to be tampered with.

(Section 42U)

Advertisement¹

In relation to therapeutic goods, advertisement includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

Agent

A person duly authorised in writing to act on behalf of the sponsor of the goods.

AHMAC

The Australian Health Ministers' Advisory Council and subcommittees of the Council acting on its behalf.

Analysis²

Includes examination and testing.

Animal³

An invertebrate or vertebrate member of the animal kingdom.

Antibiotic

A selective antimicrobial agent, other than disinfectants, antiseptics and substances used solely as antineoplastics, that, on application to living tissue or by systemic administration, kills or prevents the growth of susceptible micro-organisms.

Appellant

In the terms of the *Therapeutic Goods Act 1989* – a person seeking a review of a decision under the provisions of Section 60 of the Act or Regulation 48 of the Regulations to the Act. (Section 60)

Applicant²

In relation to advertisements for therapeutic goods, means an applicant for approval of an advertisement. (Section 5B)

In relation to Part 3, division 4, means an applicant of the use of a restricted representation in an advertisement about therapeutic goods. (Regulation 6AA)

Application

An application made to TGA under the following sections of the *Therapeutic Goods Act 1989* (note that where the Section / Regulation number is **highlighted**, the word 'application' is used in the legislation):

- Section 14 (exemption from compliance with a Standard);
- Section 19 and 41HB (special and experimental uses); and
- Section 23, 24, 25 and 26 (Registration or Listing)

[Note that each application results in a single Registration or Listing or the inclusion of a separate and distinct product within a grouped Registration or Listing]; or

- Section 9C (request for copy of ARTG entry)
- Section 9D (request to vary information about an ARTG entry)
- Section 37 and 38 (manufacturer's licence)
- Section 41EB (conformity assessment certificates)
- Section 58 (export certification)
- Section 61(6) (information from ARTG)
- Regulation 14 (transfer of goods Registered / Listed)
- Regulation 14A (reassignment of Registration / Listing numbers).

(See also **Submission**.)

Approval holder²

In relation to a restricted representation, means the person to whom notice of approval of the use of the restricted representation was given. (*Regulation 6AA*)

Approval number¹

The distinguishing number allocated to an approved advertisement by the Secretary under Regulation 5J of the Therapeutic Goods Regulations 1990. (*Section 42B*)

Approved advertisement^{1,2}

An advertisement which is approved under regulation 5G, or taken to be approved by the Secretary under Sub regulation 5H(2), or approved by the Minister on review under regulation 5M, of the Therapeutic Goods Regulations 1990 and the approval has not been withdrawn. (*Section 42B*)

Approved type³

A type that has been examined and approved by the Secretary under the type examination procedures.

ARTG

Australian Register of Therapeutic Goods.

ARTG entry

Refers to a separate and distinct product included in the ARTG, as described by the criteria in subsection 16(1) of the *Therapeutic Goods Act 1989*. Grouped products represent two or more ARTG entries under a single ARTG number.

ARTG purpose

Relates to the basis for inclusion of the goods in the ARTG. Goods are included in the Register as a mechanism indicating approval for supply in Australia and / or approval for export from Australia. Goods Listed for export will have an ARTG purpose of 'export' only, all others will have a purpose of 'supply'.

ARTG status

A term which describes the Registration / Listing status of therapeutic goods in relation to their inclusion, or otherwise, in the ARTG. It includes Registered, Listed, cancelled by Secretary and cancelled by sponsor.

ASMI²

The Australian Self-Medication Industry Incorporated (ABN 55 082 798 952).

AUST L

See **Listing number**.

AUST R

See **Registration number**.

Australian Approved Name (AAN) for pharmaceutical substances

A name for an ingredient, or a plant or other organism included in the formulation of a medicinal product, which is included in the list of *Australian Approved Names for Pharmaceutical Substances* published by the TGA. The list comprises three parts:

- AAN chemical substances list;
- AAN biological substances list; and
- AAN herbal substances list.

(See **TGA Approved Terminology for Drugs**.)

Australian Approved Names List²

The document entitled *TGA Approved Terminology for Medicines* (July 1999), as in force from time to time, published by the TGA.

Note 1 The Australian Approved Names List includes:

- a. Australian Approved Names – Chemicals List; and
- b. Australian Approved Names – Biologicals List; and
- c. Australian Approved Names – Herbal Substances List.

Note 2 The Australian Approved Names List may be published as part of a larger document; for example, the document entitled *TGA Approved Terminology for Medicines*.

Australian legal unit of measurement³

Has the meaning given by the *National Measurement Act 1960*.

Authorised delegate

A delegate of the Secretary exercising a power to decide whether to Register therapeutic goods.
(Section 60A(8))

Authorised officer²

An officer of the Department, or of another Department or authority of the Commonwealth; or an officer of:

- i. a Department of State of a State;
- ii. a Department or administrative unit of the Public Service of a Territory;
- iii. an authority of a State or Territory

that is a Department, unit or authority the functions of which relate to health matters; who is authorised in writing by the Secretary to exercise powers under that Provision. (*Regulation 23*)

Note: may also refer to persons authorised to examine records of the importation of therapeutic substances in accordance with regulation 5A of the Customs (Prohibited Imports) Regulations or to persons authorised to grant import permission for goods listed in Schedule 8 of the Customs (Prohibited Imports) Regulations.

Note: Regulation 2A provides for the Secretary to authorise certain officers to exercise powers under that provision.

Authorised person^{1, 2, 3}

In relation to any provision of the Act, a person authorised by the Secretary to exercise powers under that provision; or in relation to a provision of Part 6-2, a member of the Australian Federal Police or a Customs officer exercising powers in a Customs place (within the meaning of Section 183UA of the *Customs Act 1901*).

Note: may also refer to person authorised to grant import permission for therapeutic substances under regulation 5A of the Customs (Prohibited Imports) Regulations.

Batch¹

A quantity of a product that is;

- a. uniform in composition, method of manufacture and probability of chemical or microbial contamination; and
- b. made in one cycle of manufacture and, in the case of a product that is sterilised or freeze dried, sterilised or freeze dried in one cycle.

Bioburden¹

The quantity and characteristics of micro-organisms present in the goods or to which the goods may be exposed in a manufacturing environment.

Biologic⁴

In relation to therapeutic goods, a good in which the active ingredient is a biological substance.

Biological products

Products in which the active ingredient is a biological substance including antisera, antivenins, monoclonal antibodies and products of recombinant technology.

Biological substance⁴

Substances of biological origin, which are frequently chemically complex and have molecular weights over 1000, such as hormones, enzymes and related substances, but not including herbal substances and antibiotics. Biological substances are not uniquely defined by a chemical name because their purity, strength and composition cannot readily be determined by chemical analysis. Substances which can be isolated as a low molecular weight pure substance, such as purified steroids, digoxin and ergotamine, are considered to be chemical substances.

Body orifice³

A natural opening, or a permanent artificial opening, in a human being's body; includes the external surface of a human being's eyeball.

British Pharmacopoeia¹

The edition of the book of that name, including any additions or amendments, that was in effect for the purposes of the [Therapeutic Goods Act 1989](#) (the Act) immediately before the commencement of this section and, if additions or amendments of that book are made after that commencement, or new editions of that book are published after that commencement, includes those additions or amendments, or those new editions, from the day specified by the Minister by order published in the *Gazette*.

Broadcaster

In relation to an advertisement for therapeutic goods, means a person (other than a person who is required to enter those goods on the Register) who undertakes, as a business activity in its own right:

- a. the broadcasting of the advertisement in broadcast media; **OR**
- b. the placement of the advertisement for such broadcasting.

(Section 42B)

Broadcast media

In relation to an advertisement or generic information, means any means (other than a means declared in the regulations to be an exempted means) by which the information is disseminated electronically in a visible or audible form or a combination of such forms. (Section 42B)

Business name

The name of the person or corporation for which particulars are being supplied or which is making an application. It may be either the name Registered with the Australian Securities Commission, or the name of the person or persons who conduct the business. Trading names are not usually included in the business name for Australian applicants, but may be supplied in particular for overseas companies. Also referred to as client name / ID. (See also **Client**)

Certified product details (CPD)

A statement of product details, specifications and test methods generated by the sponsor at the request of the TGA.

CHC²

The Complementary Healthcare Council of Australia.

Charge

The sum payable annually for activities identified under the *Therapeutic Goods (Charges) Act 1989* (e.g. Registration, Listing and manufacturing licence).

Client

A person or organisation having an involvement in the import, export, manufacture or supply of therapeutic goods. An enterprise can include sponsors, manufacturers and agents.

Client identification code (Client ID)

Identification code assigned by the TGA to a client.

Clinical trial

A planned study in humans designed to investigate or report upon the effectiveness and / or safety of a therapeutic good. (See **experimental purposes in humans**.)

Committee^{1, 2}

A number of committees are defined in the *Therapeutic Goods Act 1989* (the Act) and the Therapeutic Goods Regulations 1990 (the Regulations):

- Therapeutic Goods Committee – Regulation 34 of the 1990
- Advisory Committee on Prescription Medicines – Regulation 35 of the Regulations
- Advisory Committee on the Safety of Medicines – Regulation 37 of the Regulations
- Advisory Committee on Non-prescription Medicines – Regulation 36 of the Regulations
- Advisory Committee on Complementary Medicines – Regulation 39 of the Regulations
- Advisory Committee on Medicine Scheduling – Section 52B of the Act and Regulation 42ZCA of the Regulations.
- Therapeutic Goods Advertising Code Council – Regulation 42A of the Regulations
- Complaint's Resolution Panel – Regulation 42R of the Regulations
- Advisory Committee on Medical Devices – Regulation 38 of the Regulations.

Commonwealth authority¹

A body corporate, or an unincorporated body, established for a public purpose by or under an Act; or a tribunal or authority established by or in accordance with an Act.

Commonwealth officer¹

- a. a Minister
- b. a person holding:
 - i. an office established by or under an Act
 - ii. an appointment made under an Act
 - iii. an appointment made by the Governor-General or a Minister but not under an Act
- c. a person who is a member or officer of a Commonwealth authority
- d. a person who is in the service or employment of the Commonwealth or engaged under an Act or regulations made under an Act.

Complaint²

In relation to Part 6, Division 3, subdivision 2 of the Regulations, means a complaint about an advertisement of generic information made to the Complaints Resolution Panel (CRP) in accordance with Regulation 42ZCAB of the Therapeutic Goods Regulations 1990.

Complaints Resolution Panel²

The panel established under Regulation 42R of the Therapeutic Goods Regulations 1990.

Advisory Committee on Complementary Medicines (ACCM)²

The committee established under Regulation 39 of the Therapeutic Goods Regulations 1990.

Composite pack¹

A medicinal product where the primary pack or the container includes at least two kinds of medicinal products and does not contain any medical devices. The medicinal products must be for use as a single treatment or as a single course of treatment, and it is necessary that the medicines

be combined before administration or that they must be administered in a particular sequence. (*Section 7B(2)*).

Examples include:

- a strip or blister pack containing tablets or capsules with differing formulations to be taken in a specified order
- a primary pack containing an active ingredient in one vial and a diluent in another vial
- a primary pack containing separate containers of different formulations for use as part of a single regimen of treatment.

Consumer Medicine Information (CMI)

Document required to be provided to patients with Schedule 10 medicines Registered on the Australian Register of Therapeutic Goods on or after 1 January 1993. It provides patients with a 'plain English' explanation of the product. (See also **Product information** and **Patient information document**.)

Container¹

The vessel, bottle, tube, ampoule, syringe, vial, sachet, strip pack, blister pack, wrapper, cover or other similar article that immediately covers the goods, but does not include an article intended for ingestion. (See also **Primary pack**.)

Container type

The Act describes a container as a 'vessel, bottle, tube, ampoule or other similar article that immediately covers the goods ...'. Types of containers are defined in the TGA list *Types of Containers* published in the latest edition of *TGA Approved Terminology for Drugs*. It describes container types for the purposes of Subsection 16(1)(g) of the *Therapeutic Goods Act 1989*. Container types are independent of the material used to make them.

Contract manufacture

Where all or part of the manufacturing process of therapeutic goods is carried out on a contract basis by a person other than the sponsor. Can include principal manufacturers and other (sub)manufacturers.

Corporation¹

A body corporate that is:

- a. a foreign corporation **OR**
- b. a trading corporation formed within the limits of the Commonwealth or a financial corporation so formed.

Corresponding State law¹

A State law declared by the regulations to correspond to the *Therapeutic Goods Act 1989* or the Therapeutic Goods Regulations 1990, including such a law as amended from time to time. (*Regulation 3*)

Counterfeit¹

Therapeutic goods which contain false representations in the label or presentation of the goods, any document or record relating to the goods or their manufacture or in any advertisement for the goods. (*Section 42E*)

Current Poisons Standard¹

The documents prepared in accord with Section 52A. (*Section 52A*)

Customs Officer

An officer of Customs within the meaning of the *Customs Act 1901*.

Data-processing device¹

Any article or material (e.g. a disc) from which information can be reproduced with or without the aid of any other article or device.

Decision

Has the same meaning as in the *Administrative Appeals Tribunal Act 1975*. (*Section 60(1), Regulation 48*)

Delegate

An officer who has been given authority by the Minister or Secretary to exercise a power that the Act or Regulations confer on the Minister / Secretary. (*Section 57, Regulation 47 and Regulation 47A*).

Designated active ingredient

An active ingredient, or a kind of active ingredient, mentioned in Schedule 14 to the Therapeutic Goods Regulations 1990.

Designated therapeutic goods²

Therapeutic goods other than:

- a. therapeutic devices
- b. goods included in Schedule 3 to the Poisons Standard that are not included in Appendix H of that statement
- c. goods included in Schedule 4 or 8 to the Poisons Standard.

Directions for use¹

Includes information on:

- a. appropriate uses of the therapeutic goods
- b. the method of administration or use of the goods
- c. the frequency and duration of treatment for each indication of the goods
- d. the use of the goods by persons of particular ages or by persons having particular medical conditions.

Dosage form

The pharmaceutical form in which a product is presented for therapeutic administration, e.g. tablet, cream. A list of dosage forms and their definitions for the purposes of recording information in the Australian Register of Therapeutic Goods is included in the *TGA Approved Terminology for Drugs*.

Drug

See **Medicine**. Note that legislative definitions apply in both singular and plural forms.

Engage in conduct

To do an act or to omit to perform an act. (*Section 6AA(3A), Section 22(3A) and Section 35(3)*)

Enterprise

A person or organisation having an involvement in the import, export, manufacture or supply of therapeutic goods. An enterprise can include sponsors, manufacturers and agents.

Enterprise name

See **Business name**.

Ethics committee¹

A committee:

- a. constituted and operating as an ethics committee in accordance with guidelines issued by the National Health and Medical Research Council under the *National Health and Medical Research Council Act 1992*
- b. which has notified its existence to the Australian Health Ethics Committee established under the *National Health and Medical Research Council Act 1992*.

Evidential material

- a. any thing with respect to which an offence against the *Therapeutic Goods Act 1989* has been committed or is suspected, on reasonable grounds, to have been committed, **OR**
- b. any thing as to which there are reasonable grounds for suspecting that it will afford evidence as to the commission of any such offence, **OR**
- c. any thing as to which there are reasonable grounds for suspecting that it is intended to be used for the purpose of committing any such offence.

(Section 45A)

Excipient

Any component of a finished dosage form other than an active ingredient (in some cases the distinction between an active ingredient and an excipient may not be clear cut, e.g. use of sodium chloride to adjust tonicity of an injection is an excipient).

Excluded goods

Goods which might be considered to be therapeutic goods but which are specifically declared not to be by an Order of the Secretary (and therefore not subject to any requirements of the *Therapeutic Goods Act 1989*). (Section 7)

Exempt goods¹

Therapeutic goods that are exempted from the requirements to be Registered or Listed, or are exempted from licensing requirements by the Therapeutic Goods Regulations 1990.
(Part 3-2)

Exempt person¹

A person exempted by the Therapeutic Goods Regulations 1990 from the operation of Part 3-3 in relation to exempt goods.

Experimental purposes in humans

As used in the Act and Regulations, refers to use of drugs or devices in clinical trials subject to approval under Section 19(1)(b) of the *Therapeutic Goods Act 1989* or to notification under item 3 of Schedule 5A of the Therapeutic Goods Regulations 1990.

Expiry date²

The date (expressed as the month and year) after which the goods should not be used.

Export certification

Can include a WHO Certificate of a Pharmaceutical Product for drugs, a Certificate of Free Sale (Devices) or an Export Certificate (Devices). (Section 58)

Export name

The proprietary name used for the goods for supply in another country where that name is different from the proprietary name used for the goods for supply in Australia.

Export only medicine¹

A medicine that:

- a. is manufactured in Australia for export only, or imported into Australia for export only
- b. is Listable goods only because it is so manufactured or imported (and not for any other reason).

Fee

A sum payable for activities or events identified in Schedule 9 of the Therapeutic Goods Regulations 1990 (e.g. evaluation fee).

Financial corporation¹

A financial corporation within the meaning of paragraph 51(xx) of the Constitution.

Finished goods

The finished or final dosage form of the therapeutic good when all stages of manufacture, other than release for sale, have been completed.

First Poisons Standard¹

The latest edition of the document known as the *Standard for the Uniform Scheduling of Medicines and Poisons* published by the Australian Government under the *Therapeutic Goods Act 1989*. (Section 52A)

FOI Act

The *Freedom of Information Act 1982*.

Foreign corporation¹

A foreign corporation within the meaning of paragraph 51(xx) of the Constitution.

Formulation

A list of the ingredients used in the manufacture of a dosage form and a statement of the quantity of each ingredient in a defined weight, volume, unit or batch.

For the Australian Register of Therapeutic Goods database, the recorded formulation excludes ingredients not present in the finished goods (e.g. water in lyophilised powders), and excludes overages. Where ingredients used in the manufacture of a dosage form react chemically with one another, the ingredient formed as a result of this reaction is recorded, not the original ingredients.

Gazette

Commonwealth Government Notices Gazette (published by the Attorney-General's Department).

Gazetted therapeutic goods group^{1*}

A group of medicines which have common characteristics, that are identified in an order published in the *Gazette*. (Subsection 16(2))

Generic information²

In relation to therapeutic goods, it includes any statement, pictorial representation or design, however made, about the composition, properties or other characteristics of therapeutic goods, but does not include:

- a. an advertisement about the goods
- b. generic information included in an advertisement about therapeutic goods
- c. *bona fide* news.

Generic medicine²

A medicine that, in comparison to a Registered medicine:

- a. has the same quantitative composition of therapeutically active substances, being substances of similar quality to those used in the Registered medicine
- b. has the same pharmaceutical form
- c. is bioequivalent
- d. has the same safety and efficacy properties.

Gene Technology Regulator¹

Has the same meaning as is defined in the *Gene Technology Act 2000*.

Genetically modified (GM) product¹

Has the same meaning as is defined in the *Gene Technology Act 2000*.

Good manufacturing practice (GMP)

The acronym GMP is used internationally to describe a set of principles and procedures which, when followed by manufacturers of therapeutic goods, helps ensure that the products manufactured will have the required quality. A basic tenet of GMP is that quality cannot be tested into a batch of product but must be built into each batch of product during all stages of the manufacturing process.

Good manufacturing practice (GMP) Code

A code of principles and practices to be followed in the manufacture of therapeutic goods to provide assurance of product quality and compliance with product Registration or Listing on the Australian Register of Therapeutic Goods.

Grouped therapeutic goods¹

Therapeutic goods included in:

- a. a gazetted therapeutic goods group; or
- b. a gazetted therapeutic devices group; or
- c. a gazetted kits group.

Grouping

The mechanism whereby goods, which would normally need to be included in the Australian Register of Therapeutic Goods (ARTG) under different ARTG Registration or Listing numbers (because they are 'separate and distinct by virtue of Subsection 16(1) of the *Therapeutic Goods Act 1989* (the Act)), may be included in the ARTG under the one ARTG Registration or Listing number, thereby attracting a single annual charge for the group of goods. Each product (as defined by Subsection 16(1)) is still regarded as a separate ARTG entry and all controls under the Act apply discretely to each separate and distinct product (e.g. application fees, conditions, cancellation).

Health professional³

Includes a person who is a medical practitioner, a dentist or any other kind of healthcare worker Registered under a law of a State or Territory; or a biomedical engineer, chiropractor, optometrist, orthodontist, osteopath, pharmacist, physiotherapist, podiatrist, prosthetist or rehabilitation engineer.

Herbal substance²

All or part of a plant or substance (other than a pure chemical or a substance of bacterial origin):

- a. that is obtained only by drying, crushing, distilling, extracting, expressing, comminuting, mixing with an inert diluent substance or another herbal substance or mixing with water, ethanol, glycerol or aqueous ethanol
- b. that is not subjected to any other treatment or process other than a treatment or process that is necessary for its presentation in a pharmaceutical form.

Homoeopathic preparation²

A preparation:

- a. formulated for use on the principle that it is capable of producing in a healthy person symptoms similar to those which it is administered to alleviate
- b. prepared according to the practices of homoeopathic pharmacy using the methods of
 - i. serial dilution and succussion of a mother tincture in water, ethanol, aqueous ethanol or glycerol **OR**
 - ii. serial trituration in lactose.

Indications¹

The specific therapeutic uses of therapeutic goods.

Individual patient data¹

In relation to therapeutic goods, individual patient data means information, derived from clinical trials, relating to individuals before, during and after the administration of the goods to those individuals, including but not limited to, demographic, biochemical and haematological information. (Section 24)

Informed consent²

In relation to treatment or proposed treatment, means consent freely given by a person on the basis of information concerning the potential risks and benefits of the treatment that was sufficient information to allow the person to make an informed decision whether to consent to the treatment. (Regulation 12A)

Initial decision^{1, 2}

Refers to decisions of the Secretary (or authorised delegate) under various sections of the *Therapeutic Goods Act 1989* and Therapeutic Goods Regulations 1990. (Section 60(1) and Regulation 48)

International instrument¹

A treaty, convention, protocol, agreement or other instrument (or part thereof) that is binding in international law.

Jurisdictional member²

A person on a committee who has been nominated under subsection 52B(3) of the *Therapeutic Goods Act 1989* or a person appointed as a representative under paragraph 42ZCD(4)(c) or (d). (Regulation 42CE)

Kit¹

Section 7B(1) describes a kit for the purposes of the *Therapeutic Goods Act 1989*. Kits are listed as either medicine or device kits.

Label¹

A display of printed information:

- (a) on or attached to the therapeutic goods **OR**
- (b) on or attached to a container or primary pack in which the goods are supplied **OR**
- (c) supplied with such a container or pack.

Licence¹

A licence under Part 3-3 of the *Therapeutic Goods Act 1989*.

Licence number

The number of the licence issued by the TGA to a manufacturer of therapeutic goods for use in humans under Part 4 of the *Therapeutic Goods Act 1989*.

Listable goods¹

Therapeutic Goods that are required, under Schedule 4 of the Therapeutic Goods Regulations 1990 or required by a notice published in the *Gazette* under subsection 17(5), to be included in that part of the Australian Register of Therapeutic Goods relating to Listed goods.

Listed goods¹

Therapeutic goods that are included in the part of the Australian Register of Therapeutic Goods for goods known as Listed goods.

Listing number¹

Any combination of number, symbols and letters assigned to Listed goods under Section 27 of the *Therapeutic Goods Act 1989*. When printed on a label it must be positioned in accordance with the requirements of Regulation 15 of the Therapeutic Goods Regulations 1990 and preceded by "AUST L".

Mainstream media

Any magazine or newspaper for consumers containing a range of news, public interest items, advertorials, advertisements or competitions. (*Section 42B*)

Manufacture^{1*}

The production of medicines or any part of the process of producing medicines or bringing the goods to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for supply of the goods or of any component or ingredient of the goods as part of that process.

Manufacturer

Corporation or person carrying out one or more of the steps specified in the definition of manufacture.

Manufacturing licence

A licence granted under Part 3-3 of the *Therapeutic Goods Act 1989*, or a licence granted under a State or Territory law relating to therapeutic goods, relating to manufacturing therapeutic goods.

Manufacturing premises¹

Premises (including premises that comprise two or more sites):

- a. that are for use in the manufacture of a particular kind of therapeutic goods
- b. at which the same persons have control of the management of the production of the goods and the procedures for quality control.

Manufacturing principles¹

The principles for the time being having effect under Section 36 of the *Therapeutic Goods Act 1989*. This includes codes of Good Manufacturing Practice (GMP).

Medical practitioner^{1,3}

A person who is registered, in a State or Territory, as a medical practitioner.
(Section 19(9) and Section 41HC(7))

Medicine^{1*}

Medicines are:

- a. therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal
- b. any other therapeutic goods declared by the Secretary, for the purposes of the definition of therapeutic device, not to be therapeutic devices.

Previously referred to as drugs.

Medicinal component

The name applied by the Australian Register of Therapeutic Goods to any one item within a composite pack.

Medicinal product

An alternative term to medicine for the finished, packaged goods.

Medicines Regulations

The Therapeutic Goods Regulations 1990.

Member of European Community¹

A country declared by the Minister under Section 3A of the *Therapeutic Goods Act 1989* to be a member of the European Community.

Mother tincture^{2*}

A product of the process of solution, extraction or trituration, from which homoeopathic preparations are made.

Mutual Recognition Convention¹

The convention for the Mutual Recognition of Inspections in respect of the Manufacture of Pharmaceutical Products, which was agreed at Geneva on 8 October 1970.

Name

As used in relation to differentiation between therapeutic goods in Section 16 of the *Therapeutic Goods Act 1989* may include the brand name, a descriptor of the goods or generic name, together with a sponsor's name or logo, or a banner name of a product range, i.e. all elements which, together, serve to make the product recognisable as a particular item of commerce or supply.

Name of the goods

As defined by the Therapeutic Goods Order No. 69 - *General Requirements for Labels for Medicines*, the non-proprietary name, including the name of the dosage form or a synonym for the name of the dosage form, used to describe the goods in a specific standard. Listing and Registration names include the *name of the goods* but may include further information to differentiate between forms of presentation.

National Manager of the Therapeutic Goods Administration¹

The person holding the position of National Manager of the Therapeutic Goods Administration or, if the position of National Manager ceases to exist or ceases to exist by that name, the person holding a position determined in writing by the Secretary.

New information

Information that:

- a. was in existence at the time a decision referred to in subsection (1) was made
- b. was not made available to the Secretary or authorised delegate for the purpose of making the decision
- c. is relevant to that decision

and includes any opinions that are wholly or substantially based on such information (whether or not the opinions were formed before or after the decision was made).

(Section 60A(8))

NFAA²

Nutritional Foods Association of Australia.

Non-proprietary name

The name used to describe the goods (particularly medicines) in a specific standard. It includes the name of the dosage form. If no standard exists, a name may comprise the Australian Approved Name (AAN) of the active ingredient and the name of the dosage form.

Notification

Advice to the Therapeutic Goods Administration in accordance with the requirements of:

- Section 29A (information about Registered goods different from previously given); **OR**
- Section 29B (adverse effects of goods—Registration application withdrawn); **OR**
- Section 9D (variation to goods which may be notified as specified in guidelines); **OR**
- Schedule 5A item 3 (clinical trial); **OR**
- Regulation 13 (change in sponsorship); **OR**
- Regulation 21 (change in QC manager—licensed premises); **OR**
- Regulation 22 (change of licence holder).

Occupier

In relation to premises, includes a person present at the premises who is in apparent control of the premises. (Section 45A)

Official analyst²

A person approved by the Secretary under Regulation 25 of the Therapeutic Goods Regulations 1990.

Official sample

A sample of goods taken under the provisions of Part 5 of the Therapeutic Goods Regulations 1990. A certificate of official analyst is issued.

Open shelf life²

For therapeutic goods, means the time, from when the container holding the goods is opened, after which the goods should not be used.

Oral

Taken through the mouth into the gastrointestinal system.

OTC medicines²

Over-the-counter medicines. Therapeutic goods mentioned in Part 3 of Schedule 10 of the Therapeutic Goods Regulations 1990.

Pack size

The size of the goods in terms of the quantity contained in the container (e.g. volume in a multi-use container) and / or the number of items in the primary / unit pack (e.g. number of tablets in a bottle).

Partially processed goods

Therapeutic goods whose manufacture has not been completed to the stage of final packaging and labelling.

Patient information document

A drug information document as described in Schedule 12 to the Therapeutic Goods Regulations 1990, for supply to patients; must be available for certain drugs as specified in Regulation 9A (see also Consumer Medicine Information).

Person apparently responsible²

In relation to a complaint about an advertisement or generic information, means the person who, based on the complaint and the assessment of the Complaints Resolution Panel (CRP), appears to be responsible for requesting the publication or insertion of the advertisement or generic information in specified media. (*Regulation 42ZCAA*)

Pharmaceutical benefit²

A Commonwealth pharmaceutical benefit under the *National Health Act 1953* or the *Veterans' Entitlements Act 1986*.

Poison¹

An ingredient, compound, material or preparation the use of which may cause death, illness or injury. Includes any ingredient, compound, material or preparation referred to in a schedule to the current Poisons Standard.

Poisons Schedule

A schedule of the *Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)*.

Poisons Standard²

Has the same meaning as **Current Poisons Standard**.

Premises¹

Includes:

- a. a structure, building, aircraft, vehicle or vessel;
- b. a place (whether enclosed or built upon or not); and
- c. a part of a thing referred to in items (a) or (b).

Prescribed quality and safety criteria

Quality and safety requirements referenced in the Therapeutic Goods Regulations 1990 for particular Listable goods or categories of Listable goods. (*Section 26(1)(k)*)

Presentation¹

The way in which the therapeutic goods are presented for supply, and includes matters relating to the name of the goods, the labelling and packaging of the goods, and any advertising or other informational material associated with the goods.

Practice Guidelines²

The Guidelines for Good Clinical Practice, as in force from time to time, published jointly by the International Conference on Harmonisation on Technical Requirements for Registration of Pharmaceuticals for Human Use and the Committee for Medicinal Products. (*Regulation 12AB(2)(a)*).

Primary pack¹

The complete pack in which the goods, or the goods and their container, are to be supplied to consumers.

Principal investigator^{2, 3}

In relation to a clinical trial of therapeutic goods, the person who is in charge of the conduct of the trial.

Principal manufacturer

The manufacturer who manufactures the goods or who performs one or more steps in the manufacture of the goods and also contracts with, or controls the use of other sub-manufacturers for the performance of the remaining steps in manufacture of the goods. (Note: manufacturers listed in the Australian Register of Therapeutic Goods may not always fulfil this definition.)

Principal Regulations³

The Therapeutic Goods Regulations 1990.

Problem report

Report of a suspected deficiency of quality, safety or efficacy in a therapeutic good.

Product

The commercial presentation or marketed entity of therapeutic goods, *excluding pack size*. Where a therapeutic device, it excludes such fine details as size or gauge; and, where a kit / tray or pack containing one or more medicines, it is an individual medicine entity within the kit.

Product information

Information relating to the safe and effective use of the goods, including information regarding the usefulness and limitations of the goods. (*Section 9D(5)*) Also referred to as PI. (Note that PI is used also as an abbreviation for proprietary ingredient.)

Product material

This term is used in Australian Register of Therapeutic Goods (ARTG) application forms and guides when asking for copies of information provided about the goods for medical practitioners and / or patients / users. It includes Consumer Medicine Information (CMI), Product Information (PI) and promotional material. Other information about the product required by ARTG applications includes labels, information shown on packaging, and package inserts. For devices, it may also include operating and service manuals. The ARTG computer system codes the information held in hard copy by Therapeutic Goods Administration.

Product name - medicines

The proprietary name as shown on the label or where there is no proprietary name, the Registration / Listing name.

Product number

Reference number assigned by Australian Register of Therapeutic Goods to each product grouped under one Registration or Listing.

Prohibited representation²

A representation referred to in Subregulation 8(1) of the Therapeutic Goods Regulations 1990.

Proprietary ingredient

Formulated ingredients, usually commercially obtained, for which the formulation may not be available to the sponsor of the final product. Examples are perfumes and flavourings. Some active ingredients may be supplied as proprietary ingredients. Also referred to as PI. (Note that PI is used also as an abbreviation for product information.)

Proprietary name

The Registered trademark of the therapeutic goods or the unique name assigned to the goods by the sponsor and appearing on the label.

Protected information¹

Information is protected if it was given to the Secretary in relation to an application to Register a therapeutic good and it relates to the active component of the therapeutic goods. It applies only to active components which are new (not previously included in the Australian Register of Therapeutic Goods) and if the goods became Registered after the commencement of subsection 25A of the *Therapeutic Goods Act 1989*. Protected information lasts for five years after the Registration of the product unless the person to whom the new goods are Registered provides the Secretary permission in writing for the Secretary to use the information.

Public submission²

A submission under Regulation 42CT by a person who is not a Committee member.

Publisher

A person whose business it is to publish or insert, or to arrange for the publication or insertion of, advertisements in any publication. (*Section 42B*)

Publishing

In relation to an advertisement, includes inserting material within the pages of an item of mainstream media.

Quality¹

Includes the composition, strength, potency, stability, sterility, purity, bioburden, design, construction and performance characteristics of the goods.

Quarter²

A period of three months commencing on 1 January, 1 April, 1 July or 1 October in a year.

Recall

The permanent removal of therapeutic goods from supply or use for reasons relating to deficiencies in the quality, safety or efficacy of the goods.

Recall for product correction

The repair, modification, adjustment or relabelling of therapeutic goods for reasons relating to deficiencies in the quality, safety or efficacy of the goods.

Record of ARTG entry

Refer S32(1) re copy of entry. A print out of the information about a product that has been entered in the Australian Register of Therapeutic Goods database.

Register¹

The Australian Register of Therapeutic Goods (ARTG) maintained under Section 9A of the *Therapeutic Goods Act 1989*.

Registered goods¹

Therapeutic goods included in the part of the Australian Register of Therapeutic Goods for goods known as Registered goods.

Registrable goods

Goods that are required under Part 3 of the *Therapeutic Goods Act 1989* and specified in Schedule 3 of the Therapeutic Goods Regulations 1990 to be included in that part of the Australian Register of Therapeutic Goods for Registered goods.

Registration / Listing name - medicines

The name which will appear on the Certificate of Registration / Listing. The Registration / Listing name is a fully descriptive name which enables clear identification of the goods as they are presented for supply.

Where goods have a name that applies to more than one product, the name must be followed by sufficient details to enable unique identification. That include:

- the proprietary name (if any);
- the non-proprietary name; **or**
- a descriptive name that includes a commercial identifier such as the sponsor's name; and must include the dosage form and, where appropriate, the strength and container type.

Registration number¹

Any combination of numbers, symbols and letters assigned to therapeutic goods under Section 27 of the *Therapeutic Goods Act 1989*. When printed on a label the Registration number must be positioned in accordance with the requirements of Regulation 15 of the Therapeutic Goods Regulations 1990 and preceded by 'AUST R'.

Relevant test²

In relation to the analysis of therapeutic goods (other than medical devices), means a test that, under Subregulation 28(1) of the Therapeutic Goods Regulations 1990, is a relevant test for the purpose of determining whether goods of a class in which the first-mentioned goods are included are goods that conform with a standard applicable to the goods. (*Regulation 23*)

Required representation²

A representation referred to in Subregulation 8(2) of the Therapeutic Goods Regulations 1990.

Responsible analyst²

In relation to the analysis of a sample of therapeutic goods, means an official analyst who is nominated as a responsible analyst for the sample under paragraph 25(3)(c) of the Therapeutic Goods Regulations 1990. *(Regulation 23)*

Restricted goods^{1*}

Medicines (including progesterone antagonists and vaccines against human chorionic gonadotrophin) intended for use in women as abortifacients.

Restricted representation²

A representation referred to in subregulation 7A(1) of the Therapeutic Goods Regulations 1990.

Reviewable decision¹

Refers to decisions of the Minister (or delegate) about reviews of initial decisions. *(Section 60 and Regulation 48)*

Route of administration

Route by which a therapeutic good is applied on or introduced into the body.

Sample²

Includes part of a sample.

Samples officer²

An officer of the Department performing duties under the direction of an official analyst. *(Regulation 23)*

Schedule 10 medicines

A medicinal product of a type described in Schedule 10 of the Therapeutic Goods Regulations 1990 as requiring evaluation by the Office of Medicines Authorisation.

Scheduling¹

In relation to a substance, means determining the schedule or schedules to the current Poisons Standard in which the name or a description of the substance is to be included. *(Section 52A)*

Scheduling meeting²

A meeting of the National Drugs and Poisons Schedule Committee for the scheduling of a substance. *(Regulation 42ZCT)*

Secretary¹

The Secretary of the Department.

Seize¹

Includes secure against interference. *(Section 45A)*

Serious^{2, 3}

In relation to a form of a disease, condition, ailment or defect, means a form of the disease, condition, ailment or defect that is:

- a. generally accepted as not being appropriate to be diagnosed or treated without consulting a suitably qualified healthcare professional; **OR**
- b. generally accepted to be beyond the ability of the average person to evaluate accurately, or treat safely, without regular supervision by a suitably qualified healthcare professional.

Service goods

Therapeutic goods that are required in the public interest but whose supply does not offer financial incentive for the sponsor.

Single step of manufacture

For the purpose of annual licence charge classification only. For example, one of the following: tablet coating; capsule filling from bulk; aerosol filling from bulk; storage other than for sale; packaging including labelling; sterilisation; testing including analysis; releasing for sale (by a person not involved with actually preparing the goods).

Site identification

Identification code assigned by the Office of Manufacturing Quality to a manufacturing site(s) for an enterprise that is involved with the manufacture of therapeutic goods.

Specialist²

Has the same meaning as in the *Health Insurance Act 1973*.

Specified media²

In relation to an advertisement or generic information, means:

- a. mainstream media within the meaning of Section 42B of the Act; **OR**
- b. cinematograph films; **OR**
- c. displays about goods, including posters;
 - i. in shopping malls (except inside an individual shop);
 - ii. in or on public transport; or
 - iii. on billboards.

Sponsor^{1, 3}

A person who exports, imports or manufactures a therapeutic good, or who arranges the exportation, importation or manufacture of the goods for supply. It does not include a person who exports, imports or manufactures the goods or arranges the exportation, importation or manufacture of the goods on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in Australia.

Standard¹

Matters specified in an order determined by the Minister and published in the *Gazette*. Must be specified in a Therapeutic Goods Order or an approved pharmacopoeia (British Pharmacopoeia, European Pharmacopoeia and United States Pharmacopoeia). A general standard applies to all products of a particular dosage form. A specific standard for drugs refers to a particular dosage form of a particular active ingredient(s). (*Section 10*)

Standard AS / NZS²

A joint Australian and New Zealand Standard published by Standards Australia International Limited and the body known as Standards New Zealand.

State

A State of the Commonwealth. The term also covers the Australian Capital Territory and the Northern Territory.

State law¹

A law of a State, of the Australian Capital Territory or of the Northern Territory.

Step in manufacture

Any part of the process of bringing goods to their final state and which may be completed separately from other parts of the process.

Strength

The quantity of an ingredient in a drug or a formulated or medicated device expressed:

- for discrete units, as the nominal weight of the ingredient in the unit
- for other dosage forms, as the nominal weight or volume per unit weight or volume.

Sub-manufacturer

A manufacturer who completes part of the manufacturing process of therapeutic goods on behalf of the principal manufacturer (no longer used in the Australian Register of Therapeutic Goods. Replaced by *manufacturer* with an identified step in manufacture).

Submission

A series of related applications (as defined) made under Section 23 of the *Therapeutic Goods Act 1989* on the same day and under the same covering letter.

Substance

Any medicine or poison. (*Section 52A*)

Supply¹

Includes supply by way of sale, exchange, gift, lease, loan, hire or hire purchase. It also includes whether free of charge or otherwise, samples or advertisements, supply for testing the safety or efficacy, and for treatment of person or animal.

Tamper¹

Therapeutic goods are tampered with if they are interfered with in a way that affects, or could affect, the quality, safety or efficacy of the goods, and the interference has the potential to cause, or is done for the purpose of causing, injury or harm to any person.

TGA Identification Number (TGAIN)

Number assigned by the Trans Tasman and Business Management Group (TTBMG) (formerly the Trans Tasman Group (TTG) and the Business Management Unit (BMU)) to each transaction or event. Proposed to become the core element in TGA tracking systems.

The Act²

The *Therapeutic Goods Act 1989*.

Therapeutic medicine - device combination

A therapeutic good in which the presentation of the medicinal product(s) includes therapeutic device(s). These goods are classified as medicines for Registration / Listing in the Australian Register of Therapeutic Goods (ARTG) but details of both the medicine and device component are required for inclusion in the ARTG.

Therapeutic goods¹

Goods:

- a. that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any reason, likely to be taken to be:
 - i. for therapeutic use; **OR**

- ii. for use as an ingredient or component in the manufacture of therapeutic goods; **OR**
- iii. for use in a container or part of a container for goods of the kind referred to in subparagraph (ii) or (iii); **OR**
- b. that are included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii)
and includes medical devices and goods declared to be therapeutic goods under an order in force under Section 7, but does **not** include:
- c. goods declared not to be therapeutic goods under an order in force under Section 7; **OR**
- d. goods in respect of which such an order is in force, being an order that declares the goods are not therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; **OR**
- e. goods for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined under subsection 3(1) of the *Food Standards Australia New Zealand Act 1991*; **OR**
- f. goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

Therapeutic Goods Advertising Code^{1,2}

The Code known as the Therapeutic Goods Advertising Code notified in the *Gazette* with effect from the date of commencement of Schedule 1 to the *Therapeutic Goods Amendment Act (No 1) 2003* together with any amendments of the Code published by the Minister in the *Gazette* from time to time.

Therapeutic goods information¹

Information in relation to therapeutic goods that came into the possession of the Department in connection with the performance of the Department's functions (including functions relating to the European Community (EC) Mutual Recognition Agreement or the European Free Trade Association (EFTA) Mutual Recognition Agreement). (*Section 61*)

Therapeutic Goods Order (TGO)

A document published in the *Gazette* that specifies a standard for therapeutic goods or a class of therapeutic goods identified in the order. Sponsors should refer to the Publications page on the website for information about current TGOs.

Therapeutic use^{1,2}

Use in or in connection with:

- a. preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; **OR**
- b. influencing, inhibiting or modifying a physiological process in persons or animals; **OR**
- c. testing the susceptibility of persons or animals to a disease or ailment; **OR**
- d. influencing, controlling or preventing conception in persons; **OR**
- e. testing for pregnancy in persons; **OR**
- f. the replacement or modification of parts of the anatomy in persons or animals.

Topical

Applied to a certain area of the skin for a localised effect.

Transdermal

Applied to the skin for a systemic effect by the diffusion or continuous absorption of the active ingredient through the skin.

Trade name²

The commercial name given to goods of that kind by the manufacturer and under which the goods are supplied.

Trading corporation¹

A trading corporation within the meaning of paragraph 51(xx) of the Constitution.

Traditional use

Use of a designated active ingredient that is well-documented, or otherwise established, according to the accumulated experience of many traditional healthcare practitioners over an extended period; and accords with well-established procedures of preparation, application and dosage.

Visual broadcast media

Broadcast media that is intended to be viewed by its audience. (*Section 42B*)

Withdraw²

In relation to an approved advertisement, includes withdrawal by any delegate under subregulation 5Q(2) or (3) of the Therapeutic Goods Regulations 1990, whether or not that delegate gave the approval and, in the case of an approval given by the National Food Authority of Australia (NFAA), includes a withdrawal by the Complementary Healthcare Council of Australia.

22. Abbreviations and acronyms used in the Australian Regulatory Guidelines for Complementary Medicines

AAN	Australian Approved (chemical substance) Name
AAT	Administrative Appeals Tribunal
ABN	Australian (approved) Biological substance Name
ACCM	Advisory Committee on Complementary Medicines
ACNM	Advisory Committee on Non prescription Medicines
ADR	adverse drug reaction
AFN	Australian (approved) Food Name
AGRD	Australian Guidelines for the Registration of Drugs (replaced by ARGCM, ARGOM and / or ARGPM)
AHN	Australian (approved) Herbal Name
AHS	Australian (approved) Herbal Substance
ALT	alanine aminotransferase
AOAC	Association of Official Analytical Chemists (International)
ARGCM	Australian Regulatory Guidelines for Complementary Medicines
ARGOM	Australian Regulatory Guidelines for Over-the-Counter Medicines
ARGPM	Australian Regulatory Guidelines for Prescription Medicines
ARTG	Australian Register of Therapeutic Goods (the Register)
ASMI	The Australian Self-Medication Industry Incorporated
AQIS	Australian Quarantine Inspection Service
AUC	area under the curve
AUST L	Australian Listing Number (for Listed medicines)

AUST R	Australian Registration Number (for Registered medicines)
BP	British Pharmacopoeia
CAS	Chemical Abstracts Service (Registry)
CHC	The Complementary Healthcare Council of Australia
CD	compact disc
CHMP	Committee for Medicinal Products for Human Use (previously CPMP)
CIOMS	Council for International Organizations of Medical Sciences
CIR	Cosmetic Ingredient Review (Group) of the USA
CITES	Convention on International Trade in Endangered Species (of Wild Fauna and Flora)
C_{max}	Maximal blood concentration
CMI	Consumer Medicine Information
C(PI) Regs.	Customs (Prohibited Import) Regulations
CPMP	Committee for Proprietary Medicinal Products (of the EMEA)
CTD	Common Technical Document
CTFA	Cosmetic, Toiletry and Fragrance Association (USA)
CTN	Clinical Trial Notification scheme
CTX	Clinical Trial Exemption scheme
DNA	deoxyribonucleic acid
EC	European Commission
ECD	electrochemical detection
EEC	European Economic Community
EFTA	European Free Trade Area
ELF 3	Electronic Listing Facility – Version 3
EMA	European Medicines Agency (previously European Agency for the Evaluation of Medicinal Products)
EPA	Environmental Protection Agency (of the United States of America)
EP	European Pharmacopoeia (also known as PH. Eur.)
EU	European Union
EudraLex	The Rules Governing Medicinal Products in the European Union
FAO	Food and Agriculture Organization (of the United Nations)

FDA	Food and Drug Administration (of the United States of America)
FEMA	Flavour and Extract Manufacturers Association (of the United States of America)
FOI	Freedom of Information
FSANZ	Food Standards Australia and New Zealand
FSTA	Food Science and Technology Abstracts
GC	gas chromatograph(y)
GCP	good clinical practice
GLP	good laboratory practice
GM	genetically modified
GMO(s)	genetically modified organism(s)
GMP	good manufacturing practice
GRAS	generally regarded as safe
HACCP	Hazard Analysis Critical Control Points
HCN	(Australian approved) Herbal Component Name
HDL	high-density lipoprotein
HDPE	high-density polyethylene
HPLC	high-performance liquid chromatography
HREC	Human Research Ethics Committee
HSDB	Hazardous Substances Databank
IBIDS	International Bibliographic Information on Dietary Supplements
ICH	International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
IV	intravenous
LCS	Listing Compliance Section (of the OCM)
LD₅₀	The dose required that is lethal for 50 per cent of the animal study group
LDL	low-density lipoprotein
LDPE	low-density polyethylene
MRA	Mutual Recognition Agreement
MS	mass spectrometry
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOAEL	no observable adverse effect level

NHMRC	National Health and Medical Research Council
NMT	not more than
OCM	Office of Complementary Medicines
ODBT	Office of Blood, Devices and Tissues
OECD	Organisation for Economic Co-operation and Development (International)
OTC	over-the-counter
PBS	Pharmaceutical Benefits Scheme
PCBs	polychlorinated biphenyls
PDF	portable document format
pH	Negative logarithm of hydrogen-ion concentration
PH Eur	European Pharmacopoeia (also known as EP)
PI	product information
PI	proprietary ingredient
PO	(<i>per os</i>) oral administration
PPM	parts per million
PRCP	People's Republic of China Pharmacopoeia
PREMAS	Pre-Market Assessment Section (of the OCM)
PRV	provisional
PVC	polyvinyl chloride
PVDC	polyvinylidene chloride
QA	quality assurance
qs	(<i>quantum satis</i>) sufficient quantity
RCT	randomised controlled trial
RH	relative humidity
RTECS	Register of Toxic Effects of Chemical Substances
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TEP	tamper-evident packaging
TGA	Therapeutic Goods Administration
TGAC	Therapeutic Goods Advertising Code
TGACC	Therapeutic Goods Advertising Code Council
TGAIN	TGA Identification Number

TGO	Therapeutic Goods Order
TLC	thin-layer chromatography
T_{max}	Time to maximal blood concentration
TSE	transmissible spongiform encephalopathy
URPTG	Uniform Recall Procedure for Therapeutic Goods
USP	United States Pharmacopoeia
USP-NF	United States Pharmacopoeia – The National Formulary
UDS	unscheduled DNA synthesis
US FDA	Food and Drug Administration (of the United States of America)
UV	ultraviolet
VLDL	very low density lipoprotein
WHO	World Health Organization

23. Hyperlink references contained in the Australian Regulatory Guidelines for Complementary Medicines

This section is divided into the following subsections:

- 23.1. [Therapeutic Goods Act 1989](#)
- 23.2. [Therapeutic Goods Regulations 1990](#)
- 23.3. [TGA guidance](#)
- 23.4. [Other guidance](#)
- 23.5. [Forms](#)
- 23.6. [Therapeutic Goods Orders](#)
- 23.7. [Other legislation](#)
- 23.8. [E-mail contacts](#)
- 23.9. [Other regulatory agencies](#)
- 23.10. [Miscellaneous](#)

Links to external documents (hyperlinks) have been electronically inserted into the Australian Regulatory Guidelines for Complementary Medicines (ARGCM) text for the ease of sponsors seeking additional guidance (who read/refer to the ARGCM documents electronically / on-line).

In order to provide the same level of assistance to sponsors referencing the hard (printed) copy of the ARGCM, a list of hyperlinks has been compiled and is included below.

A list of European Union (EU) Guidelines referenced in the ARGCM is included in Section 5 of Part V. Accordingly, EU Guidelines have not been included in the list below.



Note: While every effort will be made to keep this list up-to-date, the OCM cannot ensure the integrity of these hyperlinks (particularly to those on the Attorney-General's Department website, SCALEplus).

23.1. Therapeutic Goods Act 1989

Document Link Name	Internet Address
<i>Therapeutic Goods Act 1989</i>	http://www.comlaw.gov.au/Series/C2004A03952

23.2. Therapeutic Goods Regulations 1990

Document Link Name	Internet Address
<i>Therapeutic Goods Regulations 1990</i>	http://www.comlaw.gov.au/Series/F1996B00406

23.3. TGA guidance

Document Link Name	Internet Address
Access to Unapproved Therapeutic Goods – Clinical Trials in Australia	http://www.tga.gov.au/industry/clinical-trials-guidelines.htm
Advertising Therapeutic Goods – Restricted Representations	http://www.tga.gov.au/industry/advertising-restricted-representations.htm
<i>Regulatory system for Medical devices</i>	http://www.tga.gov.au/industry/devices.htm
Australian Approved Terminology for Medicines	http://www.tga.gov.au/industry/medicines-approved-terminology.htm
Australian Code of Good Manufacturing Practice for Medicinal Products	http://www.tga.gov.au/industry/manuf-medicines-cgmp.htm
Australian Pharmacovigilance Guideline	http://www.tga.gov.au/safety/australian-pharmacovigilance-guideline.htm
Australian Regulatory Guidelines for OTC Medicines (ARGOM)	http://www.tga.gov.au/industry/otc-argom.htm
Australian Regulatory Guidelines for Prescription Medicines (ARGPM)	http://www.tga.gov.au/industry/pm-argpm.htm
<i>Colourings Permitted in Medicines for Oral Use</i>	http://www.tga.gov.au/industry/pm-argpm-guidance-22.htm

Document Link Name	Internet Address
Cosmetic Claims Guidelines – May 1997	http://www.nicnas.gov.au/Current_Issues/Cosmetics.asp
ELF 3 User Guide	http://www.tga.gov.au/about/ebs-elf-userguide.htm
EU Guidelines adopted by the TGA	http://www.tga.gov.au/industry/pm-euguidelines-adopted.htm
<i>Exporting Medicines from Australia – Operational Guidelines</i>	http://www.tga.gov.au/industry/export-medicines-guidelines.htm
Guidance for GMP clearance for Overseas Manufacturers	http://www.tga.gov.au/industry/manuf-overseas-medicines-gmp-clearance.htm
<i>Guidelines for Levels and Kinds of Evidence to Support Indications and Claims</i>	http://www.tga.gov.au/industry/cm-evidence-claims.htm
<i>Literature Based Submissions – Points to Consider</i>	http://www.tga.gov.au/industry/pm-literature-based-submissions.htm
Guidance on Product Changes in ELF 3	http://www.tga.gov.au/about/ebs-elf-product-changes.htm
<i>Questions & Answers for the Identification of Herbal Materials and Extracts</i>	http://www.tga.gov.au/industry/cm-identification-herbal-extracts.htm
<i>Questions & Answers on the Stability Testing of Listed Complementary Medicines</i>	http://www.tga.gov.au/industry/cm-stability-testing-qa.htm
<i>Quantified By Input</i>	http://www.tga.gov.au/archive/cm-qbi.htm
Reporting Problems with Medicines	http://www.tga.gov.au/safety/problem.htm
Substances that may be used as active ingredients in 'Listed' medicines in Australia	http://www.tga.gov.au/industry/cm-listed-substances.htm
<i>Summary Classification of Medicines</i>	http://www.tga.gov.au/industry/basics-medicines-classification.htm
<i>Supplementary Requirements for Therapeutic Goods for Minimising the Risk of TSEs</i>	http://www.tga.gov.au/industry/tse-supplementary-requirements.htm

Document Link Name	Internet Address
Tamper-Evident Packaging Guideline	http://www.tga.gov.au/industry/packaging-tamper-evident-guideline.htm
TGA Guidelines for Sterility Testing of Therapeutic Goods	http://www.tga.gov.au/industry/manuf-sterility-testing-guidelines.htm
<i>Therapeutic Goods Order 77 – Microbiological standards for medicines</i> (TGO 77)	http://www.comlaw.gov.au/Details/F2008L03574
<i>Therapeutic Goods Administration (TGA) Policy for the Export of Medicines from Australia</i>	http://www.tga.gov.au/industry/export-medicines-policy.htm
Uniform Recall Procedure for Therapeutic Goods	http://www.tga.gov.au/safety/recalls-urptg.htm

23.4. Other guidance

Document Link Name	Internet Address
Chemical Abstracts Service (CAS) Registry	http://www.cas.org/
Guidance for Industry – Bioavailability and Bioequivalence Studies for Orally Administered Drug Products – General Considerations FDA (Revision 1 – March 2003)	http://www.fda.gov/cder/guidance/5356fnl.pdf
<i>National Statement on Ethical Conduct in Research Involving Humans</i> , NHMRC, 1999	http://www.nhmrc.gov.au/publications/synopses/e35syn.htm
Standard for the Uniform Scheduling of Drugs and Poisons (SUSMP)	http://www.tga.gov.au/industry/scheduling-poisons-standard.htm
Therapeutic Goods Advertising Code (TGAC)	http://www.tgacc.com.au/codeList.cfm
Appendix 6 of the TGAC	http://www.tgacc.com.au/code.cfm?sectionheading=APPENDIX%206

23.5.Forms

Document Link Name	Internet Address
<i>Application form for proposing a chemical name (AAN or ADN and chemical PRV)</i>	http://www.tga.gov.au/industry/medicines-approved-terminology.htm#forms
<i>Application form for proposing a biological name (ABN and biological PRV) or term</i>	http://www.tga.gov.au/industry/medicines-approved-terminology.htm#forms
<i>Application form for proposing a botanical name for a herb (AHN and herbal PRV)</i>	http://www.tga.gov.au/industry/medicines-approved-terminology.htm#forms
<i>Application form for proposing a herbal substance name (AHS and herbal substance PRV)</i>	http://www.tga.gov.au/industry/medicines-approved-terminology.htm#forms
<i>Application form for proposing a herbal component name (HCN)</i>	http://www.tga.gov.au/industry/medicines-approved-terminology.htm#forms
<i>Application form for proposing a Label-AAN (for all name types)</i>	http://www.tga.gov.au/industry/medicines-approved-terminology.htm#forms
<i>Application form for proposing approved name(s) be added to a Label-AAN group (all name types)</i>	http://www.tga.gov.au/industry/medicines-approved-terminology.htm#forms
Registered (Complementary) Medicine Variation Form	http://www.tga.gov.au/industry/cm-forms-registered-variation.htm
eBS Client Details Form	https://www.ebs.tga.gov.au/
eBS e-business Document	https://www.ebs.tga.gov.au/

23.6. Therapeutic Goods Orders

Document Link Name	Internet Address
Current TGOs	http://www.tga.gov.au/industry/legislation-tgo.htm
TGO 78 – <i>Standard for tablets, and capsules</i>	http://www.comlaw.gov.au/Details/F2008L04287
TGO 80 – <i>Child-Resistant Packaging for Therapeutic Goods</i>	http://www.comlaw.gov.au/Details/F2008L03428
TGO 69 – <i>General requirements for labels for medicines</i> incl. TGO 69A, B, C – Amendments to TGO 69	http://www.comlaw.gov.au/Details/F2009C00264
Code of Practice for <i>Tamper-Evident Packaging (TEP) of Therapeutic Goods</i>	http://www.tga.gov.au/industry/packaging-tamper-evident-guideline.htm
TGO 77 – Microbiological standards for medicines	http://www.comlaw.gov.au/Details/F2008L03574
TGO 70B – Standards for export only medicine	http://www.comlaw.gov.au/Details/F2007L00555

23.7. Other legislation

Document Link Name	Internet Address
<i>Customs Act 1901</i>	http://www.comlaw.gov.au/Series/C2004A07371
<i>Environment Protection and Biodiversity Conservation Act 1999</i>	http://www.comlaw.gov.au/Series/C2004A00485
<i>Freedom of Information Act 1982</i>	http://www.comlaw.gov.au/Details/C2011C00052
<i>Gene Technology Act 2000</i>	http://www.comlaw.gov.au/Series/C2004A00762
<i>Therapeutic Goods (Medical Devices) Regulations 2002</i>	http://www.comlaw.gov.au/Series/F2002B00237

23.8.E-mail contacts

Document Link Name	Internet Address
TGA Office of Medicines Safety Monitoring Report an event (electronically)	adr.reports@tga.gov.au https://www.ebs.tga.gov.au/ebs/ADRS/ADRSRepo.nsf?OpenDatabase
eBS Help Desk	eBs@tga.gov.au
TGA Information Officer (e-mail)	info@tga.gov.au
Office of Complementary Medicines	ocm@tga.gov.au
TGA Office of Medicines Safety Monitoring Report an event (electronically)	adr.reports@tga.gov.au https://www.ebs.tga.gov.au/ebs/ADRS/ADRSRepo.nsf?OpenDatabase

23.9 Other regulatory agencies

Document Link Name	Internet Address
European Medicines Agency (EMA)	http://www.emea.europa.eu/
US Food and Drug Administration (US FDA)	http://www.fda.gov

23.10. Miscellaneous

Document Link Name	Internet Address
<i>Code of Practice for Ensuring Raw Material Quality & Safety</i> (Complementary Healthcare Council of Australia)	http://www.chc.org.au/AboutUs/CodeofPractice/
National Industrial Chemicals Notification and Assessment Scheme (NICNAS)	http://www.nicnas.gov.au/

Document Link Name	Internet Address
Oxford Centre for Evidence-Based Medicine (CEMB)-	http://www.cebm.net/cebm.net/
TGA eBusiness Services home page	https://www.ebs.tga.gov.au/
Summary of TGA Fees and Charges	http://www.tga.gov.au/about/fees.htm

Historical document

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