



White paper: How to list or register a medicine in Australia

Every year, thousands of Australians avoid hospitalisation, surgery or death because of safe and effective lifesaving prescription medicines.

So who regulates these medicines? Are all medicines regulated in the same way? What is the regulatory process to get approval to sell these medicines in Australia? This White Paper highlights the key requirements for listing or registering medicines in Australia.

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An Overview of Australia's Regulatory System for Medicines

In addition to the Therapeutic Goods Administration (TGA), there are four other key roles in Australia's regulatory framework for medicines. These can be separate legal entities or combined. They are:

Who?	Role
Manufacturers	To legally manufacture the medicine in Australia or overseas
Sponsors	To import, export, or manufacture medicines. An Australian manufacturer may also act as a sponsor. The sponsor must be a resident of Australia or be an incorporated body in Australia, with the representative of the company residing in Australia.
Sales organization / Distributers	Distributers can be third-party logistics providers or fourth party logistics providers
Agents	Consultants, such as PharmOut, who act on behalf of manufacturers or sponsors, to register medicines in Australia

In order to list or register a medicine in Australia, you need to first ensure that the manufacturer is licensed (Australian) or certified (International) by the TGA. This is to ensure that the manufacturer is in compliance with the requirements of Good Manufacturing Practice (GMP). You must also:

- assess the risk of your medicine
 - low-risk medicines must be assessed for safety and quality and **listed** on the [Australian Register of Therapeutic Goods \(ARTG\)](#)¹ before supply in Australia
 - high-risk medicines must be assessed for safety, efficacy and quality and **registered** on the ARTG before supply in Australia
- implement post-market surveillance systems and adverse event reporting programs
- ensure that advertising and labelling is performed in accordance with the [Therapeutic Goods Advertising Code](#).
- pay initial and annual fees for listing or registering your product for supply in Australia.

¹ The ARTG is a database of all therapeutic goods approved for supply in or export out of Australia. The ARTG was established under the Therapeutics Goods Act 1989 and can be viewed at:

<https://www.ebs.tga.gov.au/ebs/ANZTPAR/PublicWeb.nsf/cuMedicines?OpenView>

What is a medicine?

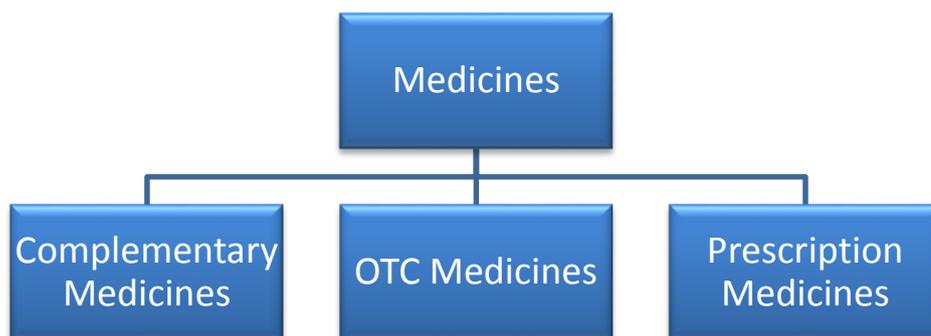
The Therapeutic Goods Act 1989 defines **medicines** as:

'therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human.'

These include goods Australians rely on every day, such as vitamin tablets and sunscreens, through to goods used to treat serious conditions, such as prescription medicines, vaccines, and blood products. The TGA is responsible for ensuring that therapeutic goods available for supply into or export from Australia are safe and fit for their intended purpose. The TGA also regulate the supply of in vitro diagnostics (IVDs) and medical devices (surgical implants, pacemakers etc). The regulatory process for these products is outside the scope of this White Paper. Please refer to other White Papers on how to register medical devices and in vitro diagnostic devices, which are available on the PharmOut website.

Some products that may not be considered as medicines in other countries may be classified as medicines in Australia, based on their ingredients, dosage form and/or health benefit claims.

The TGA categorises medicines into the following groups for regulatory evaluation:



What is a complementary medicine?

The Therapeutic Goods Administration Act 1989 defines **complementary medicines** as:

'therapeutic goods consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and:

- (a) a traditional use; or*
- (b) any other use prescribed in the regulations.'*

Traditional use is defined as:

'in relation to a designated active ingredient, means use of the designated active ingredient that:

- (a) is well documented, or otherwise established, according to the accumulated experience of many traditional health care practitioners over an extended period of time; and*
- (b) accords with well-established procedures of preparation, application and dosage.'*

Complementary medicines (also known as 'traditional' or 'alternative' medicines) include the following products:

- vitamins
- minerals
- herbs
- aromatherapy
- homoeopathic.

The Office of Complementary Medicines (OCM) is responsible for the evaluation of complementary medicines at the TGA.

Complementary medicines can be regulated as listed medicines or non-prescription registered medicines.

What is an OTC medicine?

An over-the-counter (OTC) medicine is a therapeutic good mentioned in Part 3 of Schedule 10 of the Therapeutic Goods Act 1989, that does not meet the criteria for mention in Schedule 4, 8 or 9 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). Examples include:

- antiseptics
- sunscreens
- all other therapeutic goods, except for a therapeutic device, not mentioned in another Part of Schedule 10
- an excipient in therapeutic goods mentioned in Schedule 10
- therapeutic goods referred for evaluation to the Scheduling and Over The Counter Drug Evaluation Section of the TGA.

The Office of Medicines Authorisation (OMA) is responsible for evaluating OTC medicines at the TGA.

The majority of OTC medicines are non-prescription registered medicines and examples include mild analgesics, cough/cold preparations, and anti-fungal creams.

What is a prescription medicine?

Prescription medicines are high-risk medicines that contain ingredients that are described in Schedule 4, Schedule 8 or Schedule 9 of the SUSMP and are available by prescription only.

The TGA Drug Safety Evaluation Board (DSEB) evaluates the majority of prescription medicine applications. Examples of prescription medicines are all antibiotics (e.g. amoxil) and all injectable products (e.g. insulin for diabetics).

All prescription medicines must be **registered**.

How do you determine the regulatory path for your product as a listed or registered medicine?

In order to select the appropriate regulatory evaluation process for your medicine, you need to determine whether your medicine is a **listed** or **registered** product, which is in turn determined by the level of potential risk.

How does the TGA assess the level of risk?

The TGA assesses the medicine as low or high risk by asking the following questions:

- Does the medicine contain a substance scheduled in the SUSMP (see next section below)?
- What is the dosage form of the medicine?
- What are the promotional or therapeutic claims made for the medicine?
- Are there any significant side effects associated with the use of the medicine?
- Is the medicine used to treat life-threatening or very serious illnesses?
- Are there any adverse effects from prolonged use or inappropriate self-medication?

Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)

The SUSMP lists all the substances, their classifications, labelling and packaging requirements. The classification takes into account a substance's toxicity profile, pattern of use, indications, product formulation and dosage, potential for abuse and need for access.

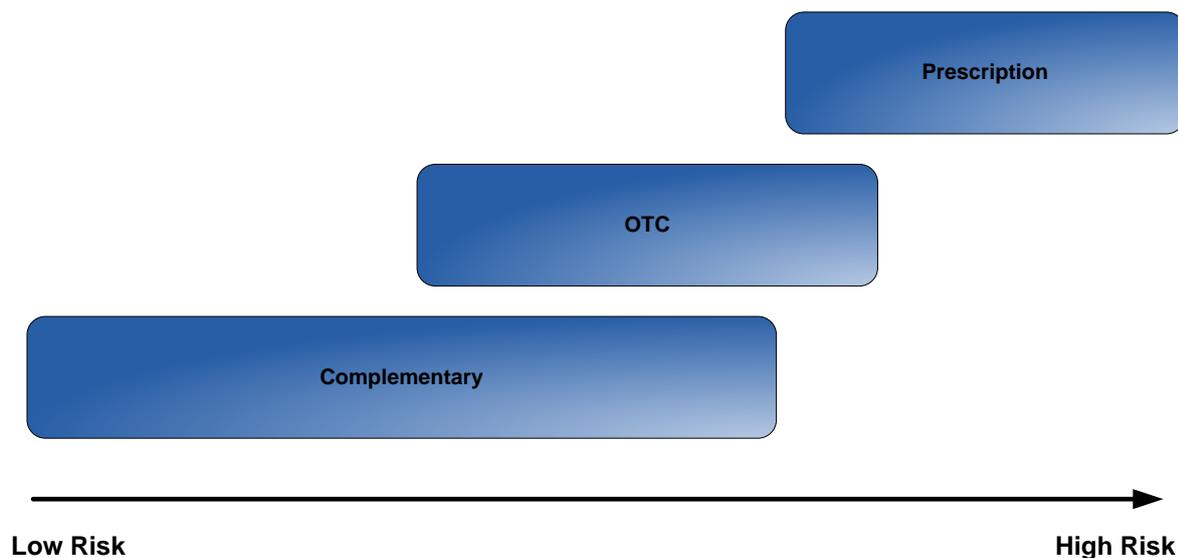
Medicines listed in the SUSMP are considered high-risk and must be registered.

The table below shows some examples:

Schedule	Description	Use	Example
2 (S2) Pharmacy Medicine	Non-prescription medicines sold in pharmacies. A pharmacist's advice may be required for their safe use.	Therapeutic (drugs)	Daily use of 1200 mg or less of ibuprofen in preparations for oral use
3 (S3) Pharmacist only Medicine	Non-prescription medicines for supply by a pharmacist only.	Therapeutic (drugs)	Ventolin aerosol inhaler containing measured doses of 100 mcg (or less) salbutamol
4 (S4) Prescription Only Medicine / Prescription Animal Remedy	Prescription only medicines for supply by a pharmacist only.	Therapeutic (drugs)	Amoxicillin, Pneumococcal vaccine

Schedule	Description	Use	Example
5 (S5) Caution	Substances with a low potential to cause harm; appropriate labelling and packaging can reduce the extent of the harm.	Agricultural, domestic and Industrial	Turpentine oil in preparations containing more than 25% turpentine oil
6 (S6) Poison	Substances with a moderate potential to cause harm; distinctive packaging with strong warnings and safety directions on the label can reduce the extent of the harm.	Agricultural, domestic and Industrial	Sulfuric Acid except in fire extinguishers or in preparations containing 0.5 % or less of sulfuric acid
7 (S7) Dangerous Poison	Substances with a high potential for causing harm at low exposure and require special precautions during manufacture, handling or use.	Agricultural, domestic and Industrial	Cyanides except ferricyanides, ferrocyanides or if specified in other schedules
8 (S8) Controlled Drug	Substances that require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.	Therapeutic (drugs)	Methadone, Morphine
9 (S9) Prohibited Substance	Substances which may be abused or misused; manufacture, possession, sale or use should be prohibited by law except when required for medical or scientific research	Medical or Scientific research	Heroin, coca leaf

The following diagram represents how the level of risk is categorised for medicines.



As described above, complementary medicines can be listed (low risk) or registered as non-prescription medicines (higher risk). This is the same for OTC medicines. All prescription medicines are categorised as high risk and must be registered.

Listed Medicines (low-risk)

A listed medicine is one that contains chemical, biological, or herbal ingredients that are well-known and considered safe to the user. They are considered as low-risk because:

- their ingredients appear on the TGA's approved list of substances and do not appear in the SUSMP
- the therapeutic claim for the medicine relates to health maintenance, health enhancement, or non-serious, self-limiting conditions.

The TGA assesses listed medicines for safety and quality only. Sponsors are responsible for certifying that they hold evidence to support all indications and claims made for the product. The TGA can audit this evidence.

Registered Medicines (high-risk)

There are two kinds of registered medicines:

- prescription registered
- non-prescription registered which may include registered complementary and OTC products.

High-risk medicines must be registered. The TGA assesses registered medicines for safety, quality, and efficacy.

How do the TGA assess the product for registration?

For registration of a product, the TGA will make an assessment of the safety, quality and efficacy of the product and an assessment of the safety and quality of any new substances that are in the product. These assessments are based on information supplied in the application including:

- manufacturer's GMP license issued by the TGA or a regulatory authority participating in the Pharmaceutical Inspection Co-operation Scheme (PIC/S)
- manufacturing process and controls, including development and validation of processes
- testing reference materials, test procedures, validation and results, including results for strength, purity and stability on storage
- non-human pharmacology and toxicology data
- human clinical trial and other data for safety and efficacy .

In addition, copies of intended packaging, labels, product information and consumer information must be included in the application. All information supplied to the TGA for evaluation must be in English.

The content and format of the information for assessment must comply with the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use Common Technical Document (CTD) for prescription medicines. The CTD format is not a mandatory requirement for a new registered complementary medicine application, however, presentation in the CTD format will expedite evaluation by the TGA. For more information on CTD see the [PharmOut website](#) or [contact PharmOut](#).

How do the TGA assess the product for listing?

To be a listed medicine on the ARTG a product:

- can only contain certain low risk ingredients in acceptable amounts that are permitted for use in listed medicines by the TGA (in the Australian Approved Names List for Therapeutic Substances),
- must be manufactured in accordance with the principles of Good Manufacturing Practice (GMP)
- must not be required to be sterile
- can only make therapeutic claims for use for health maintenance and health enhancement or certain indications for non-serious, self-limiting conditions.

The TGA will make an assessment of the safety and quality of the product. The assessments are based on information to be supplied in English in the application including:

- manufacturer's GMP license issued by the TGA or a regulatory authority participating in the Pharmaceutical Inspection Co-operation Scheme (PIC/S).
- ingredients and their quantities. The ingredients must be low risk ingredients in acceptable amounts as published in the Ingredients Australian Approved Names List for Therapeutic Substances available via the TGA eBusiness Services website
- indications for use of the medicine
- warnings for use of the medicine

The TGA may assess that you are required to submit evidence of, or information to establish the safety or efficacy of the products in the listing application. Sponsors must hold information or evidence to demonstrate that your medicine:

- meets all specifications for the shelf life of the medicine, the recommended storage conditions and the expiry date stated on the medicine label
- meets any indication or claim that you make about your medicine. This may include non-human pharmacology and toxicology data, human clinical trial and other data for safety and efficacy data.

In addition, copies of intended packaging, labels, product information and consumer information must be held by the sponsor.

For a complementary medicine containing a new substance, the application for evaluation may require a different process

How much does it cost to register a medicine in Australia?

The current² application and annual fees for registering or listing a medicine on the ARTG are:

Medicine Type	Application Fee* (\$AUD)	Annual Charge (\$AUD)
Prescription (new chemical entry)	221,400	Biologics 6,585 Non-Biologics 3,955
Prescription (generic)	84,600	Biologics 6,585 Non-Biologics 3,955
Non Prescription OTC and Complementary Medicine	from 11,110	9,665
Listed Medicine OTC and Complementary Medicine	from 760	965

*For registration of medicines, the TGA fees include application and evaluation. The evaluation fees for non-prescription medicines vary according to the level of supporting information required, which is based on the level of perceived risk.

Where can I find more information about how to get my medicine approved for supply in Australia?

PharmOut have a number of resources to provide helpful information on how to get medicines approved for supply in Australia, including:

- White Papers providing more detail on how to get TGA approval to supply the different categories of medicines in Australia including Prescription, Complementary, and OTC medicines
- links to websites where more information is available.

A glossary for TGA terms and their meanings is provided overleaf.

² As at 1 July 2014. For fees and charges updates check TGA website <http://www.tga.gov.au/>.

Glossary

Term	Meaning
Active Ingredient	The therapeutically active component in a medicine's final formulation that is responsible for its physiological or pharmacological action.
Australian Approved Names List	<p>The TGA has developed and maintains lists of Australian approved terminology, to ensure accuracy and consistency in the information compiled in the ARTG. For medicines, the lists cover substances (active ingredients and excipients), containers, dosage forms, routes of administration and units of expression and proportion.</p> <p>The current list of approved ingredient names (chemical, biological and herbal) is located on the Ingredients Database on the TGA eBusiness Services website.</p> <p>The list of other approved terminology for medicines (routes of administration, dosage forms etc.) are located in the Code Tables on the TGA eBusiness Services website.</p>
Australian Register of Therapeutic Goods (ARTG).	A list of therapeutic goods that have been entered on a computer database and are regulated by the TGA.
Complementary Medicine	<p>Therapeutic goods consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and:</p> <p>(a) a traditional use; or</p> <p>(b) any other use prescribed in the regulations.</p>
Consumer Medicine Information	A leaflet that contains information about a medicine written specifically for consumers
CTD-Common Technical Document	<p>The CTD provides the framework for the order in which documents must appear in the TGA submission, organized across 5 modules. Module 1 is unique to Australia, while modules 2-5 are globally harmonised.</p> <p>The CTD is the preferred format for TGA for medicine registration applications.</p>

Term	Meaning
Directions for use	Information relating to: <ul style="list-style-type: none"> (a) appropriate doses of the goods; and (b) the method of administration or use of the goods; and (c) the frequency and duration of treatment for each indication of the goods; and (d) the use of the goods by persons of particular ages or by persons having particular medical conditions.
ELF (Electronic Listing Facility)	An online regulatory submission process for listing complementary medicines in the ARTG.
Excipient	Any ingredient, excluding the drug substances, incorporated in a formulation for enhancing stability, usefulness or elegance, or facilitating preparation; for example, base, carrier, coating, colour, flavour, preservative, stabilizer, and vehicle
Generic Medicine	A medicine in comparison to a registered medicine that: <ul style="list-style-type: none"> (a) has the same quantitative composition of therapeutically active substances, being substances of similar quality to those used in the registered medicine; and (b) has the same pharmaceutical form; and (c) is bioequivalent; and (d) has the same safety and efficacy properties.
GMP-Good Manufacturing Practice	A quality assurance system for the manufacture of therapeutic goods based on best international practice. GMP includes quality management, manufacturing processes, documentation and inspection.
Herbal substance	All or part of a plant or substance (other than a pure chemical or a substance of bacterial origin): <ul style="list-style-type: none"> (a) that is obtained only by drying, crushing, distilling, extracting, expressing, comminuting, mixing with an inert diluent substance or another herbal substance or mixing with water, ethanol, glycerol or aqueous ethanol; and (b) that is not subjected to any other treatment or process other than a treatment or process that is necessary for its presentation in a pharmaceutical form.

Term	Meaning
Medicine	(a) therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal; and (b) any other therapeutic goods declared by the Secretary, for the purpose of the definition of therapeutic device, not to be therapeutic devices.
OPAL-OTC Products Application Lodgement	An online regulatory submission process for entering OTC medicines in the ARTG.
PREMIER – Prescription Medicines Electronic Lodgement System	An online regulatory submission process for entering Prescription medicines in the ARTG.
Product Information	A document that contains sufficient information to ensure safe and effective use of a medicine under nearly all circumstances. It presents a scientific, objective account of the medicine’s usefulness and limitations, as shown by the data supporting application for registration of medicine with the TGA.
Quality	Degree to which a set of inherent properties of a product, system or process fulfills its requirement.
Risk	The combination of the probability of occurrence of harm and the severity of that harm.
Substance	Any medicine or poison.
Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)	The document through which a uniform national approach to medicine availability, labelling and packaging is achieved.
Therapeutic goods	Goods used for therapeutic use, including medicines and medical devices.
Therapeutic Goods Administration (TGA)	The current regulator of therapeutic goods in Australia.

Term	Meaning
Therapeutic use	Use in or in connection with: <ul style="list-style-type: none"> (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or (b) influencing, inhibiting or modifying a physiological process in persons or animals; or (c) testing the susceptibility of persons or animals to a disease or ailment; or (d) influencing, controlling or preventing conception in persons; or (e) testing for pregnancy in persons; or (f) the replacement or modification of parts of the anatomy in persons or animals.
Traditional use	<ul style="list-style-type: none"> (a) is well documented, or otherwise established, according to the accumulated experience of many traditional health care practitioners over an extended period of time; and (b) accords with well established procedures of preparation, application and dosage.

References

List all references used

Therapeutic Goods Administration

www.tga.gov.au

TGA - Australian register of therapeutic goods (ARTG)

<https://www.ebs.tga.gov.au/>

TGA – Therapeutic goods advertising code

http://www.tga.gov.au/industry/legislation-tgac.htm#.U7Xj0_mSxid

Therapeutic Goods Regulations 1990,

[http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/0/C85AFC5800F19F8ECA257308002F4D8E/\\$file/TherapeuticGoodsRegs1990.pdf](http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/0/C85AFC5800F19F8ECA257308002F4D8E/$file/TherapeuticGoodsRegs1990.pdf)

Therapeutic Goods Act 1989,

[http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/72D440E51DF66177CA257375000E52B1/\\$file/TherapeuticGoods1989_WD02_Version2.pdf](http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/72D440E51DF66177CA257375000E52B1/$file/TherapeuticGoods1989_WD02_Version2.pdf)

Standard for the Uniform Scheduling of Medicines and Poisons No. 1, Poisons Standard

<http://www.tga.gov.au/industry/scheduling-poisons-standard.htm#.U6OovvmSwYE>

TGA eBusiness Services

<http://www.tga.gov.au/about/ebs.htm#.U7XkGPmSxid>

Ingredients Australian Approved Names List

<https://www.ebs.tga.gov.au/>

Sources

Links used within this document are prone to change. Please refer to the appropriate source for the most recent information. We endeavour to keep an up-to-date record of information at

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