Australian Government
Department of Health
Therapeutic Goods Administration

General guidance for listed medicines

Australian regulatory guidelines

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TGA Health Safety Regulation

Contents

Abbreviations

Refer to the TGA acronyms & glossary for terms, definitions and acronyms

General guidance for listed medicines

Information: This guidance replaces archived ARGCM V8.0 Part B: Listed complementary medicines.

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

This guidance applies to applicants (the person who submits an application) for a listed medicine for listed medicines (AUST L) and assessed listed medicines [AUST L(A)].

Overview of pathways for listing medicines in the ARTG

Listed medicines are considered to pose a low risk to consumers than registered medicines based on their ingredients and/or the therapeutic indications they carry. Listed medicines included in the ARTG can be sold to the general public without undergoing a full pre-market assessment of safety, quality and efficacy by the TGA because they satisfy certain 'low risk' criteria. This allows for rapid market access compared with registered medicines.

A sponsor can apply to list a medicine in the ARTG if:

- the medicine is eligible for listing- see Certification that the medicine is eligible for listing
- the medicine complies with the requirements of section 26A and 26AB of the Act

There are two different processes for including listed medicines in the ARTG. There are:

- listed medicines (AUST L ARTG number)
- assessed listed medicines (AUST L(A) ARTG number)

AUST L(A) medicines differ from AUST L listed medicines in that they can make indications that are above those available for AUST L listed medicines. Like other listed medicines, assessed listed medicines are entered in the ARTG following self-certification by the applicant of the safety and quality of the product. However, unlike other listed medicines, assessed listed medicines undergo a TGA pre-market assessment of the efficacy evidence supporting the product's indications.

AUST L(A) medicines are eligible to include a TGA assessed claim on their medicine label and other advertising material indicating that the TGA has assessed the evidence the sponsor holds for the medicine's indications. The use of the TGA assessed claim is optional for the product sponsor – refer to TGA assessed claim for assessed listed and registered complementary medicines.

Refer to Entering medicines in the ARTG for a comparison of the regulatory requirements for listed, assessed listed and registered complementary medicines. See How to apply to include a list a medicine in the ARTG for more information on the process of listing a medicine in the ARTG.

Listing a medicine in the ARTG

Legislative requirements for listing medicines in the ARTG

A medicine is listed in the ARTG on the basis of:

- information provided by the applicant
- certification by the applicant at the time of listing that the goods (that are the subject of the application) meet the relevant legislative requirements – see Listed medicine applicant/sponsor certifications under the Act.

Important: An incorrect sponsor certification could result in the product listing being cancelled from the ARTG [under the provisions of paragraph 30(2)(ba) of the Act].

Once a medicine is accepted for inclusion in the ARTG, sponsors must be compliant with all the conditions of listing applicable to the medicine - see Conditions of listing.

Listed medicine applicant certifications under the Act

At the time listing their medicine in the ARTG, applicants make a number of certifications under the applicable part of the Act.

For AUST L listed medicines the applicant certifications are made against:

- subsection 26A(2) (a)–(k) of the Act inclusive; and
- if applicable, subsection 26A(2A) of the Act

For AUST L(A) assessed listed medicines the applicant/sponsor certifications are made against:

- subsection 26AB(2) (a)–(q) of the Act inclusive; and
- if applicable, subsection 26AB(3) of the Act

Details on the required applicant/sponsor certifications are provided below.

Certification that the medicine is eligible for listing

Applicants certify [against subsections 26A(2)(a) or 26(AB)(2)(a)of the Act] that their medicine is eligible for listing.

AUST L: A medicine is eligible for inclusion in the ARTG as a listed medicine under section 26A of the Act if:

- the medicine only contains ingredients and complies with the requirements specified in the Permissible Ingredients Determination
- the proposed indications are covered by the Permissible Indications Determination and meet any specified requirements
- the medicine is not required to be sterile

- the medicine does not contain a substance included in a Schedule to the Poisons Standard

AUST L(A): A medicine is eligible for inclusion in the ARTG as an assessed listed medicine under section 26AB of the Act if:

- the medicine only contains ingredients and complies with the requirements specified in the Permissible Ingredients Determination
- the indications proposed for the medicine:
  - only refer to:

    (i) preventing, curing or alleviating a non-serious form of a disease, ailment, defect or injury; or

    (ii) serious form of a disease, condition, ailment or defect (as identified in the Therapeutic Goods Advertising Code), other than its prevention, cure or alleviation

  - do not refer to a prohibited representation (within the meaning of Part 5-1 of the Act)
- the medicine is not required to be sterile
- the medicine does not contain a substance included in a Schedule to the Poisons Standard

Certification that the medicine is safe for the purposes for which it is to be used

Applicants for listing are required to certify [against subsections 26A(2)(b) or 26AB(2)(b) of the Act] that their medicine is safe for the purposes for which it is to be used. Certain regulatory restrictions and/or controls may be imposed to ensure that the use of a listed medicine is low risk, such as label advisory statements, restrictions on dosage and restrictions on route of administration.

Sponsors must ensure that they are aware of every condition or restriction affecting the use of ingredients (including proprietary ingredients) in their products so that the product fully complies with all legislative requirements applicable in Australia.

Certification that the presentation of the medicine is not unacceptable

Applicants of all listed medicines are required to certify [against subsections 26A(2)(c) or 26AB(2)(c)of the Act] that the presentation [as per definition under Section 3(1) of the Act] of the medicine is not unacceptable. The presentation of therapeutic goods is unacceptable if it is capable of being misleading or confusing as to the content or proper use or identification of the goods. For more information refer to: Listed medicine presentation and labels.

Certification that the medicine only contain permissible ingredients and complies with ingredient requirements

Applicants of all listed medicines are required to certify [against subsections 26A(2)(ca)and 26A(2)(cb)or 26AB(2)(d) and 26AB(2)(e)] that their medicine only contains low risk ingredients permissible for use in listed medicines, as included in the Permissible Ingredients Determination.

Important: It is the sponsor's responsibility to ensure that all ingredient restrictions and in the Poisons Standard are met. For example: vitamin B6 above a certain dose is scheduled in the Poisons Standard and therefore a medicine in which it is included as an ingredient could not be a listed medicine.

Applicants also certify that their medicine complies with any requirements relating to the use of ingredients included in the Permissible Ingredients Determination, for example: label advisory statements.

The majority of ingredients that can be included in listed medicines are those that were included in therapeutic goods supplied in Australia before the Act came into operation in 1991. Since then, all new active and excipient ingredients have undergone a safety assessment by the TGA. If a person wishes to include an active or excipient ingredient that is not currently approved for use in listed medicines, the substance must be evaluated by the TGA before such use is permitted - refer to Applications for new substances in listed medicines for information on this process.

Certification that the medicine conforms with all applicable standards

Applicants of all listed medicine certify [against subsections 26A(2)(da) and 26AB(2)(f)] that their listed medicine complies with applicable standards before they can be entered in the ARTG.

Important: Criminal or civil penalties can be imposed on persons who import, export, manufacture or supply goods that do not comply with applicable standards (unless you have consent to supply such a good under section 14 of the Act).

Certification that the medicine conforms with all advertising requirements

Applicants of all listed medicines certify [against subsections 26A(2)(da) and 26AB(2)(g)] that their medicine complies with any requirement applicable under:

- The Therapeutic Goods Advertising Code
- Part 5-1 (Advertising and generic information) of the *Therapeutic Goods Act 1989*
- The Therapeutic Goods Regulations 1990

For guidance on advertising medicines, refer to:

- Advertising to the public: complying with the Therapeutic Goods Advertising Code
- Australian Regulatory Guidelines for Advertising Therapeutic Goods

Certification that the medicine complies with manufacturing requirements

Applicants of all listed medicines are required to certify that their medicine complies with applicable manufacturing requirements. Unless exempt, (see Products exempt from certain manufacturing requirements in Overview of the Regulation of listed medicines and registered complementary medicines) all listed medicines included in the ARTG must be manufactured in accordance with the principles of Good Manufacturing Practice (GMP).

Australia has codes of GMP and quality system requirements for the manufacture of therapeutic goods, including complementary medicines. For more information—refer to Manufacturing principles for medicinal products.

Certification that all the manufacturers of the listed medicine are nominated

Applicants of all listed medicines certify [against subparagraphs 26A(2)(h) and 26AB(2)(o) of the Act] that that all the manufacturers of their medicine are included in the medicine's ARTG entry. Use of a manufacturer who is not nominated on the product ARTG entry is an incorrect certification.

Certification of written agreements between sponsor and manufacturers

Applicants of listed medicines also certify [against subparagraphs 26A(2)(i) or 26AB(2)(p) of the Act] that the applicant has written agreements with manufacturers of the medicine.

Certifications for medicines manufactured in Australia

Applicants of listed medicines certify [against subparagraphs 26A(2)(e) or 26AB(2)(e)] of the Act] that each step in the manufacture of the medicine is carried out by a licensed manufacturer who is the holder of a manufacturing licence to carry out that step (unless the therapeutic good is exempt from this requirement)—refer to Manufacturing therapeutic goods.

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 under Part 3-3 of the Act, unless specifically exempted.

Important: It is an offence, carrying heavy penalties, to manufacture therapeutic goods for human use without a licence unless the manufacturer or goods are exempt. The manufacturer's licence carries details of the types of manufacture permitted under the licence.

Certifications for medicines manufactured overseas

Where a product is imported, or if any steps in the manufacture of a listed medicine take place outside Australia, the international manufacturer must hold a TGA GMP license, or a license accepted by the TGA—refer to Manufacturing standards for overseas manufacturers.

Where a product is imported, each nominated international manufacturer must demonstrate an acceptable standard of good manufacturing practice (GMP) as would be required of an Australian manufacturer. Pre-clearance of international manufacturers is mandatory for listed medicines—refer to Manufacturing standards for overseas manufacturers.

For information: While each step in the manufacture of the medicine is required to be manufactured in accordance with the principles of GMP, not all steps are required to be entered in the medicine's ARTG entry. Refer to Listed medicines application and submission user guide.

Certification that the listed medicine complies with quality and safety criteria

The sponsor of the listed medicine is responsible for the quality of their listed medicine. The sponsor must hold information or evidence to demonstrate that their medicine:

- complies with all legislative requirements
- meets all specifications for the shelf life of the medicine, the recommended storage conditions and the expiry date stated on the medicine label

Applicants are required to certify [against subparagraphs 26A(2)(f) or 26AB(2)(i)] of the Act] at the time of listing that they hold this information. A Delegate of the Secretary can request information or documents about the quality of a listed medicine under subparagraph 31(2) (ca) of the Act; and can cancel a medicine's listing if they determine that the quality of the medicine is unacceptable.

For more information, refer to guidance on Quality for listed medicines

Certification that the listed medicine's specifications comply with requirements

The applicant of all listed medicine certifies [against subparagraphs 26A(2)(fa) and 26A(2)(fc) or 26AB(2)(j) 26AB(2)(l)) of the Act] that:

- their medicine's specifications comply with any requirements that are prescribed by the regulations applicable to their medicine
- they hold information or evidence showing the medicine's specifications will be maintained under the conditions set out on the medicine's label until the medicine's expiry date

Certification that the medicine label complies with requirements

The applicant of all listed medicine certify [against paragraphs 26A(2)(fb) or 26AB(2)(k)] of the Act] that the medicine label does not include any claim that is inconsistent with the information for the medicine included in the ARTG and, must comply with any requirements prescribed by the Regulations, applicable standards and advertising requirements.

Refer to Listed medicine presentation and labels

For information: TGA assessed label claim for AUST L(A) assessed listed medicines

AUST L(A) assessed listed medicines (and AUST R registered complementary medicines - see Applications for registered complementary medicines) that have been assessed for efficacy by the TGA are eligible to include a TGA assessed claim on their medicine label and other advertising material indicating that the TGA has assessed the evidence the sponsor holds for the medicine's indications. For more information refer to TGA assessed claim for assessed listed and registered complementary medicines.

Certification that the medicine only contain permissible indications and all requirements relating to those indications are met

Applicants of AUST L listed medicines are required to certify [against subparagraph 26A(2)(fd) of the Act] that each indication on the medicine label is covered by the Permissible Indications Determination and, is included in the ARTG entry for the medicine. The applicants also certify [against paragraph 26A(2)(fd) of the Act] that all requirements relating to those indications in the Determination are met.

Certification that the medicine does not contain substances that are prohibited imports for the purposes of the Customs Act 1901

Applicants of all listed medicines are required to certify [against subparagraph 26A(2)(g)or 26AB(2)(n) of the Act] that the medicine does not contain substances that are prohibited imports for the purposes of the *Customs Act 1901.*

Certification that evidence is held for all indications and claims

At the time of the application for listing, applicants of AUST L listed medicines certify [against subparagraph 26A(2)(ja) of the Act] that they hold evidence to support any permitted indication for their medicine and comply with all requirements for that indication in the Permissible Indications Determination. Applicants also certify [against subparagraph 26A(2)(j) of the Act] that they hold evidence to support any claims (that are not indications) made for the medicine. Evidence guidelines: Guidelines on the evidence required to support indications for AUST L listed complementary medicines assist you to determine the appropriate evidence to support therapeutic indications made in relation to your AUST L listed medicine.

For AUST L(A) assessed listed medicines, applicants certify [against subparagraph 26AB(2)(m) of the Act] that they have information to substantiate each claim and each indication for the medicine. Sponsors of AUST L(A)assessed listed medicine must provide their evidence to the TGA for pre-market assessment.

Assessment of efficacy data for an AUST L(A) assessed listed medicine is based on the finished product (rather than active ingredients in isolation) and includes a detailed evaluation of evidence to support all intermediate and lower level indications – refer to Assessed listed medicines evidence guidelines.

Important: Subsection 28(6) of the Act provides, as a condition of listing, that sponsors must hold evidence to support any claims (that are not therapeutic indications) made for the medicine: at the time of listing; while the medicine remains in the ARTG; and sponsors must provide this evidence to the TGA if requested.

After listing, the medicine may be subject to a compliance review of evidence held by the sponsor as part of the TGA's random and targeted post-market monitoring activities or in response to either product safety concerns, or as a result of a complaint about a product.

Certification that the information in the ARTG is correct

Applicants of all listed medicines must certify [against subparagraphs 26A(2)(k) or 26AB(2)(q) of the Act] that all information in the medicine's ARTG entry is correct.

Certification of compliance with that applicable requirements in the regulations

Applicants of all listed medicines must certify [against subparagraphs 26A(2A) or 26AB(3) of the Act] that the medicine complies with any other applicable requirements in the Regulations.

Application process to list a medicine in the ARTG

How to include an AUST L listed medicine in the ARTG

AUST L listed medicines are included in the Australian Register of Therapeutic Goods (ARTG) via a streamlined online listed medicine application and submission portal which is part of the TGA Business Services framework.

All necessary tools required to lodge, change and maintain an application for a listed medicine are accessible via TGA Business Services. The Listed medicines application and submission user guide fully describes the AUST L listed medicine application and submission process.

Step 1: Obtain access to TGA Business Services and the online application portal

To access the application portal you will require a user name and password. You must first submit an Organisation details form to obtain a client identification number. Having obtained a client identification number, you can submit a TGA Business Services Access Request Form to become the 'Business Administrator' for your company and then can apply for user accounts for yourself and other personnel in your company.

For further information about obtaining a client identification number or gaining access to TGA Business Services, contact the TGA by phone 1800 010 624 or email ebs@health.gov.au.

Step 2: Medicine details entered in the TGA Business Services application portal

The Listed medicines application and submission user guide provides a step-by-step description on how to enter your medicine details.

Step 3: Application passes validation in TGA Business Services application portal

During validation, the application and all related sub-documents are checked against the listed medicine business rules. The application must pass validation before it can be submitted to the TGA.

Important: Successful validation of an application does not mean that the product has been approved by the TGA, nor that the product meets all the requirements for listing. The TGA Business Services application portal is a tool designed to allow electronic submission of an application for a listed medicine. The onus of responsibility is with the sponsor of the medicine to certify, upon submission, that the goods that are the subject of the application meet all the requirements of listing.

If you have problems with your application, you can contact the TGA by email: complementary.medicines@health.gov.au or by phone: 1800 020 653.

Step 4: Submission

When the application has passed validation, the applicant (who will become the sponsor of the medicine) must electronically sign a statutory declaration certifying (as per Part 26A of the Act) that the application meets all conditions of listing and that the information provided in the application is correct.

The application can then be submitted.

Step 5: Application fees paid

Fees for a listing application are non-refundable and non-transferable and must be paid within 14 days of the application being submitted to the TGA. If payment is not made within 14 days,

you will receive an email notifying you that the application has been rejected. Should you wish to continue, you will need to draft a new application.

Step 6: TGA processing of the application

- Once payment is finalised:
- the application is recorded in the ARTG
- the medicine is assigned an AUST L number
- a 'Certificate of medicine listing' is generated for the medicine

Step 7: Finalisation

The sponsor of the medicine:

- is notified by email of application completion and provided with the AUST L number
- downloads the 'Certificate of medicine listing' from TGA Business Services
- can market the product

A listed medicine may be subject to any number of compliance reviews while it remains in the ARTG. Medicines may be randomly selected or targeted for a review. For more information refer to Listed complementary medicine compliance reviews.

For information: The product details will usually be viewable on the TGA Business Services the day after the information has been recorded in the ARTG.

How to include an AUST L(A) assessed listed medicine in the ARTG

AUST L(A) assessed listed medicines are included in the ARTG via a streamlined online listed medicine application and submission portal which is part of the TGA Business Services framework.

Assessed listed medicines are included in the ARTG following self-certification by the applicant of the safety and quality of the product, and a TGA assessment of the efficacy evidence supporting the proposed indications. Only products supported by scientific evidence (not evidence of traditional use only) will be accepted for pre-market assessment.

Applicants must provide the required data and a draft label for the product, which is assessed before the product can be listed. The assessment will include a detailed evaluation of evidence to support proposed intermediate level indications and any lower level indications to determine if the data supplied adequately supports those indications.

All necessary tools required to lodge, change and maintain an application for a listed medicine are accessible via TGA Business Services.

The Listed and assessed listed medicines: Application and submission user guide describes the AUST L listed medicine application and submission process

The Guidance for completing the application form for an assessed listed medicine describes the AUST L(A) assessed listed medicine application and submission process.

The Assessed listed medicines evidence guidelines provide details on the:

- application categories
- evidence requirements
- dossier requirements
- application steps and approval process
- evaluation timeframes and fees

After a medicine is listed in the ARTG

Conditions of listing

All listings in the ARTG are subject to conditions of listing and additional conditions may be imposed by the TGA where it is appropriate.

Statutory conditions of listing

Section 28 of the Act provides a number of statutory conditions of listing that automatically apply when a medicine is listed in the ARTG. Failure to comply with a condition of listing may result in the cancellation of the medicine from the ARTG. Statutory conditions of listing are displayed in a listed medicine's ARTG certificate. Among the statutory conditions of listing is the following, regarding a sponsor's pharmacovigilance obligations:

- In accordance with paragraphs 28(5)(ca) and (e) of the Act and Regulation 15A of the Therapeutic Goods Regulations 1990, sponsors of listed medicines are required to comply with any record-keeping and reporting requirements set out in the document published by the TGA titled Pharmacovigilance Responsibilities of Medicine Sponsors, as in force from time to time. This includes, but is not limited to the following requirements to notify the TGA:
  - of your pharmacovigilance contact person within 15 calendar days of the first ARTG entry or of any detail updates
  - within 72 hours of any significant safety issues
  - within 15 calendar days of any serious adverse reaction reports

General additional conditions of listing

Section 28 of the Act provides legislative powers for the Secretary to impose, vary or remove additional conditions on all listed therapeutic goods at the time the medicine is listed, or any time thereafter. There are a number of general 'Additional Conditions of Listing' imposed by the delegate of the Secretary at the time a medicines is listed in the ARTG, which are displayed in the listed medicine's ARTG certificate, including the following:

- The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements in relation to such manufacture shall be kept.
- The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the TGA, upon request.
- The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the ARTG.
- The sponsor shall not supply the listed medicine after the expiry date of the goods.
- Where a listed medicine is distributed overseas, as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the TGA, immediately as soon as the action or information is known to the sponsor.

Substance-specific conditions of listing

Specific conditions of listing may be imposed on all listed medicines in relation to specific ingredients included in the medicine. These conditions are imposed when the product is listed in the ARTG and are displayed in the listed medicine's ARTG certificate. For example, the following condition of listing is imposed on listed complementary medicines that contain preparations of the herbal material, *Ginkgo biloba* leaf extract:

> 'The *Ginkgo biloba* leaf extract used in the manufacture of this medicine must comply with the requirement of Identification Test B of the monograph Powdered Ginkgo Extract in the United States Pharmacopeia 32—National Formulary 27 (USP32-NF27). This condition does not apply to powdered or dried leaf'.

Additional conditions of listing for the TGA assessed claim

Additional conditions of listing under Section 28(3) of the Act will be imposed on sponsors who are eligible and wish to use a TGA assessed claim on their assessed listed or registered complementary medicine label - see TGA assessed claim.

Imposition and changes to conditions of listing and sponsor's rights to appeal

Under subsections 28(2B) and 28(3) of the Act, while a medicine is listed in the ARTG, new conditions of listing may be imposed and/or existing conditions may be varied or removed, as determined by a Delegate of the Secretary. A sponsor may also request that a condition of listing be imposed or varied (an application fee may apply)—the Delegate of the Secretary will review the request and sponsors will be advised in writing of the decision.

The imposition or variation of a condition will take effect:

- on the day on which the notice is given, if the notice states that the action is necessary to prevent imminent risk of death, serious illness or serious injury; or
- in any other case, on the day specified in the notice, which will be a day not earlier than 28 days after the notice is given.

Sponsors are advised in writing of any conditions of listing and may appeal against a decision to impose, vary or remove a condition of listing. Rights of appeal will be advised in the letter from the TGA imposing the conditions—refer to Appeal mechanisms.

Compliance reviews of listed medicines

The regulatory process for listed medicines allows for early market access for low-risk medicines. In facilitating early market access, there is reliance on a comprehensive risk-based system of post market monitoring. We review a proportion of listed medicines for compliance with the regulatory requirements. These reviews may be:

- random reviews: a proportion of newly listed medicines are randomly selected by computer
- targeted reviews of listed medicines identified with potential non-compliance issues

For more information on the random and targeted compliance reviews, including possible regulatory actions and appeal rights, refer to Listed medicine compliance reviews.

Medicines which are found to be non-compliant may be cancelled from the ARTG and can no longer be sold in Australia. Cancellations from the ARTG following compliance review are routinely published on our website.

Further to the product compliance reviews described above, specific safety and efficacy reviews in response to issues arising in the market place may be carried out for: ingredients; individual medicines; and medicine groups.

How to make a change to a listed medicine's ARTG entry

Legislative basis for varying listed medicines

Section 9D (1), (2) and (3) of the Act provides the circumstances under which a sponsor may request an amendment to the ARTG entry for their AUST L listed or AUST L(A) assessed listed medicine:

- 9D(1): correction of an ARTG entry of a medicine that is incomplete or incorrect
- 9D(2): making certain safety-related variations to an ARTG entry of a medicine. A variation is safety-related if it reduces the patient population (e.g. removing an indication), or has the effect of adding a warning or precaution (e.g. an adverse effect or interaction)
- 9D(3): other variations to an ARTG entry of a medicine to be made, provided that the Delegate of the Secretary is satisfied that the change does not reduce the quality, safety or efficacy of the medicine

Separate and distinct goods and the Groups order

Some changes may result in a medicine considered as separate and distinct good from the medicine currently included in the ARTG. Subsection 16(1A) of the Act outlines those criteria which make medicines that are listed goods (other than export only medicines) separate and distinct from the existing goods:

> (a) different active ingredients; or
> (b) different quantities of active ingredients; or
> (c) different dosage form; or
> (d) such other different characteristics as the regulations prescribe;

Currently, regulation 11 of the Regulations prescribes that different characteristics are:

> (a) a different name; or
> (b) different indications; or
> (c) a different excipient; or
> (d) for medicines that contain any restricted ingredients:
> (i) a different quantity of a restricted ingredient that is an excipient; or
> (ii)if the restriction on a restricted ingredient relates to its concentration in a relevant medicine – a different concentration of the restricted ingredient; or
> (iii)if the restriction on a restricted ingredient relates to its quantity in the recommended single or daily dose in a relevant medicine – different directions for use setting out a different recommended single or daily dose.

The 'new' good must be separately entered in the ARTG. However, depending on the nature of the change, the provisions of the Therapeutic Goods (Groups) Order No. 1 of 2001 (the 'Groups Order') may allow the AUST L or AUST L(A) number to be retained for the new medicine. A grouping is appropriate when the goods are intended to replace the currently supplied goods, enabling the transition of one product to another. However, individual products within the group remain separate and distinct products under subsection 16(1A) of the Act.

When a change to a product record is made that will result in a separate and distinct good, the online listed medicine application and submission portal will, upon validation, recognise if the type of change meets the criteria for grouping.

How to apply for a change to listed medicines

All changes to listed medicines (other than those listed for export only) are made via the online listed medicine application and submission portal which is part of the TGA Business Services framework. Refer to the Listed medicines application and submission user guide for more information.

For information on the changes that can be made to AUST L listed medicines and whether they will incur a fee, refer to Guidance on product changes in ELF 3.

There is a provision in the application and submission portal to request the same change to be made across a number of currently listed medicines. Each medicine change will incur any applicable fees. Refer to Registered complementary and OTC medicines applications and submissions

Version history

Version	Description of change	Author	Effective date
V1.0	This document, 'General guidance for listed medicines' has been extracted from ARGCM v.8 April 2018 pages 45 to 62 (previously named 'ARGCM Part B'). 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. Technical content has been extracted to the following standalone guidance documents: • Quality for listed medicines: guidance for sponsors (ARGCM V.8 pages 54 to 60) New guidance has been included on changes to the regulatory framework for listed medicines, including: • permitted indications • the assessed listed pathway • the TGA assessed label claim Other changes include: • information on pharmacovigilance reporting included under statutory conditions of listing • information on changing a listed medicine's ARTG entry (previously included in ARGCM V.8.0 Part A)	TGA	May 2020

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