Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Navigating the listed medicines framework

Checklist for new sponsors

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Navigate the listed medicines framework

This document is provided as a checklist by the Therapeutic Goods Administration (TGA) to assist new sponsors navigate and understand the legislative framework for medicines listed in the Australian Register of Therapeutic Goods (ARTG) under section 26A of the *Therapeutic Goods Act 1989* (the Act). These medicines are known as 'listed medicines' and display an AUST L number on their label.

This document is provided as a useful resource only - **you do not need to submit it to the TGA**.

This document is not intended to serve as a complete source of information. It is provided to assist sponsors find information available on the TGA website and for you to then determine the applicability of that information to your individual circumstance. This document should not be relied upon as a substitute for your legislative and regulatory obligations. Sponsors remain responsible for understanding and complying with all applicable legislative and regulatory requirements. If you require assistance, you may choose to seek advice from a regulatory affairs consultant.

Listed therapeutic sunscreens and assessed listed medicines [AUST L(A)] are also regulated under the listed medicine framework, and in addition to the information provided below we have the following guidance for these goods:

- Understanding the regulation of therapeutic sunscreens (URTS)
- Understanding the application requirements for an assessed listed medicine

For information on medicines that are listed in the ARTG as 'Export Only' medicines under section 26 of the Act, see Exporting medicines from Australia.

Starting out: Determine if you have a therapeutic good

Find out whether your product is regulated as a therapeutic good.

Resources	Noted
Is my product a therapeutic good?	☐
Understanding complementary medicine interface issues	☐
Boundary and combination products	☐
Food-Medicine Interface Guidance Tool (FMIGT)	☐
Therapeutic Goods (Excluded Goods) determinations	☐
Declared goods orders	☐

Therapeutic goods regulation

Understand the legislation that supports therapeutic goods regulation.

Resources	Noted
Therapeutic goods are regulated by the TGA under the *Therapeutic Goods Act 1989* and supporting: Therapeutic Goods Regulations 1990 Legislative instruments (Determinations and Orders)	☐ ☐ ☐
About the Australian therapeutic goods legislation	☐
To be supplied, imported or exported from Australia therapeutic goods need to be included in the Australian Register of Therapeutic Goods (ARTG)	☐

Is your therapeutic good eligible for listing in the ARTG?

Check whether your medicine meets the requirements to be listed in the ARTG.

Resources	Noted
Listed medicines	☐
Understanding the legislative framework for listed medicines	☐
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 Therapeutic Goods (Permissible Ingredients) Determination. Searchable database: TGA eBusiness Services.	☐
• The proposed indications (therapeutic uses) **are** covered by the Therapeutic Goods (Permissible Indications) Determination and meet any specified requirements. Searchable database: TGA eBusiness Services	☐
• The medicine is **not** required to be sterile.	☐
• The medicine does **not** contain a substance that is included in a Schedule to the Poisons Standard (the SUSMP).	☐

Your responsibilities as the sponsor of the medicine

Understand your responsibilities as the sponsor of your medicine.

Resources	Noted
Role of the sponsor	☐
An applicant (who will become the sponsor) self-lists **AUST L** medicines in the ARTG without pre-market assessment by the TGA. The sponsors makes a number of certifications [under paragraphs 26A(2)(a) to (k) and, if applicable, subsection 26A(2A)] of the Act] that their product meets all legislative requirements for safety, quality and efficacy.	☐
Sponsors must comply with the applicable conditions set out in the Therapeutic Goods (Listed Medicines—Conditions of Listing) Determination and in section 28 of the Act.	☐
As the sponsor, you must comply with any additional conditions that may be imposed at any time the medicine remains listed in the ARTG.	☐
At any time, the medicine remains listed in the ARTG, it can be subject to a TGA post market review of compliance with legislative requirements.	☐
Sponsors must also comply with post market requirements.	☐

Understand the legal framework for listed medicines

Understand the key legislation that applies to listed medicines.

Resources	Noted
Listed medicines information for new sponsors	☐
Australian Regulatory Guidelines for Listed Medicines (ARGLM)	☐
• Understanding listed and registered complementary medicine regulation	☐
• Understanding the legislative framework for listed medicines	☐
• Certifying that your listed or assessed listed medicines meet all regulatory requirements	☐
• TGA approved terminology for therapeutic goods	☐
What do I require to have a listed medicine in the ARTG?	☐
Ingredients	
Permissible Ingredients Determination	☐
Complying with ministerial and default standards for medicines	☐
Compositional guidelines	☐

Resources	Noted
Overview of compositional guidelines and templates	☐
Naming ingredients	☐
TGA approved terminology for therapeutic goods	☐
Herbal ingredients	☐
Colourings used in medicines for topical and oral use	☐
Proprietary ingredient formulations and how they are used	☐
Notification of a new proprietary ingredient	☐
Sponsors should also be aware of other legislation such as the *Customs Act 1901* or the Customs (Prohibited Imports) Regulations 1956.	☐
Applications for new ingredients	
Evaluation of substances for use in listed medicines and assessed listed medicines: user guide	☐
Mandatory requirements for an effective application to vary the Permissible Ingredients Determination	☐
Understanding the application requirements for a new substance in listed medicines	☐
Understanding the application requirements for microorganisms in listed or registered complementary medicine	☐
Comparable Overseas Bodies (COBs)	☐
• List of Comparable Overseas Bodies (COBs)	☐
• Using the Comparable Overseas Bodies process for registered complementary medicines, assessed listed medicines and substances in listed medicines	☐
• Comparable Overseas Bodies (COB) checklists	☐
Indications for listed medicines	
Permissible Indications Determination	☐
Permitted indications for listed medicines	☐
Permitted indications for listed medicines guidance	☐
Evidence for listed medicines	
Supporting claims and indications for listed medicines	☐
Using literature based submissions for listed, assessed listed and registered complementary medicines	☐
Manufacturing	
Manufacturing Medicines	☐
Therapeutic Goods (Manufacturing Principles) Determination	☐
PIC/S Guide to GMP for medicinal products	☐
Listed and complementary medicine GMP guidance	☐

Resources	Noted
Complying with the PIC/S Guide to Good Manufacturing Practice for medicinal products	☐
Dosage forms	
Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019	☐
Labelling	
Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines Labelling Order (TGO 92)	☐
Understanding labelling and presentation requirements for listed medicines	☐
Packaging	
Therapeutic Goods Order No. 95 – Child-resistant packaging requirements for medicines (TGO 95)	☐
Understanding child-resistant packaging requirements for medicines	☐
Advertising	
Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021	☐
Applying the Advertising Code	☐
Quality of listed medicines	
Therapeutic Goods (Microbiological Standards for Medicines) (TGO 100) Order 2018	☐
Meeting microbiological standards for medicines	☐
Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019	☐
Complying with quality standards for tablets, capsules and pills	☐
Understanding quality requirements for listed medicines	☐
Demonstrating the quality of listed probiotic medicines	☐
Stability testing of listed complementary medicines	☐
Analytical procedure validation for complementary medicines	☐
Nitrosamine risk in listed medicines	☐
International guidelines	
International scientific guidelines adopted in Australia	☐
European Union guidelines for herbal medicinal products	☐

Application to list a medicine

Learn how to apply to include your medicine in the ARTG.

The Electronic Listing Facility (ELF) checks against the system's inbuilt rules for listing. However, note that 'Passing validation' by ELF is **an automated** process and does not replace the sponsor's responsibility to meet all regulatory requirements.

Resources	Noted
Summary of fees and charges	☐
Apply for access to TGA Business Services (TBS).	☐
Ensure **a separate application** is lodged for each individual product so that each has a unique and identifiable AUST L number.	☐
Listed and assessed listed medicines: application and submission user guide	☐
Certifying that your listed or assessed listed medicines meet all regulatory requirements	☐
Validate the completed application in TBS.	☐
Submit the completed application in TBS.	☐
Download invoice from TBS and make payment.	☐
AUST L number issued and product included in ARTG.	☐

Post-market obligations

Understand what your responsibilities are once your medicine is included in the ARTG.

At any time a medicine remains listed in the ARTG, it can be subject to a TGA post market review of compliance with legislative requirements.

Resources	Noted
Supply and distribution of medicines	☐
Requirements for the ongoing supply, import, export, storage and handling of listed medicines	☐
Product quality reviews	☐
Understanding listed medicines compliance reviews	☐
Listed medicine compliance reports	☐
Pharmacovigilance Inspection Program	☐
Pharmacovigilance responsibilities of medicine sponsors	☐
Obligations to report adverse events	☐
Pharmacovigilance obligations of medicine sponsors - frequently asked questions	☐
Updates and changes to a product's ARTG entry	☐
• Changing a listed or an assessed listed medicine in the Australian Register of Therapeutic Goods (ARTG)	☐
• Therapeutic Goods (Groups) Order No. 1 of 2001 ('the Groups Order')	☐
• Checklists for correcting an ARTG entry for a listed medicine under paragraph 9D(1)(a) of the Act	☐

Stay up to date

Keep informed about changes and updates that may affect your medicine and your ongoing responsibilities.

Resources	Noted
Note: It is the responsibility of medicine sponsors to maintain regulatory compliance. Do not rely on the TGA to individually notify sponsors of regulatory changes.	☐
News and other regulatory changes published by the TGA.	☐
TGA consultations	☐
TGA media releases	☐
Changes to the Permissible Ingredients Determination and Permissible Indications Determination	☐

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Business Improvement and Support Section	May 2026

OFFICIAL

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