



White paper:

How to list or register a complementary medicine in Australia

Vitamins, nutritional supplements, herbs, minerals, homoeopathic, aromatherapy preparations and other medicinal products with specific active ingredients are considered to be complementary medicines in Australia. This white paper discusses the actions you must take if you are seeking to supply or sell a complementary medicine in Australia.

Pharm  **Out**[®]

This document was prepared in February 2016, any content including links and quoted regulation may be out of date. Please refer to the appropriate source for the most recent information. We endeavour to keep an up-to-date record of information at www.pharmout.net.

©2016 PharmOut. This document has been prepared solely for the use of PharmOut and its clients. Copying is prohibited.

MKT_TMP200_01_r06

Is your product a complementary medicine or not?

In Australia, complementary medicines include vitamin, mineral, herbal, aromatherapy and homoeopathic products. These products are often supplied by practitioners of traditional or alternative medicines.

Products that may be considered to be food supplements or nutritional supplements in other countries are deemed to be complementary medicines in Australia. Multi-vitamin tablets are one such example.

If your product meets one or more of the following criteria then it is possibly a complementary medicine and may be subject to regulation by the Therapeutic Goods Administration (TGA).

1. The product includes any of the following ingredients¹:
 - an amino acid
 - charcoal
 - a choline salt
 - an essential oil
 - plant or herbal material (or a synthetically produced substitute for material of that kind), including plant fibres, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll
 - a homeopathic preparation
 - a microorganism, whole or extracted, except a vaccine
 - a mineral including a mineral salt and a naturally occurring mineral
 - a mucopolysaccharide
 - non human animal material (or a synthetically produced substitute for material of that kind) including dried material, bone and cartilage, fats and oils and other extracts or concentrates
 - a lipid, including an essential fatty acid or phospholipid
 - a substance produced by or obtained from bees, including royal jelly, bee pollen and propolis
 - a sugar, polysaccharide or carbohydrate
 - a vitamin or provitamin
2. If the product shape or dosage looks like a medicine e.g. the product is in the form of tablets or capsules.
3. You are claiming that the product can prevent or treat a disease or has health benefits, i.e. a therapeutic claim.

¹ Check the [tga.gov.au](https://www.tga.gov.au) website for the current list of designated active ingredients for complementary medicines as they can change [<https://www.ebs.tga.gov.au/>].

PharmOut Pty Ltd, ABN: 85 117 673 766, Unit 10, 24 Lakeside Drive, Burwood East, Victoria 3151.

Ph: +61 3 9887 6412, Fax: +61 3 8610 0169, Email: info@pharmout.net Web: www.pharmout.net

If your product does not meet one of these criteria then it is likely not considered a complementary medicine and will not be regulated by the TGA under the framework for complementary medicines.

How are complementary medicines regulated in Australia?

There are three classes of medicines in Australia, based on the health risk they represent to the person taking them. The three classes (from low risk to high risk) are:

- **Food** - which includes food supplements
- **Listed** medicines – which includes most complementary medicines. This class is for lower risk products
- **Registered** medicines – these higher risk products include some complementary products, over the counter (OTC) medicines or prescription medicines².

Your medicine may fall under either the 'listed' or 'registered' category, depending on the ingredients and the claims you are making about what the product does.

The first step is to determine if all of the active ingredients (those ingredients that have the effect on the health of the person using the medicine) in your product are already on the TGA's list of low-risk ingredients. Search the TGA website for 'Substances that can be used in listed medicines' to find the current list. If all of the active ingredients in your product are on the list and you are using them in the way they have been approved for e.g. for topical use only or under a certain concentration, then your product fits into the TGA's 'Listed' medicine category. Refer to the next section of this document for the next steps.

If your product contains ingredients that are not on the TGA's "Substances that can be used in listed medicines" list then getting your product approved for supply in Australia is a much more complicated and expensive process. You will need professional help to have your ingredients reviewed and added to the approved list by the TGA. That process is not covered in this white paper, however there are many other PharmOut White Papers, available on www.pharmout.net that may assist you.

² Please refer to the separate PharmOut white paper on how to register products in this class

PharmOut Pty Ltd, ABN: 85 117 673 766, Unit 10, 24 Lakeside Drive, Burwood East, Victoria 3151.

Ph: +61 3 9887 6412, Fax: +61 3 8610 0169, Email: info@pharmout.net Web: www.pharmout.net

My product is a listed complementary medicine, now what?

In essence, only an Australian legal entity i.e. person or company, can supply or sell a medicine in Australia. You can get an Australian company, or person to act as your local 'sponsor' for this purpose. They are the ones whom the TGA will deal with in regards to your product. The sponsor can also appoint an 'agent' to act on their behalf. An agent would normally be experienced and knowledgeable about dealing with the TGA. The different roles are defined below.

If your product is manufactured in a manufacturing facility that has:

- A TGA manufacturing licence (Australian manufacturers only), or
- A certificate (international manufacturers), or
- an overseas clearance

then the process of getting the product "listed" by the TGA is easy (refer to "Getting a manufacturing facility authorised by the TGA" later in this document).

If your product is manufactured in a manufacturing facility that does NOT have a TGA manufacturing authorisation then you will need to submit information to the TGA to begin the process of getting the facility licenced. Refer to "Getting a manufacturing facility authorised by the TGA" later in this document.

If you intend to sell complementary medicines into Australia there are four roles that the TGA requires you to have in place. A single person/company can fulfil one or more role. If you have different companies in each role then there needs to be appropriate technical, quality and /or commercial agreements in place defining who is responsible for what.

The roles are:

Sponsor

This is the person or corporation who:

- exports, or arranges the export of the complementary medicines from Australia; or
- imports, or arranges the importation of the complementary medicines into Australia; or
- in Australia, manufactures complementary medicines or arranges for another person to manufacture them for supply.

Foreign manufacturers often appoint domestic sponsors in Australia to act on their behalf. The Sponsor is legally accountable for the product quality on the Australian market.

Manufacturer

This is the person, corporation or organisation in Australia or elsewhere who:

- produces complementary medicines; or
- engages in any part of the process of producing the medicines or bringing the medicines to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for sale of the medicines or of any component or ingredient of the medicines as part of that process.

Only products that are manufactured in facilities that have been TGA-approved are allowed to be imported and distributed in Australia.

Agent

This is any consultant, corporation or other organisation or person who is appointed by the Sponsor or Australian Manufacturer to represent them in consultations with TGA. The Agent cannot be a member of the particular sponsor/manufacturer client. Agent does not mean a sponsor who is the 'Australian Agent'/distributor of an overseas manufacturer.

Distributor

This is the person, corporation or organisation in Australia that will be responsible for the sale and distribution of the product.

The overall GMP and legal responsibility of all the above parties will be discussed later. All legal responsibilities must be clearly defined and documented.

Getting a manufacturing facility authorised by the TGA

As discussed above, only products that are manufactured in facilities that have been TGA-authorized are allowed into Australia.

Note that the TGA treats manufacturing facilities differently, depending on where they are located:

- Domestic Manufacturers - If the facility is located in Australia then the TGA issues a **Manufacturing Licence**
- International Manufacturers - If the facility is located outside of Australia then
 - the TGA inspects the manufacturer and, if acceptable, issues a **Manufacturing Certificate**, or
 - the manufacturer can go through the **Overseas Clearance process**, which is the cheapest and quickest method.

In all instances the manufacturing facility must first comply with the TGA's current Good Manufacturing Practices (cGMP) requirements before a TGA approval application is made for the product.

Local Australian manufacturers typically have a high level of engagement with the TGA. They will not be discussed in this document.

For overseas manufacturers there are two possible pathways: Overseas Clearance and Onsite Inspection by the TGA.

Overseas Clearance is by far the quickest and most cost effective but relies on the manufacturer holding a comparable certification from another “respected agency” i.e. the equivalent to the TGA in another country with similar GMP standards for therapeutic goods.

Most commonly, international manufacturers of food supplements, nutraceutical, cosmetic or confectionary seek to extend their product range by producing complementary medicines. Usually these manufacturers have excellent existing quality management systems appropriate for food grade manufacture, but are not aware of the specific GMP implications or the initial capital and ongoing operational costs required for complementary medicines. The costs involved in getting a facility to GMP level quality and keeping it that way can be considerable.

Assuming that a GAP analysis has been performed at the facility, costs are fully understood and issues have been remediated, you can proceed to get the facility TGA authorised as follows:

To start the listing process, you will need the following documentation for the manufacturing facility:

- Site Master File
- Quality Manual

The manufacturing facility should be able to provide these (in English) (if they can't then the facility is probably not suitable for manufacturing medicines).

You (or your Agent) then need to submit the documents to the TGA. This is done by via the TGA's eBusiness Portal (eBS) - <https://www.ebs.tga.gov.au/>.

If you don't already have a login for the eBS portal then you will need to download and complete a 'Client Details' form and an eBusiness access request form – these are available from the eBS portal (under eBS access forms). Submission details are on the forms. Within approximately two weeks you will receive the login details for the portal.

Once you have submitted the documents the TGA will review them and, if they are suitable, will start the process of certifying/licencing the facility.

The manufacturing facility will need to be checked and approved by the TGA. As mentioned before, this can happen one of two ways:

- Either the TGA will inspect the facility themselves, or
- The TGA will accept the inspection and licencing by an equivalent to the TGA in another country. This is done via the “GMP clearance of overseas medicine manufacturers” process.

The Good Manufacturing Practice (GMP) clearance of overseas medicine manufacturers process requires that the manufacturing facility has been inspected by a competent authority, usually the equivalent to the TGA in that country or another country that products from the facility are sent to. If the facility has been licenced by a [participating authority](#) of the pharmaceutical inspection cooperation scheme (PIC/S) then this is usually treated as equivalent to a TGA licence. The TGA charge a fee to assess the GMP evidence from the competent authority.

If the facility is not currently licenced by a TGA-equivalent then it will probably need to be brought up to a suitable level in terms of the quality processes, layout and other areas that could impact the quality of the products made at the facility.

It is strongly recommended that you get an assessment of the facility done by a company familiar with TGA audits (PharmOut offers this service). This assessment will identify things that need to be fixed before the TGA arrives for their inspection. It's much cheaper to find and fix the things that are wrong beforehand, than to pay the TGA to inspect the facility and let them find the problems!

When the facility is ready, you can then proceed with getting it inspected by the TGA. They schedule their audits on a quarterly basis. You should allow approximately six months from the time you submit the documents (the Site Master File and Quality Manual) to the inspection date.

The assigned TGA Inspector will use the submitted documents to plan the inspection of the facility. The initial inspection typically takes 3-5 days.

The TGA will provide an estimate of the costs (they charge approx. \$600 per hour per inspector for Australian sites and \$1200 per hour per inspector for overseas sites – check the schedule of fees on TGA website for current fees) plus shared travel costs (business class flights + accommodation). This fee **must** be paid by the Sponsor prior to the TGA audit.

Prior to the inspection, the TGA should send an audit agenda to the facility being inspected, if one has not been sent, it should be requested. The facility should indicate the normal office hours of the site and the inspector will usually work within these hours. The TGA has a strong track record of being firm, fair and consistent. Refer to the white paper titled "[Preparing for GMP audits](#)" on the PharmOut website for more information about how the inspection process works.

During the inspection, the TGA inspector will note any deficiencies he/she finds in a list of 'items for discussion'. These will be discussed at the close-out meeting at the end of the inspection. You can also ask for these to be discussed at the end of each day if you wish.

The Inspector takes this list back to the TGA where a committee uses a risk-based approach to classify the findings into three categories:

- Critical
- Major
- Other

These categories are based on the potential impact on patient safety.

The assessment of the findings is independently reviewed prior to an inspection report being issued. Typically it takes 4-5 weeks after the completion of the inspection for the inspection report to be issued to the manufacturer.

If the inspection report contains one or more findings classified as 'Critical' then the TGA will not issue a certificate/licence and the whole process has to be repeated (and another fee paid).

If the report includes findings classified as 'Major' then the facility is given time to resolve the issues to the TGA's satisfaction. A certificate/licence will be issued once the findings have been successfully resolved.

Issues classified as 'other' will not prevent a TGA licence being issued – they are typically reviewed at the next scheduled TGA inspection.

Once a facility has been granted a licence/certificate it must be inspected on a regular basis by the TGA to make sure it is still meeting the required quality standards. The TGA uses a risk-based approach to determine the frequency of these inspections. The number of 'Major' findings is one of the factors used by the TGA to determine the frequency. The TGA has a publication titled '[Guidance on licencing/certification inspections](#)' that provides details on how the TGA determines inspection frequency as well as examples of critical deficiencies etc. Note that the TGA regulations are constantly changing and the facility will need to keep up to date to ensure ongoing compliance.

Once the facility has been issued a certificate/licence by the TGA you can apply to have your product listed. Refer to "Getting your product listed by the TGA", below.

Getting your product listed by the TGA

If your product contains only ingredients that appear on the TGA's "Substances that can be used in listed medicines" list and your product is manufactured in a TGA licenced facility, then you are ready to submit your product for listing by the TGA.

First, the 'recipe' for the product needs to be documented on the 'Registered medicine application form', available from the TGA website. Tip: Make sure your ingredients are named exactly as per the TGA list. You can then submit this form via the TGA's eBS portal <https://www.ebs.tga.gov.au/>.

As discussed earlier, if you don't already have a login for the eBS portal then you will need to download and complete a 'Client Details' form and an eBusiness access request form – these are available from the eBS portal (under eBS access forms). Submission details are on the forms. Within approximately two weeks you will receive the login details for the portal.

The Sponsor and the company distributing the product (the 'Distributor') must have a written Quality/Technical agreement with the manufacturer of the product. This agreement identifies who is responsible for the quality of the product on the market.

The Quality/Technical agreement should contain a table that lists who is responsible for the following:

- Adverse events
- Customer complaints
- Recalls
- Release for supply

It is also recommended that the agreement includes whether or not the Sponsor will receive a copy of any correspondence from the TGA.

The Sponsor must also have the clinical evidence to support any claims made about what the product does e.g. 'reduces the impacts of osteoarthritis'. In addition, they must have stability data to prove that the product's quality is maintained over its shelf life and under the recommended storage conditions.

The Quality/Technical agreement, clinical evidence and stability data don't have to be submitted to the TGA, but must be available if the TGA asks to see them.

After receiving the 'Registered medicine application form', the TGA will send an invoice (this is typically approximately AUD1445, but check their website for their current schedule of fees)³. Once this is paid the TGA begins reviewing the supplied documentation. They undertake to complete this within two weeks. If they accept the documentation you supplied, then the product will be listed on the Listed Product list and you can commence selling the product.

Note that the TGA randomly audits listed products to check that the clinical evidence, stability data etc. is available and valid. If your data is not supplied or is not suitable then your product will be removed from the TGA's list and you won't be able to sell it until you meet the TGA's requirements.

What do I do if I need to register the product with TGA?

As mentioned earlier, if your product contains ingredients not on the TGA's "Substances that can be used in listed medicines" list or they are being used in ways that are not approved, then getting your product approved for supply in Australia is a much more complicated and expensive process. You will need professional help to have your ingredients reviewed and added to the approved list by the TGA. Registration of a complementary medicine requires submission of a detailed dossier of information to the TGA for evaluation. This data must establish that the proposed medicine is of appropriate quality, safety and efficacy before it is approved for inclusion on the ARTG. For these applications, The TGA are requesting the supporting information to be provided in the Common Technical Document (CTD) format for review. That process is not covered in this white paper, however there are many other PharmOut White Papers, available on www.pharmout.net that may assist you, including the white paper on how to register a prescription medicine which outlines the content and format of the CTD.

³ TGA fees are reviewed annually in July. The current fees are available at TGA [Fees & payments](#)

PharmOut Pty Ltd, ABN: 85 117 673 766, Unit 10, 24 Lakeside Drive, Burwood East, Victoria 3151.

Ph: +61 3 9887 6412, Fax: +61 3 8610 0169, Email: info@pharmout.net Web: www.pharmout.net

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

The current⁴ application and annual fees for listing or registering a complementary medicine on the ARTG are:

Medicine Type	Application Fee (\$AUD)	Annual Charge (\$AUD)
Listed	from 760	965
Registered	from 11,110	9,665

⁴ fees and charges are updated annually in July.. For updates check TGA website <http://www.tga.gov.au/>.

PharmOut Pty Ltd, ABN: 85 117 673 766, Unit 10, 24 Lakeside Drive, Burwood East, Victoria 3151.

Ph: +61 3 9887 6412, Fax: +61 3 8610 0169, Email: info@pharmout.net Web: www.pharmout.net

Case Study

A South East Asian manufacturer approached PharmOut to help them import fish oil capsules into Australia.

Their manufacturing facility was certified by the appropriate Vietnamese regulatory body, but was not TGA-certified. Unfortunately, Vietnam isn't a member of the pharmaceutical inspection cooperation scheme (PIC/S), so the TGA would not accept the Vietnamese certification.

To start, PharmOut conducted a desktop audit of the company's quality management system. This identified the gap between where the system was and where it needed to be to be acceptable to the TGA. PharmOut then provided advice on how much effort was required to get the site TGA-ready.

The manufacturer fixed the identified problems, based on the advice received. Auditors from PharmOut then completed a three day onsite inspection-readiness audit of the facility. The resulting audit report described remedial actions or enhancements that would be required to meet TGA requirements. Again, the company was able to decide whether to proceed with the TGA certification, based on the cost of the work needed.

The issues were ones often seen in this situation – mostly related to contamination control, including HVAC and air cleanliness, clean room design and air lock design and performance. The requirement to have purified water used in all formulations is also a common remediation area.

The company proceeded with the required changes, with PharmOut providing expert advice along the way.

PharmOut then completed another pre-inspection readiness audit, just prior to the TGA's advised inspection. This is an optional, but recommended step.

During the TGA inspection PharmOut consultants were present to provide input and advice. It should be noted that the TGA prefers employees of the manufacturer to answer all questions and presence of an Australian consultant will not influence the outcome of the inspection.

The manufacturer was successful in obtaining TGA certification and was then able to apply to have their products listed by the TGA for sale in Australia.

PharmOut Pty Ltd, ABN: 85 117 673 766, Unit 10, 24 Lakeside Drive, Burwood East, Victoria 3151.

Ph: +61 3 9887 6412, Fax: +61 3 8610 0169, Email: info@pharmout.net Web: www.pharmout.net

©2016 PharmOut. This document has been prepared solely for the use of PharmOut and its clients. Copying is prohibited.

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 www.pharmout.net



PharmOut is an international GMP consultancy serving the Pharmaceutical, Medical Device and Veterinary industries. PharmOut specialises in PIC/S, WHO, United States FDA, European EMA, and Australian TGA GMP consulting, engineering, project management, training, validation, continuous improvement and regulatory services.

Our team includes international GMP experts who have previously held leadership roles within regulatory bodies.

For more information please visit www.pharmout.net or contact us at info@pharmout.net.

PharmOut Pty Ltd, ABN: 85 117 673 766, Unit 10, 24 Lakeside Drive, Burwood East, Victoria 3151.

Ph: +61 3 9887 6412, Fax: +61 3 8610 0169, Email: info@pharmout.net Web: www.pharmout.net

©2016 PharmOut. This document has been prepared solely for the use of PharmOut and its clients. Copying is prohibited.