



White Paper

# How to register medicines in Australia

The Australian pharmaceutical industry employed approximately 34,000 people in 2004-05 and spent \$752 million on research and development. In the 12 months to November 2007, the industry exported around \$3.9 billion making pharmaceuticals Australia's second largest manufactured export.<sup>1</sup>

Every year thousands of Australians escape hospitalisation, surgery and death because of medicines. Who regulates medicines? Are all medicines regulated in the same way? What is the process for medicine registration? This white paper highlights the key requirements to register medicines in Australia.

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<http://www.innovation.gov.au/Industry/Pharmaceuticals/Pages/AustralianPharmaceuticalsIndustryFactSheet.aspx>

## An Overview of Australia's Regulatory System for Medicines

There are four key players in Australia's regulatory system for medicines:

Who?	Role
Manufacturers	To manufacture the medicine in Australia or overseas
Sponsors	To import, export, or manufacture medicines. An Australian manufacturer may also act as a sponsor.
Therapeutic Goods Administration (TGA)	Government body that has regulatory control of therapeutic goods (including medicines) in Australia
Agents	Consultants, such as PharmOut, that act on behalf of manufacturers or sponsors, to register medicines in Australia

In order to register a medicine in Australia you need to ensure that the manufacturer is licensed and in compliance with the requirements of Good Manufacturing Practice (GMP).

You also need to:

- assess the risk of your medicine
  - a. high-risk medicines must be assessed for safety, efficacy and quality and *registered* on the Australian Register of Therapeutic Goods (ARTG)<sup>2</sup> before supply in Australia
  - b. low-risk medicines must be assessed for safety and quality and *listed* 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.

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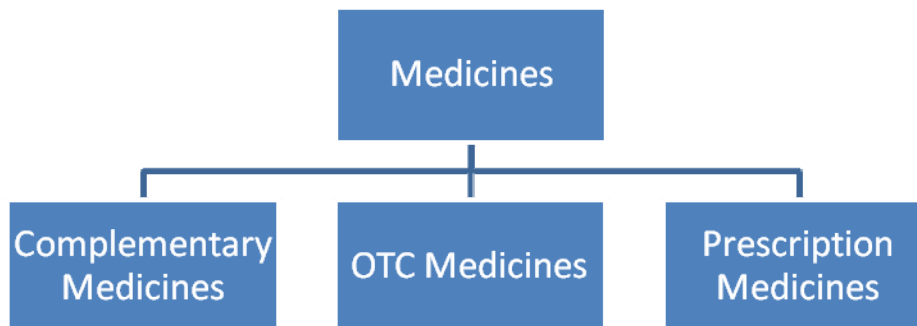
<sup>2</sup> The ARTG is a database of all therapeutic goods approved for supply or export out of Australia. The ARTG was established under the Therapeutics Goods Act 1989 and can be viewed at: <https://www.tgasime.health.gov.au/SIME/ARTG/ARTGPublicWeb.nsf?OpenDatabase>

## What is a medicine?

The *Therapeutic Goods Act 1989* defines a **medicine** 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 or animal.'*

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 vitamin, mineral, herbal, aromatherapy, and homoeopathic products.

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 Poisons Standard. 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 Non-prescription Medicines Branch (NPMB) 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 are prescription medicines?

Prescription medicines are high-risk medicines that contain ingredients on that are described in Schedule 4, Schedule 8 or Schedule 9 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) and are available by prescription only. The Drug Safety Evaluation Board (DSEB) evaluates the majority of prescription medicine applications. Examples of prescription medicines are all prescription medicines (e.g. amoxyl) and all injectables (e.g. insulin for diabetics). All prescription medicines must be registered.

## How to determine if your product is a listed or registered medicine?

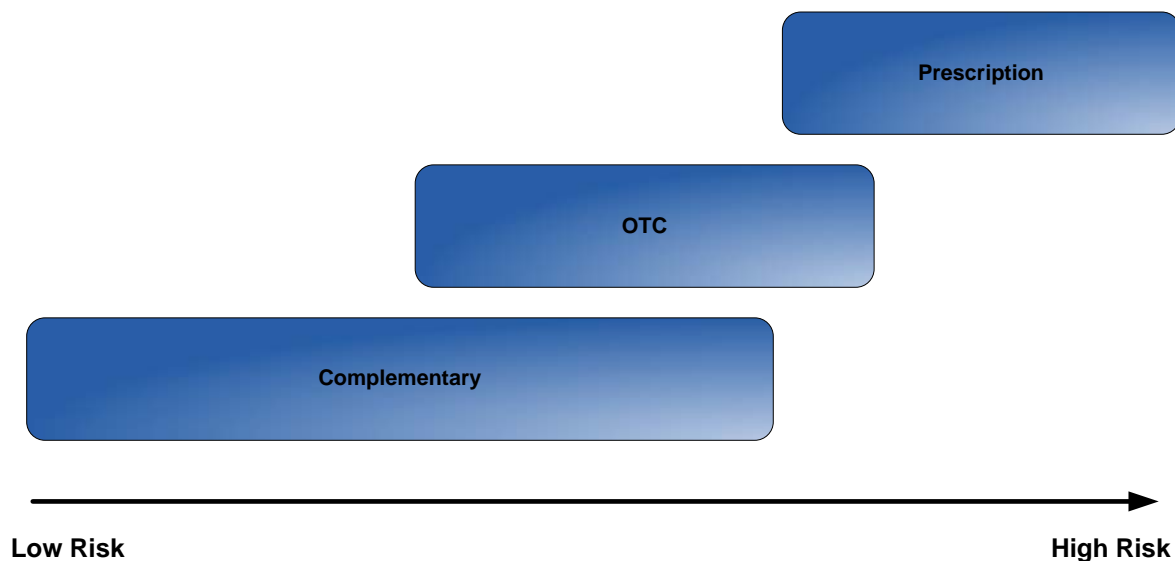
In order to select the appropriate regulatory evaluation process for your medicine you need to determine whether your medicine is a *listed* or *registered* product. As defined earlier, high-risk medicines must be *registered* on the ARTG, while low-risk medicines need to be *listed*.

## 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 SUSDP?
- 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?

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



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.

## Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)

The SUSDP lists all the substances, their classifications, labeling 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 SUSDP are considered high-risk.

The table below shows some examples:

Schedule	Description	Use	Example
<b>2 (S2) Pharmacy Medicine</b>	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
<b>3 (S3) Pharmacist only Medicine</b>	Non-prescription medicines for supply by a pharmacist only.	Therapeutic (drugs)	Ventolin aerosol inhaler containing measured doses of 100 mcg (or less) salbutamol
<b>4 (S4) Prescription Only Medicine</b>	Prescription only medicines for supply by a pharmacist only.	Therapeutic (drugs)	Amoxicillin, Pneumococcal vaccine
<b>5 (S5) Caution</b>	Substances with a low potential to cause harm; appropriate labeling and packaging can reduce the extent of the harm.	Agricultural, domestic and Industrial	Turpentine oil in preparations containing more than 25% turpentine oil
<b>6 (S6) Poison</b>	Substances with a moderate potential to cause harm; the use of 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.
<b>7 (S7) Dangerous Poison</b>	Substances with a high potential for causing harm at low exposure and require special precautions during manufacture, handling for use.	Agricultural, domestic and Industrial	Cyanides except ferricyanides, ferrocyanides or if specified in other schedules
<b>8 (S8) Controlled Drug</b>	Substances that require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or	Therapeutic (drugs)	Methadone, Morphine

Schedule	Description	Use	Example
	psychological dependence.		
<b>9 (S9) Prohibited Substance</b>	Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law. except when required for medical or scientific research	Medical or Scientific research	Heroin, coca leaf

## 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, and their ingredients appear on the TGA's approved list of substances and do not appear in the SUSDP. 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.

Examples of listed medicines include the majority of complementary medicines and sunscreens.

## Registered Medicines (high-risk)

There are two kinds of registered medicines:

- prescription registered
- non-prescription registered.

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

Examples of non-prescription registered medicines are cold preparations and anti-fungal creams. An example of a prescription registered medicine is insulin injections for diabetics.

## How do you list a complementary medicine?

In order to list a complementary medicine, you need to create an e-business account for the Electronic Listing Facility (ELF). When you have your user name and password, you can enter the TGA online website and the ELF home page. From here, you are able to create a general listing application.

In order to create a **listing**, you need the following information:

- client reference and details
- product name and any relevant export names
- product type
- whether the application is in response to a Section 30<sup>3</sup>
- payment exemption number (if you received one from the TGA)
- formulation details including dosage form, route of administration, container type, container volume, container closure, maximum single dose, maximum daily dose, minimum weight of each dosage
- ingredients including whether the ingredient is active, an excipient, active homeopathic or a proprietary ingredient
- components and their quantities
- manufacturer's details including whether the manufacturer is Australian or an overseas manufacturer. If an overseas manufacturer is selected then clearance ID or GMP Reference number must be provided
- coded warning details if required
- indication of whether you need to submit safety and efficacy data to the secretary.

When you submit your application, it becomes available for view on the ARTG listing. A random selection of submissions is subject to review by the OCM. They may request to see information relating to the presentation, advertising materials, or information about product manufacture.

## How do you register a complementary medicine?

If the complementary medicine is high risk then it must be **registered**. 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. The application should include:

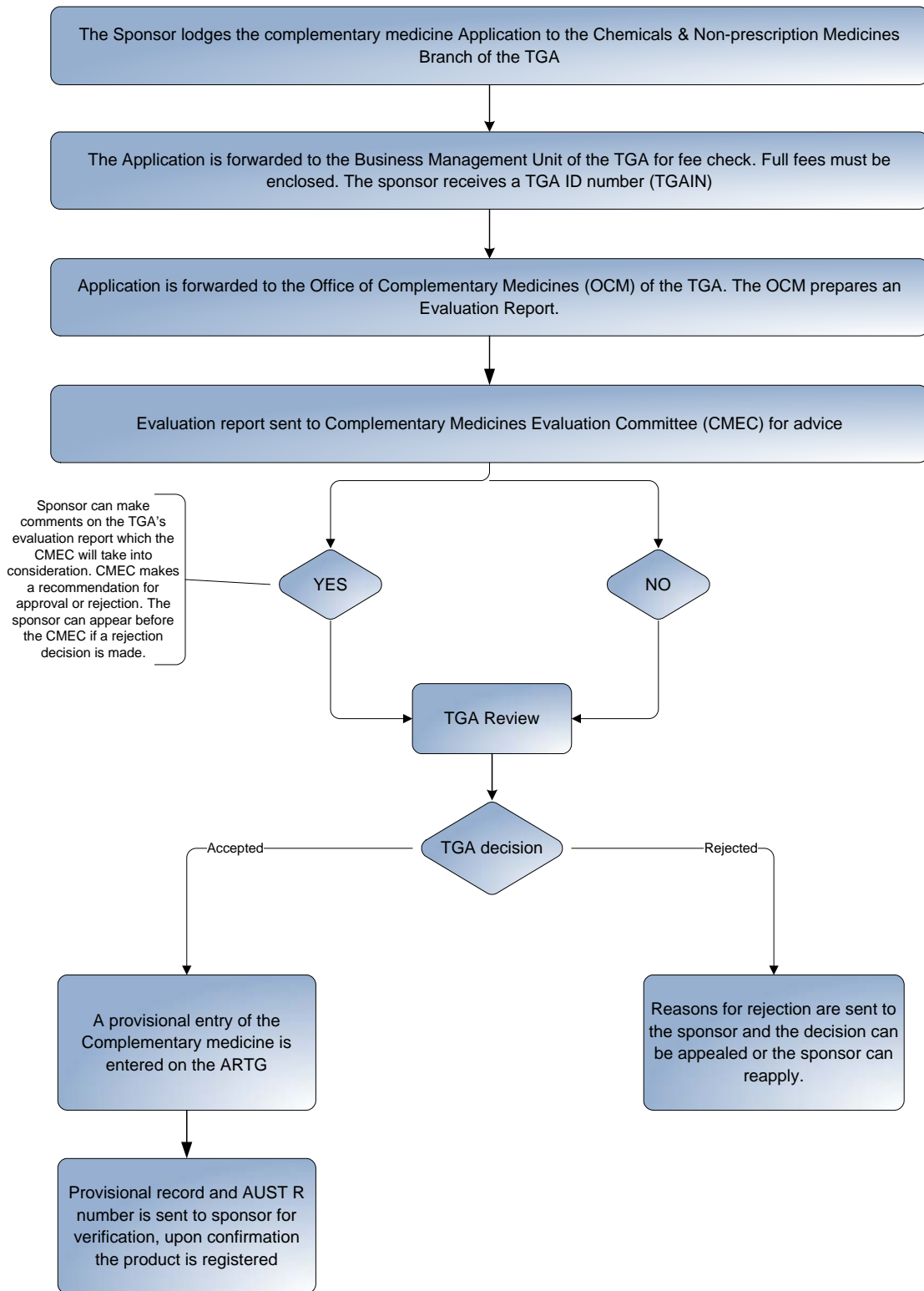
- general description of the complementary medicine
- chemical constituents
- assay procedures
- purity tests
- stability tests-including details on storage data
- non-human pharmacology and toxicology data
- human clinical trial data and other human data (in relation to the intended use)
- data to substantiate intended use

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<sup>3</sup> A section 30 is a letter from the TGA that proposes to cancel a current listed medicine

- intended dosage form
- list of adverse effects-known, potential or suspected
- list of the current regulatory status of the complementary medicine in the following countries: New Zealand, Canada, USA, European Community, United Kingdom or Sweden (or others if these are known)
- additional information to support regulatory application
- GMP license
- labeling
- post market surveillance.

Once the application is submitted, the TGA follows the procedure detailed below to assess the complementary medicine:



## Post market activities for all complementary medicines

Post-market regulatory activities are a requirement for all complementary medicines and include reporting of adverse reactions, audit of manufacturers, and laboratory testing ensure the quality, safety and effectiveness of medicines regulated by the TGA.

## How do you list an OTC Medicine?

In order to list an OTC medicine, you need to create an e-business account for the OTC Products Application Lodgment (OPAL) system. When you have your username and password, you can enter the TGA online website and the OPAL homepage. From here, you are able to create a general listing application.

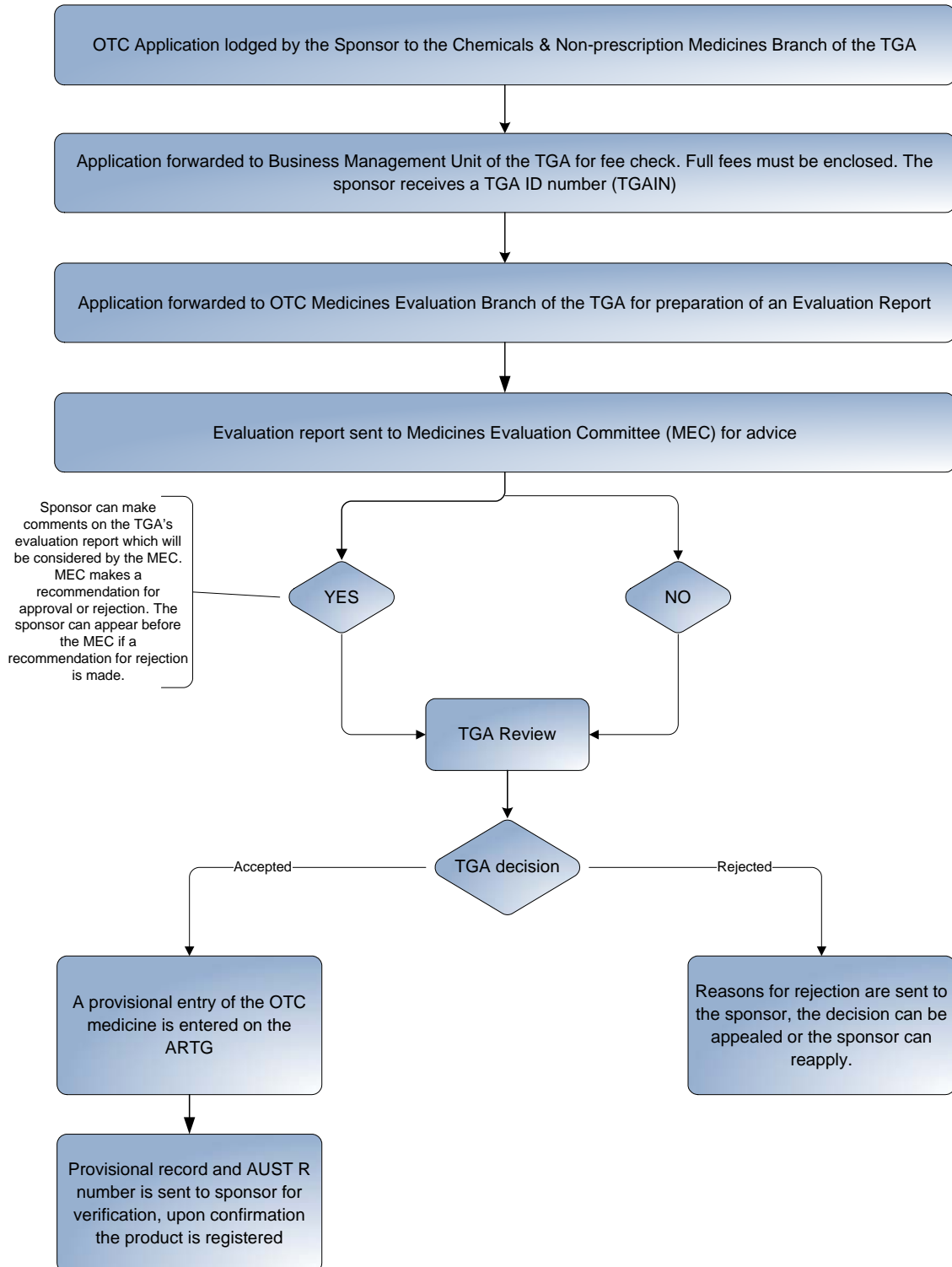
In order to create a **listing** you need the following information:

- client reference and details
- product name and any relevant export names
- product type
- payment exemption number (if you received one from the TGA)
- label name and export names (if applicable)
- proposed therapeutic indications
- pack size
- SUSDP schedule that the medicine falls under
- Dosage form, route of administration, container type and closure
- Ingredients including whether the ingredient is active, an excipient, active homeopathic or a proprietary ingredient
- components and their quantities
- shelf life details
- manufacturer's details including whether the manufacturer is Australian or an overseas manufacturer. If an overseas manufacturer is selected then clearance ID or GMP reference number must be provided
- indication of supporting data that has been sent to the TGA including chemical, stability, toxicological, clinical or other data.
- printed labeling and packaging materials.

When you submit your application, it becomes available for view on the ARTG listing.

## How do you register an OTC Medicine?

The process to register an OTC medicine is similar to complementary medicines, as detailed below.



## Technical Documentation Required

The basic technical documentation required for the evaluation of an OTC medicine is:

- specifications and stability data
- copies of all labeling including package inserts
- a copy of the Product Information and Consumer Medicine Information documents where relevant
- relevant efficacy and safety information.

## Post marketing activities for all OTC medicines

Post-market regulatory activities are a requirement for all OTC medicines and include the reporting of adverse reactions, audit of manufacturers, and laboratory testing ensure the quality, safety and effectiveness of medicines regulated by the TGA.

The TGA has a sampling program in which random samples of OTC medicines are purchased from the market, sent in from sponsors or manufacturers in Australia by TGA request, and are tested by the TGA. Products that do not meet the required standards may require corrective action, recalls or be removed from the ARTG.

## How do you register a prescription medicine?

There are three categories for registration of prescription medicines:

### Category 1

Category 1 applications are required for the following:

- a new chemical/biological entity
- a new generic medicine
- new dosage forms
- new strengths
- extensions to indications
- changes to the product information
- significant variations to an existing product.

### Category 2

Category 2 applications are required when the product to be registered is identical in all aspects to a product that has already been registered in two acceptable countries i.e. Canada, Sweden, The Netherlands, UK & USA. Two independent evaluation reports need to be submitted with the application.

### Category 3

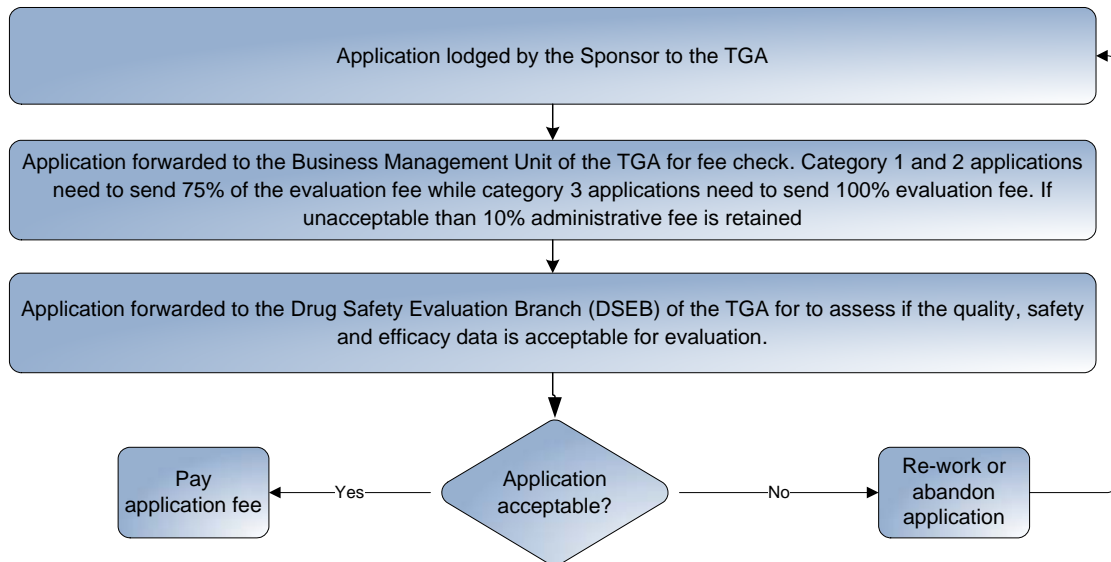
Category 3 applications are required when there are changes to the quality data of a product that has already been entered into the ARTG, and no clinical, non-clinical or bioequivalence data is required. A rationale is required to justify why clinical, non-clinical or bioequivalence data is not required.

In order to register a prescription medicine, you need to create an e-business account for the Prescription Medicine Electronic Lodgement System (PREMIER). When you have your username and password, you can enter the TGA online website and the PREMIER homepage. From here, you can create an application. Your application should include the following:

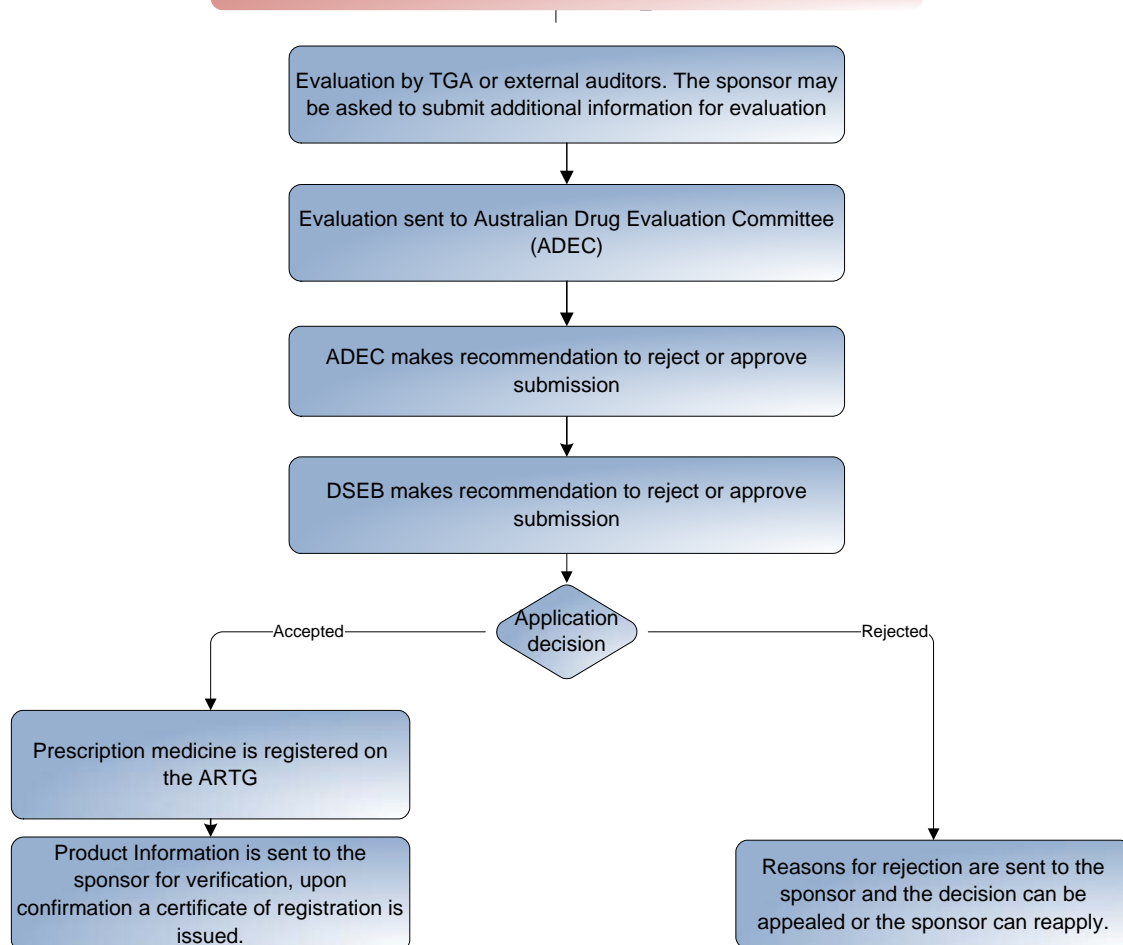
- client reference and details
- indication of the submission type (category 1 or 2)
- label name
- proposed therapeutic indications
- dosage form
- route of administration
- container type and material
- visual identification of dosage form
- ATC code
- Printed product material
- Ingredient, including whether the ingredient is active, excipient, active homeopathic, or a proprietary ingredient
- pack size
- SUSDP schedule that medicine falls under
- Shelf life details
- Manufacturer's details including whether the manufacture is Australian or an overseas manufacturer. If an overseas manufacturer is selected then clearance ID or GMP reference number must be provided

Once the application is submitted the TGA follows the procedure detailed below:

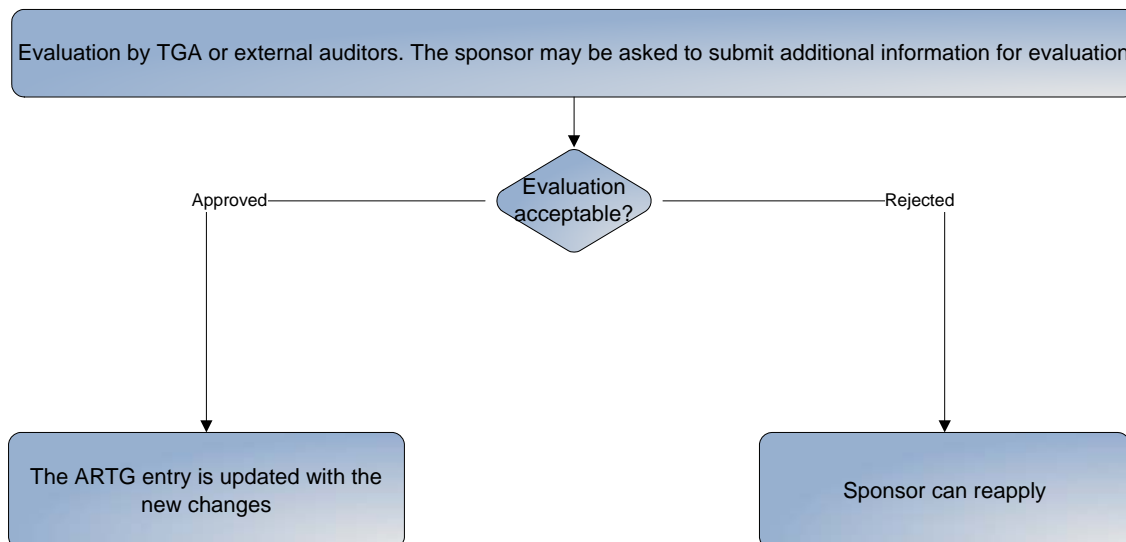
**All prescription medicine applications go through the following initial steps:**



**Category 1 and 2 Applications then go via the following path:**



**Category 3 Applications then go via the following path:**



## Technical Documentation Required<sup>4</sup>

The technical documentation for prescription medicines should be prepared according to the ICH Common Technical Document (CTD) format and consists of 5 modules. The format for Module 1 is unique to Australia. The formats for Modules 2 – 5 are globally harmonised.

- Module 1: Australian administrative requirements
- Module 2: CTD Summaries: Quality, Pre-Clinical, Clinical
- Module 3: Quality data: Drug Substance, Drug Product, Regional Requirements
- Module 4: Pre-Clinical data
- Module 5: Clinical data

Module 1 for Australia consists of:

- covering letter
- table of contents
- application form<sup>5</sup>
- labeling and packaging<sup>6</sup> includes product information, consumer medicine information and labeling mock-ups
- information about the experts who compiled the CTD summaries in Module 2
- information for specific types of applications (e.g. generics, expansion of indications, new brand names etc.)
- drug master file or EDQM Certificate of suitability details and letters of access<sup>7</sup>

<sup>4</sup> More information on the CTD can be viewed at <http://www.tga.gov.au/docs/html/eugctd.htm>. Please note that Category 3 applications do not need to submit the module 2 summaries.

<sup>5</sup> See <http://www.tga.gov.au/docs/pdf/pmrform.pdf>

<sup>6</sup> See <http://www.tga.gov.au/pmeds/pmbestpractice.htm>

<sup>7</sup> The letter of access enables the TGA to use the Drug Master File or EDQM Certificate of Suitability

- GMP Status: the GMP certificates should be sent straight to the Manufacturers Assessment Branch.
- details of any pre-submission meetings with TGA
- statement to provide individual patient data from clinical, bioavailability and bioequivalence studies if requested by TGA
- overseas regulatory status of the product, including details of submissions, approvals, withdrawals or rejections
- overseas evaluation reports
- summary of biopharmaceutical studies
- details of paediatric development program for the product (if applicable).

### Post market activities for all Prescription medicines

Post-market regulatory activities are required for all prescription medicines. Post market activities include ensuring that there is no change in the quality of the product unless authorised by the TGA, and reporting of adverse reactions or similar experiences. A log must be kept of all problems associated with the medicine and regular surveillance GMP audits of manufacturers must be performed to ensure the quality, safety and efficacy of the medicine.

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

The current<sup>8</sup> application and annual fees for listing or registering a medicine on the ARTG are:

Medicine Type	Application and Evaluation Fee (\$AUD)	Annual Charge (\$AUD)	
Prescription (new chemical entry)	170,200	Biologics	5070
		Non-Biologics	3030
Prescription (generic)	65,000	Biologics	5070
		Non-Biologics	3030
OTC	990		920
Complementary Medicine	990		920
Listed Medicine	540		690

<sup>8</sup> As at November 2007

## 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	The document entitled Australian Approved Names List for Therapeutic Substances, as in force from time to time, published by the Therapeutic Goods Administration
Australian Register of Therapeutic Goods (ARTG).	A list of therapeutic goods that have been entered on a computer database that are regulated by the TGA
Complementary Medicine	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.
Consumer Medicine Information	A leaflet that contains information about a medicine written specifically for consumers
CTD-Common Technical Document	The preferred format of the TGA for the application of a medicine. The CTD consists of 5 modules. Module 1 is unique to Australia, while modules 2-5 are globally recognised.
Directions for use	Information relating to:  (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 Australian Register of Therapeutic Goods (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

Term	Meaning
<b>Generic Medicine</b>	<p>A medicine in comparison to a registered medicine that:</p> <ul style="list-style-type: none"> <li>(a) has the same quantitative composition of therapeutically active substances, being substances of similar quality to those used in the registered medicine; and</li> <li>(b) has the same pharmaceutical form; and</li> <li>(c) is bioequivalent; and</li> <li>(d) has the same safety and efficacy properties.</li> </ul>
<b>GMP-Good Manufacturing Practice</b>	<p>A quality assurance system for the manufacture of therapeutic goods based on best international practice. GMP includes quality management, manufacturing processes, documentation and inspection.</p>
<b>Herbal substance</b>	<p>All or part of a plant or substance (other than a pure chemical or a substance of bacterial origin):</p> <ul style="list-style-type: none"> <li>(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</li> <li>(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.</li> </ul>
<b>Medicine</b>	<ul style="list-style-type: none"> <li>(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</li> <li>(b) any other therapeutic goods declared by the Secretary, for the purpose of the definition of therapeutic device, not to be therapeutic devices.</li> </ul>
<b>OPAL-OTC Products Application Lodgement</b>	<p>An online regulatory submission process for entering OTC medicines in the ARTG</p>
<b>PREMIER – Prescription Medicines Electronic Lodgement System</b>	<p>An online regulatory submission process for entering Prescription medicines in the ARTG</p>
<b>Product Information</b>	<p>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</p>

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<b>Term</b>	<b>Meaning</b>
<b>Quality</b>	Degree to which a set of inherent properties of a product, system or process fulfils it's requirement
<b>Risk</b>	The combination of the probability of occurrence of harm and the severity of that harm
<b>Substance</b>	Any medicine or poison
<b>Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)</b>	The document through which a uniform national approach to medicine availability, labelling and packaging is achieved
<b>Therapeutic goods</b>	Goods used for therapeutic use, including medicines and medical devices.
<b>Therapeutic Goods Administration (TGA)</b>	The current regulator of therapeutic goods in Australia
<b>Therapeutic use</b>	Use in or in connection with: <ul style="list-style-type: none"><li>(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or</li><li>(b) influencing, inhibiting or modifying a physiological process in persons or animals; or</li><li>(c) testing the susceptibility of persons or animals to a disease or ailment; or</li><li>(d) influencing, controlling or preventing conception in persons; or</li><li>(e) testing for pregnancy in persons; or</li><li>(f) the replacement or modification of parts of the anatomy in persons or animals.</li></ul>
<b>Traditional use</b>	<ul style="list-style-type: none"><li>(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</li><li>(b) accords with well established procedures of preparation, application and dosage.</li></ul>

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## References

[www.tga.gov.au](http://www.tga.gov.au)

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*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 Drugs and Poisons, No. 22, Commonwealth of Australia 2007.*

## About PharmOut

PharmOut is a boutique consultancy advising to the Pharmaceutical, Medical Device and Veterinary drug industries.

PharmOut specialises in GMP compliance, validation and continuous improvement consulting and training.

Some of the company's customers include -

*Abbott Australasia (Healthcare), AC Immune SA, Acrux Limited, Agronico Research Pty Ltd, Amcor Limited, APHS Pty Ltd, AstraZeneca, Ausonex Pty Ltd, Austin Nuclear Medicine and Centre for PET, Australasian Lubricant Manufacturing Co., Avexa Limited, BD - Australia / New Zealand, Bernafon Pty Ltd, BioMerieux Australia Pty Ltd, CathRx Ltd, Chemeq Limited, ClearStep Australia Pty Ltd, CSL Bioplasma, CSL Parkville, Emerson Process Management, Ensign Laboratories, Enterix Pty Ltd, Faulding FH & Co Limited, Fonterra Co-operative Group, GCL Ltd, Go Medical, GSK, Hospira Pty Ltd, House With No Steps, IDT - Institute of Drug Technology, IG Science Pty Ltd, Intellidesign, Invetech Pty Ltd, Mayne Pharma Ltd, MDI - Medical Developments International, Pall Australia, Peplin Operations Pty Ltd, Pharmatel Fresenius Kabi Pty Limited, Probe Analytical - Intertek Caleb Brett, PT. Sanbe Farma, Royal Brisbane Women's Hospital, Siemens Ltd, Supercare Pty Ltd.*

## How PharmOut can help

We offer a range of services that will assist you in all regulatory, scientific and quality matters in the areas of medicine registration in Australia including:

- medicine classification according to the SUSDP
- ARTG listing/registration
- preparation of common technical documentation
- review of technical documentation
- GMP audits
- risk assessments
- product development

We can make sure that everything is in order for product registration in order to save you time and money. Get it done right the first time.

