Australian Government
Department of Health
Therapeutic Goods Administration

Overview of the regulation of listed medicines and registered complementary medicines

Overview of the regulation of listed medicines and registered complementary medicines

Version 1.1, July 2021

TGA Health Safety Regulation

Contents

Overview of the regulation of listed medicines and registered complementary medicines

Information: This guidance replaces archived ARGCM V8.0 Part A: General guidance on the regulation of listed medicines and registered complementary medicines in Australia.

Refer to Standards, guidelines & publications for a list of all guidance relevant to listed medicines and registered complementary medicines.

Overview of the regulation of medicines in Australia

The regulatory framework for therapeutic goods regulates products according to risk. Our scientific assessments and decision-making are intended to ensure that the benefits of a medicine outweigh any risks associated with its use.

In order for the TGA to maintain public confidence in the safety, benefits and risks associated with the use of medicines on the Australian market, the TGA regulates medicines:

- before a medicine is able to be supplied to the market in Australia (pre-market) - for more information see Supplying medicines in Australia
- while a medicine is available on the market (post-market) For more information see Post-market monitoring of medicines in Australia

Australian Register of Therapeutic Goods (ARTG)

Unless exempt (refer to Medicines exempt from certain TGA regulation) medicines must be entered in the Australian Register of Therapeutic Goods (ARTG) before they can be legally imported, exported, manufactured or supplied for use in Australia. Each medicine included in the ARTG has a unique ARTG identification which starts with 'AUST', is followed by 'R', 'L' or L(A) (see Classification of medicines as registered or listed) and numbers.

The regulatory requirements, levels of assessment, timeframes and fees to enter a product in the ARTG increase with an increasing degree of risk. For more information see Entering medicines in the ARTG.

Classification of medicines as registered or listed

Australia has a two-tiered system for the regulation of medicines. Within the regulatory framework, medicines are classified as either:

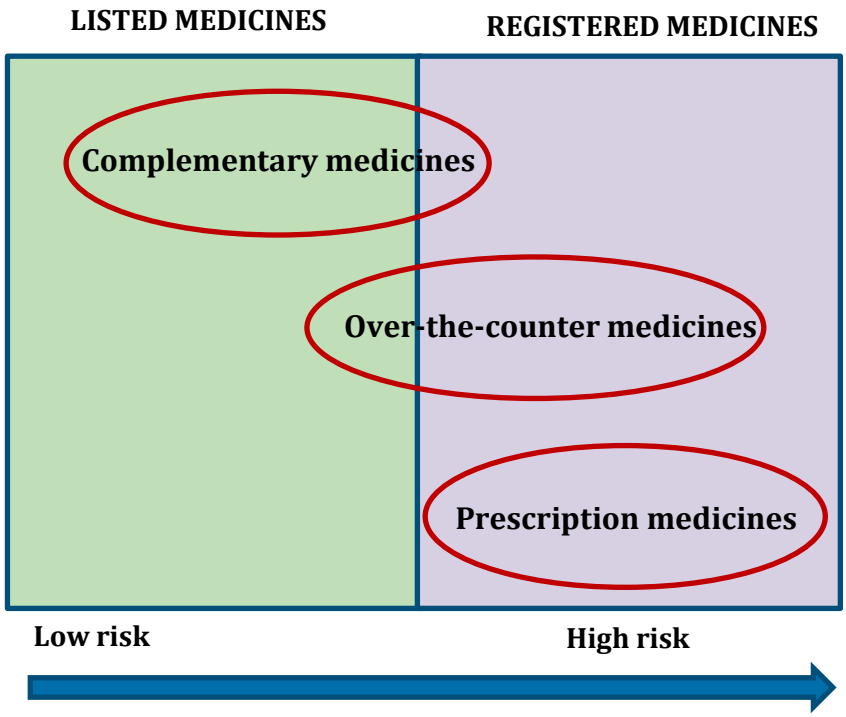
- lower risk medicines that are **listed** in the ARTG (either **AUST L** listed medicines or **AUST L(A)** assessed listed medicines)
- higher risk medicines that are **registered** in the ARTG (**AUST R** registered medicines)

The majority of listed medicines in the ARTG are complementary medicines - see What are complementary medicines? However, complementary medicines **are just a subset of listed medicines**, with some Over the Counter (OTC) products such as sunscreens and dental products also being listed in the ARTG.

Likewise, while most complementary medicines are listed in the ARTG, some complementary medicines are registered. See Diagram 1 for different medicine types that are regulated as listed

or registered medicines. More information on the classification of medicines is provided at Entering medicines in the ARTG.

Diagram 1: Different medicine types regulated as listed or registered medicines



Legislation and guidance

All products within the scope of the framework need to comply with the requirements set out in the relevant legislation administered by the TGA.

Important: Legislation is amended from time to time. It is important that sponsors know the current regulatory requirements. Copies of the legislation can be obtained from the Federal Register of Legislation.

The legislative basis for a uniform national framework of controls for the import, export, manufacture and supply of complementary medicines are:

- the *Therapeutic Goods Act 1989* (the Act)
- the *Therapeutic Goods Regulations 1990* (the Regulations)

There are also various legislative instruments, standards and Orders, which provide further details about the matters covered by the Act.

Legislative instruments

- Therapeutic Goods (Medicines Advisory Statements) Specification
- Therapeutic Goods (Permissible Ingredients) Determination
- Therapeutic Goods (Permissible Indications) Determination
- The Poisons Standard (the SUSMP)

- Therapeutic Goods Advertising Code
- Therapeutic Goods (Complementary Medicines - Information that Must Accompany Application for Registration) Determination 2018
- Therapeutic Goods (Complementary Medicines - Information that Must Accompany Application for Section 26AE Listing) Determination 2018

Refer to Legislation & legislative instruments for a full list of relevant therapeutic goods legislation that sponsors of medicines are required to comply with.

Standards

All therapeutic goods must comply with applicable standards, which determine the consistency of product quality, before they can be entered in the ARTG. The standards recognised under the Act are:

- the default standards, which are publicly available authoritative standards provided by the *British Pharmacopoeia*, *European Pharmacopoeia*, and *United States Pharmacopeia – National Formulary.*
- Therapeutic goods orders (TGOs) made by the Minister under section 10 of the Act (TGOs)

Important: Note that any matter specified in an order under section 10 of the Act has precedence over requirements of the default standards.

For information: Consent to supply goods not compliant with prescribed standards

A sponsor can apply under sections 14 and 14A of the Act, to request consent to supply goods that do not comply with a prescribed standard or aspects of a prescribed standard. Please refer to:

- Consent to import, supply or export therapeutic goods that do not comply with standards - information for industry on the TGA website.
- Application for consent to import, supply or export goods that do not comply with standards - section 14/14A available on the TGA website. Such requests incur an application fee.

Guidance applicable to all listed medicines and registered complementary medicines

Refer to Standards, guidelines & publications for a list of guidance applicable to listed medicines and registered complementary medicines.

Other legislation and requirements

Sponsors should be aware of other applicable Australian legislation and requirements, such as:

- *Environment Protection and Biodiversity Conservation Act 1999*
- *Food Standards Australia New Zealand Act 1991*
- *Customs Act 1901* and the *Customs (Prohibited imports) regulations 1956*
- and the *Industrial Chemicals (Notification and Assessment) Act 1989* and the National Industrial Chemicals Notification and Assessment Scheme
- *Gene Technology Act 2000* and the *Gene Technology Regulations 2001*
- *Competition and Consumer Act 2010* and the Australian Consumer Law
- *National Measurement Act 1960*
- Australian Dangerous Goods Code
- *Agricultural and Veterinary Chemicals Code Act 1994*

In addition, sponsors should also be aware of the requirements applicable under other Australian State and Territory legislation.

What are complementary medicines?

Part 1(2) of the Regulations provides the following definitions:

> **Complementary medicine** means a therapeutic good consisting wholly or principally of 1 or more designated active ingredients, each of which has a clearly established identity and a traditional use.
>
> **Designated active ingredients**, for a complementary medicine, means an active ingredient, or a kind of active ingredient, mentioned in Schedule 14 (to the Regulations).

Schedule 14 to the Regulations provides a list of designated active ingredients for complementary medicines:

Designated active ingredients

1. an amino acid
2. charcoal
3. a choline salt
4. an essential oil
5. plant or herbal material (or a synthetically produced substitute for material of that kind), including plant fibres, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll
6. a homoeopathic preparation
7. a microorganism, whole or extracted, except a vaccine
8. a mineral including a mineral salt and a naturally occurring mineral
9. a mucopolysaccharide
10. non-human animal material (or a synthetically produced substitute for material of that kind) including dried material, bone and cartilage, fats and oils and other extracts or concentrates
11. a lipid, including an essential fatty acid or phospholipid
12. a substance produced by or obtained from bees, including royal jelly, bee pollen and propolis
13. a sugar, polysaccharide or carbohydrate
14. a vitamin or provitamin

Table 1 provides some examples of products that are regulated as complementary medicines.

Table 1: Types of complementary medicines

Medicine type	Description
Traditional medicines	Traditional medicines include a diverse range of health practices, approaches, knowledge and beliefs incorporating medicines of plant, animal and/or mineral origin. Examples of traditional paradigms include: Traditional Chinese medicine; Ayurvedic medicine; Australian indigenous medicine; and Western herbal medicine. 'Traditional use' is defined in Part 1(2) of the Regulations. An established tradition of use is considered to be three generations of human use, equating to approximately 75 years.
Herbal medicines	Herbal medicines are therapeutic goods that are or contain herbal substances as the major active ingredient(s). Herbal substances are preparations of plants, and other organisms that are treated as plants in the International Code of Botanical Nomenclature, such as fungi, algae and yeast. The current regulatory system provides for listed medicines to contain a wide range of herbal substances provided that it can be adequately demonstrated that the herbal substance is safe.
Homoeopathic medicines	A 'homoeopathic preparation' is a medicine based upon the central tenet of homoeopathy 'let like cure like' and the principles of homoeopathic pharmacy - 'potentisation', being the serial dilution and succussion of a mother tincture. The term 'mother tincture' means a preparation prepared by the process of solution, extraction or trituration. Homoeopathic medicines are manufactured to different medicinal strengths or 'potencies' according to manufacturing standards described in homoeopathic pharmacopoeias. Homoeopathic medicines are derived from a wide variety of natural source materials, mostly plants and minerals. Some of these source materials are poisonous, for example: *Atropa belladonna*. The highly diluted nature of homoeopathic preparations is considered to render starting materials non-toxic and therefore safe for therapeutic use. For more information on the regulation of homoeopathic medicines refer to Homoeopathic preparations included/exempt from inclusion in the ARTG.
Anthroposophic medicines	Anthroposophic practitioners use a range of interventions including conventional therapies, remedies based upon homoeopathic principles, herbal medicine and external therapies.
Essential oils	Essential oils are highly concentrated oils obtained from natural raw materials either by distillation with water or steam or from the epicarp of citrus fruits by a mechanical process, or by dry distillation. It also means: (a) oils of equivalent composition derived through synthetic means; or (b) compounded oils of equivalent composition comprising a mixture of synthetic and natural components

Medicine type	Description
	The purpose of a product containing an essential oil determines which agency regulates it. That is, if the product makes only cosmetic claims it is considered a cosmetic and regulated by National Industrial Chemicals Notification and Assessment Scheme (NICNAS)[1], but if the product makes a therapeutic claim it would be considered a therapeutic good and regulated by the TGA.
Nutritional supplements	Nutritional supplements are substances such as vitamins, minerals, fatty acids, amino acids used to supplement the diet. Nutritional supplements may be regulated as foods or as therapeutic goods - refer to Medicine interface issues. Examples of nutritional substances (if presented as therapeutic goods) that are considered to be complementary medicines include fish oils, shark cartilage and krill oil. Many vitamins and minerals are scheduled in the Poisons Standard and in accordance with this scheduling, such things as pack size and container dimensions may be limited.

Other types of complementary medicines such as flower, shell and gem essences (which are highly diluted extracts of substances) are generally not regulated as medicines in Australia, unless they have therapeutic indications.

Medicine interface issues

There can be a regulatory 'interface', or potential overlap, between certain foods, medicines, devices and cosmetics. For example, even though a product may meet the definition of a complementary medicine, it may:

- be regulated as a different therapeutic good, for example: a medical device
- not be regulated as a therapeutic good, for example it may be a food or a cosmetic or be excluded from TGA regulation

The online guidance tool: Is my product a therapeutic good? will help you identify whether your product is a therapeutic good, and if so, the type of therapeutic good that it is likely to be. Some examples of goods at the medicine interface are provided in Table A2.

Important: It is the sponsor's responsibility to ensure their medicine is correctly included in the ARTG. If you believe your product is incorrectly included, you should request cancellation of the ARTG entry.

The Secretary of the Australian Government Department of Health (through the TGA) can, under section 9F of the Act, remove a product from the ARTG if satisfied that the goods are not 'therapeutic goods' as defined in the Act.

[1] The Australian Industrial Chemicals Introduction Scheme (AICIS) will replace NICNAS on 1 July 2020

Table 2: Medicine interface

Medicine interface- types of goods		
Goods regulated as therapeutic goods		
Complementary medicines	Products that meet the definition of a complementary medicine as per Part 1(2) of the Regulations.	E.g. vitamins and minerals supplements
Medical devices	Certain goods are considered to be medical devices. Refer to the Device-medicine boundary products.	E.g. a medicine impregnated dressing, barrier protectants
Goods declared to be therapeutic goods	The Secretary has declared that particular goods or classes of goods **are** therapeutic goods– refer to Orders that Goods are Therapeutic Goods.	E.g. products containing fibre in capsule, tablet or pill form
Goods not regulated as a therapeutic good		
Foods	Refer to Food and medicine regulation and Food-Medicine Interface Guidance Tool for information to help determine if a good is a food.	Energy drinks
Cosmetics	Refer to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)[2] website: Cosmetics and therapeutic goods to help determine if a good is a cosmetic.	Hair dye
Excluded goods	The Secretary has declared that particular goods or classes of goods **are not** therapeutic goods. For the list of excluded goods, refer to: Excluded goods orders.	Tinted bases

[2] The Australian Industrial Chemicals Introduction Scheme (AICIS) will replace NICNAS on 1 July 2020

Types of ingredients in listed medicines and registered complementary medicines

Table 3 lists the different ingredient types/roles for ingredients included in listed and registered medicines. Table 4 provides information on specific types of substances/ingredients in listed medicines and registered complementary medicines.

Table 3 Types of ingredients in listed medicines and registered complementary medicines

Ingredient type	Explanation
Active ingredients	Regulation 2 of the Regulations states that an active ingredient for a medicine, means a therapeutically active component in the medicine's final formulation that is responsible for its physiological or pharmacological action.
Excipient ingredients	An excipient ingredient is not therapeutically active and does not contribute to the physiological or pharmacological action within the medicine's final formulation. Types of excipient ingredients include: a fragrance, flavour, preservative, printing ink, antioxidant (protecting the formulation from oxidation), coating, binding agent, filler or an anticaking agent. Sponsors should ensure that the role of an excipient ingredient is appropriate and in an appropriate quantity for this purpose within the product formulation. Indications cannot be made for excipient ingredients.
Active Herbal Extracts	An 'Active Herbal Extract' (AHE) is a herbal extract or concentrate for which a supplier intends specific information on the extraction method, steps and/or solvent details, to remain confidential from sponsors who include the extract as an active ingredient in a medicine. To be a permitted ingredient in listed medicines, the active ingredient must comply with the definition of a herbal substance (as defined in Regulation 2 of the Regulations). In the past, suppliers notified the TGA of details of AHEs and these were entered in the TGA Proprietary Ingredient Table. The TGA no longer issues proprietary ingredient numbers for AHEs. Ingredient suppliers can still sell herbal extracts to sponsors for inclusion as ingredients in medicines, but rather than selecting the AHE ingredient from the Proprietary Ingredient Table, sponsors will need to select the individual ingredients in their application at the same time as they enter the rest of their medicines' formulation details. Note that some existing AHEs (that were included in existing medicines)still remain visible in the Proprietary Ingredient Table and are able to be selected in applications for listed medicines. Sponsors with existing AHEs in their medicines' formulation can choose to voluntarily update their ARTG entry to specify the constituent ingredients in the formulation (instead of the AHE name and identification number) by making a correction to their ARTG entry. Standard fees and processes apply. For more information see Streamlining proprietary ingredient categories.

Ingredient type	Explanation
Proprietary ingredients	Proprietary ingredients consisting of **excipient** formulations include fragrances, flavours, colouring ingredients, trans-dermal patch adhesives and printing inks. Proprietary ingredients are entered in to the TGA Business System by the TGA following submission of a Notification of a new proprietary ingredient form by the ingredient supplier. This allows for the capture of complex formulation details and other relevant information, and the provision of a unique name and number. Sponsors may select proprietary ingredients using the assigned ingredient ID number for use in their application for a listed or registered medicine. If a proprietary ingredient is to be used in a listed medicine, all ingredients within the formulation must be included in the Therapeutic Goods (Permissible Ingredients) Determination and meet the requirements of that Determination. For further information on proprietary ingredients refer to: • Products exempt from certain manufacturing requirements • 'Limits on proprietary ingredients' in Quality for listed medicines • Supplier assessment, approval and qualification for listed and complementary medicines.

Table 4 Information on specific types of substances/ingredients in listed medicines and registered complementary medicines

Ingredient type	Explanation
Australian native and endangered species in complementary medicines	For queries regarding the importation of restricted/endangered species and the general importation of plant material, please refer to the following authorities: • Department of Agriculture, Water and the Environment • Department of Home Affairs
Genetically modified substances	It is the responsibility of sponsors including genetically modified substances in their complementary medicine to ensure they comply with the provisions of all relevant legislation -refer to the Office of the Gene Technology Regulator.
Ingredients of animal origin	Ingredients derived from animal materials may present a safety risk to consumers, as they may contain certain viruses and/or agents capable of carrying Transmissible Spongiform Encephalopathies (TSEs). Information on the TGA's approach to minimising the risks associated with ingredients of human or animal origin is available in Guidance 10: Adventitious agent safety of medicines. There are some low risk materials that are eligible for self-assessment. The criteria for self-assessment are outlined in Transmissible Spongiform Encephalopathies (TSE): TGA approach to minimising the risk of exposure. If the ingredient is not eligible for self-assessment, pre-clearance of animal derived ingredients should be sought from TGA before making a medicine

Ingredient type	Explanation
	application—refer to Pre-clearance application for animal-derived ingredients.
Amino acid chelates	The TGA defines a metal amino acid chelate as a complex consisting of a metal ion with one or more proteinogenic amino acid ligands bound to it in such a way that the metal ion is part of a ring within the molecule. Currently a number of metal amino acid chelates are included in the Permissible Ingredients Determination and are therefore eligible for inclusion in medicines listed on the ARTG

Approved terminology for listed medicines and registered complementary medicines

The TGA develops and maintains approved terminology to ensure accuracy and consistency of the information about medicines on the Australian Register of Therapeutic Goods (ARTG). These approved terms are to be used in:

- applications to register or list a medicine on the ARTG
- labels and packaging for medicines
- product information documents provided with medicines
- consumer medicine information documents provided with medicines

Approved terminology for product characteristics

Australian approved terms have been created to describe the way a medicine is presented to ensure consistency in product applications and on medicine labels, for example routes of administration, dosage forms. For more information see Other terminology to describe medicines. These terms are located in the Code Tables on the TBS website.

Approved terminology for medicine ingredients

Ingredients are divided into three main categories:

- Chemical (including antibiotics)
- Biological (other than antibiotics) that are not derived from plants, algae, yeast or fungi
- Herbal, including herbal components of plant, algal, yeast or fungal origin

Guidance on Australian approved terminology is provided in the publication TGA approved terminology for medicines. Ingredient names included in the Permissible Ingredients Determination are consistent with TGA approved terminology for medicines.

Applying for new Australian approved name

When submitting an application for evaluation of a new medicine substance (including a new substance in a proposed registered complementary medicine) that does not have an approved name, the applicant should submit a proposal for a new name with that application using the appropriate form—see Application forms for proposing names.

Important: Note that assignment of a name does not imply any recommendation for the use of the substance or that the ingredient is approved for use in therapeutic goods.

TGA Business Services Ingredients Table

The Ingredients Table located on the TGA Business Services website is a searchable database of approved terminology for chemical, biological and herbal ingredients, including:

- active ingredients
- excipients
- components and equivalents of ingredients

This table will only provide the approved name or synonym for the ingredient. Instructions on searching this table are provided below.

Searching for ingredients via the TGA Business Services website

- Select 'Public TGA Information' from the left-hand menu.
- From the dropdown menu select 'Ingredients'.
- Enter the ingredient name or synonym you are looking for in the 'search field' and ensure that in 'all fields' is selected. Click 'Go'.
- When looking at the search results, the right-hand column will indicate if the ingredient is 'listable' (that is, if the ingredient is able to be included in listed medicines). The ingredient summary must be checked to determine in what context the ingredient is listable (Step 5).
- To the left of each ingredient is a down arrow icon. Click on this icon to reveal the 'Ingredient summary'. The 'Ingredient summary' provides the approved role of the ingredient (active or excipient).

Information on 'Product warnings', amongst other things, can be accessed via 'Code tables' under 'Public TGA Information' on the left-hand menu.

Supplying medicines in Australia

The pathway for supply of medicines in Australia varies depending on whether your product:

- is exempt from certain TGA regulation
- requires entry in the ARTG

Medicines exempt from certain TGA regulation

Some medicines do not need to be entered in the ARTG or may be exempt from some regulatory requirements as a result of a specific exemption or determination under the Act (refer to section 18 of the Act and Schedules 5 and 5A of the Regulations), but they may be subject to:

- specific eligibility criteria (Refer to Schedule 5 of the Regulations)
- some regulatory obligations (refer to Schedule 5A of the Regulations)

These include, for example:

- Medicines (other than those used for gene therapy) that are dispensed or extemporaneously compounded by a practitioner for use by a particular person - refer to Exemptions from inclusion in the ARTG for extemporaneously compounded medicines and dispensed complementary medicines.
- Certain homoeopathic preparations—refer to Homoeopathic preparations exempt/required to be included in the ARTG.
- Certain shampoos for the treatment/prevention of dandruff.
- Starting materials used in the manufacture of therapeutic goods, except when pre-packaged for supply for other therapeutic purposes or formulated as a dosage form.

These goods are exempt from Part 3-2 of the Act, relating to inclusion in the ARTG, however it is important to note that all other applicable requirements under the Act and the Regulations must be complied with, including:

- all relevant standards
- all advertising requirements

Exemptions from inclusion in the ARTG for extemporaneously compounded medicines and medicines dispensed by practitioners

For information: The TGA does not regulate health practitioners, we regulate therapeutic goods. The Australian Health Practitioner Regulation Agency (AHPRA) is responsible for the registration of practitioners in Australia.

The exemptions for extemporaneously prepared medicines from Parts 3-2 and 3-2A of the Act (inclusion in the ARTG) are included in Schedule 5 (item 6) of the Regulations.

The exemptions for starting materials from Parts 3-2 and 3-2A of the Act (inclusion in the ARTG) are specified in Schedule 5 (item 9) to the Regulations.

The exemptions relating to extemporaneous compounding and dispensing apply where:

- a health practitioner prepares a medicine for an individual patient either following consultation with that particular patient: or

- to fill a prescription for that particular patient.

This allows health practitioners such as pharmacists, herbalists, naturopaths, nutritionists and homoeopaths, to prepare medicines for individual patients that do not need to be assessed or evaluated by the TGA for quality, safety or efficacy. The exemption recognises the one-off nature of such medicines and the professional training of the health practitioner to prepare a medicine for the specific needs of an individual patient.

Most herbal ingredients may be used for preparing medicines that are dispensed or extemporaneously compounded. However, access to some medicinal ingredients is restricted by State and Territory drug and poisons legislation. Depending on the level of access control, some ingredients are not available for dispensing or extemporaneous compounding by health practitioners, such as: ingredients included in Schedule 4 of the Poisons Standard which are available only on prescription from an authorised prescriber registered under a law of a State or Territory.

Important: Pre-packaged (manufactured) medicines made by practitioners

The exemption from inclusion in the ARTG for extemporaneously compounded medicines does not cover situations where a health practitioner makes up medicines in advance, in anticipation of patients who may come onto the premises and ask for that medicine.

Ingredients that are either pre-packaged for other therapeutic purposes or formulated as a dosage form are subject to assessment for quality, safety and efficacy as appropriate, and are to be included in the ARTG. Unless exempt, medicines included in the ARTG need to be prepared by a person in accordance with Good Manufacturing Practice.

For information: 'For practitioner dispensing only' products

Sponsors may choose to supply their products in a dispensing pack solely to healthcare practitioners with the words 'for practitioner dispensing only', or words to that effect, included on the label. These medicines must meet the same statutory requirements relating to entry in the ARTG. This includes that labelling (apart from indications) must meet the requirements of the Therapeutic Goods labelling Order and the Therapeutic Goods Advertising Code (unless the appropriate exemption or approval to do otherwise has been granted). The only 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/therapeutic indication on the label. These medicines should only be supplied to an individual after consultation with a healthcare practitioner, at which time, the healthcare practitioner attaches a label to the medicine providing instructions for use for that individual.

There are also practitioner exemptions from manufacturing requirements – refer to Products exempt from certain manufacturing requirements.

Products exempt from certain manufacturing requirements.

Some medicines or persons are exempt from the manufacturing requirements set out in Part 3-3 of the Act. The criteria for manufacturing exemptions are provided in Section 34 of the Act, together with Schedule 7 (exempt medicines) and Schedule 8 (exempt persons) of the

Regulations. Table 5 lists different products exempt from certain manufacturing requirements. For more information on GMP requirements refer to Supplier assessment, approval and qualification for listed and complementary medicines.

Table 5: Products exempt from certain manufacturing requirements

Exemption type	Description
Manufacturing exemptions for starting materials	Schedule 7 of the Regulations provides for certain ingredients used in the manufacture of therapeutic goods to be exempt from the operation of Parts 3-3 of the Act. For example: the Australian manufacturer of a 'bulk' essential oil (the farmer extracting oil from lavender plants) does not need to be licensed for Good Manufacturing Practice (GMP). However, the Australian manufacturers who undertake steps in the manufacturing of the finished dosage form (such as filling, blending, testing, labelling and release for supply) are required to hold the appropriate GMP licence. Note that ingredients that are either pre-packaged for other therapeutic purposes or formulated as a dosage form are subject to the therapeutic goods legislation and are required to be compliant with GMP.
Manufacturing exemptions for practitioners	Schedule 8(4) of the Regulations provides an exemption for specified practitioners from the operation of Part 3-3 of the Act (Manufacturing of therapeutic goods) and therefore the requirement to manufacture certain medicines under GMP: where the preparation is for use in the course of his or her business and: a) the preparations are manufactured on premises that the person carrying on the business occupies and that he or she is able to close so as to exclude the public; and b)the person carrying on the business: i) supplies the preparation for administration to a particular person after consulting with that person; and ii) uses his or her judgement as to the treatment required
Manufacturing exemptions for homoeopathic preparations	In Australia, homoeopathic medicines that: • are not required to be sterile • only contain homoeopathic preparations that are more dilute than a 1,000 fold dilution of the mother tincture (4X or above) are exempt from the Australian requirement that the manufacturer must hold a GMP license - refer to Item 7 of Schedule 7 to the Regulations.

Exemption type	Description
Manufacturing requirements/exemptions for proprietary ingredients	Australian manufacturers who are involved in the manufacture of active ingredients, mixtures containing active ingredients and any other step taken to bring therapeutic goods to their final state (for example: intermediate manufacturing steps, testing, packaging/labelling and release for supply) are required to have a licence (TGA GMP licence) under Part 3-3 of the Act, unless specifically exempted. Where a proprietary ingredient formulation is intended to have an active role in the product formulation (e.g. a proprietary ingredient with an active and excipient ingredient/s), the manufacture of the proprietary ingredient formulation may be considered a step in the manufacture of the finished product and a TGA GMP licence or approval of the manufacturer may be required.[3] However, a proprietary ingredient formulation that has an excipient formulation with an excipient role in the medicine (for example: colours, printing inks, flavours, fragrances, and preservatives) does not require a TGA GMP licence to be manufactured. For more information on GMP requirements refer to Supplier assessment, approval and qualification for listed and complementary medicines.

Homoeopathic preparations exempt/ required to be included in the ARTG

Where a medicine meets the definition of 'homoeopathic preparation' and meets the conditions set out under Item 8 of Schedule 5 to the Regulations it is exempt from the requirement to be included in the ARTG. (Note that this does not apply where the homoeopathic preparation is part of a medicine containing other ingredients requiring inclusion in the ARTG).

Most homoeopathic preparations that are more dilute than a 1,000 fold dilution of a mother tincture (4X and above), are not required to be in the ARTG as they are considered to be sufficiently low risk, providing that the preparation:

- is not required to be sterile
- does not include an ingredient of human or specified animal origin
- is not for the cure, prevention, diagnosis or monitoring of, or testing susceptibility of persons to, a disease, condition, ailment or defect

Items 4A and 5 of Part 1 of Schedule 4 to the Regulations state the following homoeopathic preparations are required to be listed in the ARTG:

- mother tinctures and 1X, 2X and 3X potency homoeopathic preparations (that is, 1000 fold or lesser dilution of the mother tincture)'; and
- preparations more dilute then 1000 fold dilutions that make therapeutic indications.

[3] The TGA no longer issues proprietary ingredient numbers for ingredient mixtures that contain an active ingredient. For more information see Streamlining proprietary ingredient categories.

To be listed in the ARTG, homoeopathic preparations must:

- only contain ingredients specified in the Permissible Ingredients Determination
- only contain indications covered by the Permissible Indications Determination
- not be required to be sterile
- not contain a substance included in a Schedule to the Poisons Standard(other than one that is more than a 1,000 fold dilution of mother tincture)

Entering medicines in the ARTG

If your medicine is **not** exempt, then you **must** apply to include your medicine in the ARTG. To include a medicine in the Australian Register of Therapeutic Goods (ARTG) an applicant will need to:

1. Identify the appropriate approval pathway for the medicine. The Pathways for complementary medicine products assists potential sponsors of medicines to determine the most suitable pathway to enter their product in the ARTG.
2. Apply to enter the medicine in the ARTG using the appropriate form for the selected pathway.

Determining the ARTG entry pathway

The ARTG entry pathways for medicines are based on the ingredients they contain and the therapeutic indications (claimed health benefits) they use. The ARTG categories are:

- Listed medicines
  - **'AUST L' listed medicines** are considered to have a lower risk as they may only use low-risk ingredients and low-level indications that must be selected from the pre-approved lists. Listed medicines are not individually evaluated by the TGA before they are released onto the market; instead, they are automatically included in the ARTG following completion of an application and certification by the sponsor that their product meets all applicable legislative requirements in relation to safety, quality and efficacy. Listed medicines have an AUST L number on their medicine label. Refer to General guidance for listed medicines for more information.
  - **'AUST L(A)' assessed listed medicines** may only use low-risk ingredients permitted for use in listed medicines. However, they must have at least one intermediate indication (i.e. indications that are above those available for AUST L listed medicines), and may also include lower-level indications. Assessed listed medicines are entered in the ARTG following self-certification by the applicant of the safety and quality of the product and TGA pre-market assessment of the efficacy evidence supporting the proposed indications. Assessed listed medicines have an AUST L(A) number on their medicine label. Refer to General guidance for listed medicines for more information.
- **AUST R registered complementary medicines** are considered to be relatively higher risk than listed medicines, based on the ingredients they contain or the indications made for the medicine. All registered medicines are fully assessed by the TGA for quality, safety and efficacy prior to being available in the Australian market. Registered medicines have an AUST R number on the medicine's label. . Refer to Applications for registered complementary medicines for more information.

Table 6 summarises the key aspects and regulatory requirements for each ARTG entry pathway

Table 7 outlines the risk categories of medicines based on the claimed therapeutic indications.

Table 6: Regulatory requirements for the three ARTG entry pathways

	Listed medicines	Assessed listed medicines	Registered complementary medicines
ARTG no.	**AUST L**	**AUST L(A)**	**AUST R**
GMP	All medicines be manufactured in accordance with the principles of GMP		
Sterility	Must not be required to be sterile		May be required to be sterile.
Ingredients	May only include ingredients in the Therapeutic Goods (Permissible Ingredients) Determination		• May include Permissible Ingredients; and/or • ingredients not in the permitted ingredients list, provided that they do not meet the criteria for inclusion in Schedules 4, 8 or 9 of the Poisons Standard.
Indications	Can only have indications in the Therapeutic Goods (Permissible Indications) Determination	• May have indications in the Permissible Indications Determination • Must have at least one intermediate level indication.	May have: • low or intermediate level indications; and/or • high level indications which are not suitable for the listed or assessed listed medicines pathway
Evidence	Evidence held by the sponsor. Not assessed by the TGA pre-market.	Quality and safety evidence held by the sponsor. Efficacy evidence TGA assessed pre-market	Safety, quality and efficacy evidence must be assessed pre-market by the TGA.
Application and TGA pre-market evaluation	Sponsor self-certification safety, quality and efficacy. No pre-market evaluation	Sponsor self-certification of quality and safety. TGA pre-market assessment of efficacy.	Full pre-market assessment of quality, safety and efficacy by the TGA.
TGA assessed claim	**Do not** have option to use TGA assessed claim	Have the option to use a TGA assessed claim.	Have the option to use a TGA assessed claim.

	Listed medicines	Assessed listed medicines	Registered complementary medicines
Post market compliance review	All listed medicines may be selected for a post-market compliance review at any time. The TGA will check the medicine's compliance against any regulatory requirements self-certified by the sponsor.		Continuing safety, quality and efficacy of therapeutic goods in the market monitored through therapeutic product vigilance activities.

Table 7: Three-tiered risk-based hierarchy of indications

Low risk – Listed medicines	Intermediate risk – Assessed listed medicines	Higher risk – Registered complementary medicines
Permitted indications may refer to: • health enhancement • health maintenance • prevention of dietary deficiency • a disease, ailment, defect or injury other than a serious form of those diseases	Intermediate level indication may refer to: • the prevention, cure or alleviation of a non-serious form of a disease, ailment, defect or injury • restricted representations (i.e. a serious form of a disease)	High level indications may refer to: • prevention, cure or alleviation of a serious form of a disease, ailment, defect or injury (i.e. restricted representations)

For the application process for the ARTG entry pathways refer to:

- 'Application process to list a medicine' in the ARTG in General guidance for listed medicines
- 'Application process for a registered complementary medicine' in Applications for registered complementary medicines

Supplying medicines packaged with other goods

Medicines may be individually packaged with other therapeutic goods. These may be defined as a kit, a composite pack or a system and procedure pack.

Kits and composite packs are defined in the legislation under section 7B of the Act. System or procedure packs are defined in section 41BF - these are regulated as medical devices. Packs are regulated differently depending on the combination of therapeutic goods supplied.

Composite pack

- Contains two or more therapeutic goods but does not contain a medical device.
- The goods must be for administration as a single treatment or a single course of treatment, and the components are either combined before treatment or administered in a particular sequence as part of that treatment.
- Individual components within the pack are not separately listed or registered in the ARTG. That is, a composite pack has one single ARTG entry.

An example of a composite pack is a cold medication consisting of tablets for day or night time use, where the 2 different tablet formulations are presented together in a blister pack and the medicine has one ARTG listed medicine entry.

Kits

- Contains one or more goods at least one of which is a therapeutic good.
- The pack must not meet the definition of a composite pack. The individual goods can be used independently and do not need to be combined or administered in a sequence as part of a single treatment for the product's therapeutic purpose.
- Individual components within the pack must be separately listed, registered or excluded from the requirement to be in the ARTG.
- The kit (comprised of the individually regulated products) is included in the ARTG as a listed medicine (even if one of the goods in the kit is a registered medicine or an exempt good).

Example of kits are:

- A sunscreen lotion (AUST L listed medicine), and a cosmetic moisturiser (exempt good) and a sun hat (non-therapeutic good) presented together in a single package for sun care.
- A first aid kit comprising of a wound antiseptic spray (AUST L listed medicine), a band aid (a medical device) and a pair of scissors (non-therapeutic good).

System or procedure pack

A system or procedure pack contains medicine/s and at least one medical device that are required to be used together as a system or in a medical or surgical procedure. System or procedure packs are regulated as medical devices.

For information: System or procedure packs are medical devices

Information on the regulation of system or procedure packs can be found in pre-market part of the Australian Regulatory Guidelines for Medical Devices.

Administrative information

Fees and charges

The TGA has a variety of fees and charges for complementary medicines:

- an initial application fee
- evaluation fees
- an annual charge to maintain the inclusion of their product in the ARTG.

The fees payable vary depending on the type of application. For more information refer to the Fees and charges summary.

Appeal processes

If the sponsor does not agree with a decision made under the Act by the TGA, the Act provides a comprehensive system for review of administrative decisions. The appeal mechanisms are described in more detail in the TGA internal review guideline. Briefly, the formal appeal process usually involves:

- An appeal under Section 60 of the Act.

This can be followed by:

- An appeal to the Administrative Appeals tribunal (AAT).

Post-market monitoring of medicines in Australia

Important: Section 29A of the Act requires sponsors of medicines registered or listed in ARTG to report adverse reactions about which they become aware. Guidance for sponsors is provided in Australian requirements and recommendations for pharmacovigilance responsibilities of sponsors of medicines.

We adopt a risk management approach to regulating therapeutic goods including post-market monitoring activities. Information on our approach to managing compliance risk is available at: TGA regulatory framework.

The TGA has a multi-faceted program for monitoring the safety, quality and efficacy of therapeutic products that are on the market. The types of post market regulatory activities we undertake include:

- therapeutic product vigilance
- pharmacovigilance inspection program
- reporting of adverse events, counterfeit goods or medicine defects
- listed medicine compliance reviews
- advertising monitoring
- laboratories testing program
- manufacturer inspections

Once a problem has been identified possible regulatory actions the TGA can take include:

- Informing health care professionals and consumers about the risks of using the product
- Re-assessing the benefit-risk profile.
- Requiring product labelling changes.
- Requiring design or manufacturing change.
- Removal of the product from the ARTG.
- Recalling products - refer to: About recall actions.

Version history

Version	Description of change	Author	Effective date
V1.0	This document, 'Overview of the regulation of listed medicines and registered complementary medicines', has been extracted from ARGCM v.8 April 2018 pages11 to 44 (previously named 'ARGCM Part A'). The document has been simplified to be an overview of the regulatory framework. The sequence of information, headings and formatting have been changed from the original content for consistency and easier navigation. References to outdated forms have been removed. The introduction has been modified to provide an overview of the regulatory framework for medicines and explanatory information on the classification of listed and registered medicines. New guidance has been included on changes to the regulatory framework for listed medicines, including: • permitted indications • the assessed listed pathway The following technical content has been extracted to be new standalone guidance documents: • Literature-based submissions for listed medicines and registered complementary medicines: guidance for sponsors (extracted from ARGCM Part A pages 41 -43) • Listed medicine presentation and labels: guidance for sponsors (extracted from ARGCM v8 Part A pages 27 -29) Information on changing listed medicines and registered complementary medicines have been moved in to the relevant new guidance for these goods. Information on proprietary ingredients clarified and links provided to Supplier assessment, approval and qualification for listed and complementary medicines.	TGA	May 2020
V1.1	Information on Active Herbal Extracts and proprietary ingredients updated.	COMB and SEB	July 2021

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication #D21-2710978