Australian Government
Department of Health
Therapeutic Goods Administration

Guidance for completing the application form for an assessed listed medicine

Version 1.2, August 2018

TGA Health Safety Regulation

Contents

Introduction

From March 2018, complementary medicines sponsors have the option to enter their medicine in the Australian Register of Therapeutic Goods (ARTG) via a new pathway for listing – the assessed listed medicines pathway.

To be a listed medicine on the Australian Register of Therapeutic Goods (ARTG) through the assessed listed medicines pathway a product:

- can only contain certain low risk ingredients draw exclusively from the permitted ingredients list
- must be manufactured in accordance with the principles of Good Manufacturing Practice (GMP)
- make at least one 'intermediate level indication' as described in the Assessed listed medicines evidence guidelines.

Medicines listed through the assessed listed medicines pathway will be included in the ARTG following self-certification by the applicant of the safety and quality of the product, and TGA assessment of the efficacy evidence supporting the proposed indications.

The information below will assist you in providing the required information for completing (and submitting) an application for an assessed listed medicine (either for new ARTG entries or changes to existing ARTG entries).

Assumed knowledge

It is assumed that users will have an understanding of the regulation of complementary medicines in Australia and the legal obligations of a sponsor of a listed medicine. For more information, refer to the Australian Regulatory Guidelines for Complementary Medicines (ARGCM) and the Assessed listed medicines evidence guidelines.

It is assumed that the applicant has an existing client ID in the TGA Business services (TBS) portal. If not, the applicant will need to apply for a client ID through TGA Business services before lodging the application.

Accessing help

Email

For listed medicine application and submission enquiries, please email complementary.medicines@health.gov.au with as much information as possible, such as a copy of the problem application or screenshots of any error messages received.

For questions about TBS related issues and access you can contact the TBS helpdesk on ebs@health.gov.au.

Phone

You can phone Complementary medicines on 1800 020 653 or 02 6232 8634.

You can phone the TBS helpdesk on 1800 010 624.

Accessing the application form

Currently the electronic application form is accessed through the TGA Business Services portal. You will also need to complete the separate downloadable Module 1.2.1: Assessed listed

medicine general application information form with the formulation and manufacturer details, and include it in Module 1.2.1 of your CTD Module 1 application dossier. The electronic upgrades to support the assessed listed medicines will be implemented late 2018.

Completing an application

Part 1 – Applicant and agent details

Applicant details

How to complete this information

Record the information requested in the spaces provided.

Provide a postal address where this differs from your street address.

What else do I need to do?

The applicant will become the sponsor of the product once the application is approved. Please enter the name and client ID of the sponsor.

If you do not have a client ID, apply for a client ID through TGA Business Services by completing an Organisation details form before lodging your application.

Ensure the nominated contact person is available throughout the evaluation process, to respond to any questions the TGA may have.

If the contact persons or the contact information changes during the pre-submission/evaluation processes, contact the TGA at complementary.medicines@health.gov.au and advise of the change.

Agent details

How to complete this information

Complete this section only if you are an agent acting on behalf of the applicant/company seeking approval for the product.

Record the information requested in the spaces provided.

What else do I need to do?

If you do not have a client ID, you will need to apply for a client ID through TGA Business services before lodging your application. You will need to ensure that the applicant has authorised you to act on their behalf through TGA Business Services.

Part 2 – Application category

Application type

Select one of:

- **New product:** a product which is not yet listed in the ARTG.
- **Variation to existing product:** a product which exists in the ARTG that requires change to the listing. Include the AUST L(A) number in this field.

Three application categories for assessed listed medicines

Select the category relevant to the application.

Applications for assessed listed medicines are categorised into three levels, based on risk and have different fees and evaluation timeframes.

It is important that you determine the correct application level.

It is important to ensure that you select the correct application category for your application in order to ensure that it can be accepted for evaluation. The application categories and specific requirements for each category are set out in the Assessed listed medicines evidence guidelines.

If your application does not include the required data, in accordance with the application level, it will not be accepted for evaluation under subsection 23B(6) of the *Therapeutic Goods Act 1989*.

Checking guidelines and mandatory requirements

When planning your assessed listed medicine application you will need to identify and understand the relevant mandatory requirements and guidelines.

Check the Assessed listed medicines evidence guidelines for any specific requirements or advice that apply to your application.

The mandatory requirements explain what you need to do for your application to pass preliminary assessment and be accepted for evaluation:

- Mandatory requirements for an effective assessed listed medicine application; and
- CTD Module 1: Administrative information for assessed listed medicines

How to complete this information

For L(A)1 applications:

- Select either 'yes' or 'no' to indicate whether the originator medicine has been fully evaluated for efficacy by the TGA.
- Provide the ARTG number for the reference medicine.

For L(A)2 or L(A)3 applications:

- Select either 'yes' or 'no' to indicate whether your application is a literature based submission.
- Select either 'yes' or 'no' to indicate the types of efficacy data you have included in your dossier submission.
- If your application is missing data, select the checkbox to indicate a justification is included in module 5 of your dossier submission.

Part 3 – Product details

How to complete this information

Enter the product details in the spaces provided.

Refer to the TGA approved terminology for medicines guidance to find the appropriate terminology.

Field	Description
ARTG number	For variation applications only. Enter the AUST L(A) number of the medicine being varied.
Label (product) name	This is the name of the product which will appear on the label and final ARTG listing.
Dosage form	Enter the dosage form for the medicine. The dosage forms accepted for listed medicines are provided in Attachment 1.
Route(s) of administration	Enter the route(s) of administration. The following routes of administration are accepted for listed medicines: *Buccal* *Oral* *Rectal* *Dental* *Otic* *Sublingual* *Inhalation* *Nasal* *Topical* *Mucosal* *Oral application* *Vaginal*
Visual identification of dosage form	Enter the description of the medicine's visual appearance (visual ID). What you enter here must be consistent with the information specified in the medicine's Finished Product Specifications document, e.g.: white, circular, biconvex tablets.
Maximum daily dose	Enter the maximum daily dose. If the dosage form is non-dividing (for example: powder), enter the units.
Maximum single dose	Enter the maximum single dose. If the dosage form is non-dividing (for example: powder), enter the units.
Weight of divided preparation	Only required when using a divided dosage form (for example: tablet) and the formulation contains **restricted ingredients**.
Pack size (optional)	Enter the pack size(s). Separate by a comma if multiple pack sizes are being supplied.

Field	Description
Container details: **Container type, volume, closure, condition, material**	Only required when the formulation contains ingredients which have been restricted to a 'container type', 'closure' or 'size limit'. **If applicable, for products containing restricted ingredients:** • Enter the container type • Enter the **container volume** as (number) per gram/litre/microliter/milligram/millilitre • Enter the container closure Select and enter the **container condition**: • Open • Closed Enter the container material
Storage details	Enter the storage details for the product.
Shelf life (time and temperature) (optional)	Enter the shelf life of the product (time and temperature).

3.1 Formulation details

What to include:

- download the separate Module 1.2.1 Assessed listed medicine general application information form
- complete the form as instructed below
- include the form in Module 1.2.1 of your submission dossier.

Single or multi-active ingredients

Check the box to indicate whether your medicine formulation contains a single active ingredient or multi-active ingredients.

Composite packs

A 'composite pack application' is used for medicines that are to be sold together in one package, where the medicines are either combined before use or administered in a particular sequence, for a single treatment or course of treatment. For the full definition of a composite pack, refer to section 7B of the Act.

'Composite pack applications' differ from general assessed listed medicines applications only in that they require the addition of multiple formulations.

To submit a composite pack application:

- Check the box to indicate whether your medicine is a composite pack.
- For each formulation in your composite pack, include the formulation details separately using the format outlined below.

Formulation details

All ingredients (active and excipients) contained in an assessed listed medicine must be included in the *Therapeutic Goods (Permissible Ingredients) Determination* and the formulation must be compliant with any restrictions or requirements associated with those ingredients.

An application which contains ingredients which are not in the permissible ingredients determination will **not** be accepted for evaluation.

You can search for the ingredient via the catalogue of permitted ingredients. The ingredient summary provides guidance on acceptable uses of an ingredient and any associated restrictions.

Tick yes or no to indicate whether all ingredients in the medicine formulation are:

- Permitted for use in listed medicines
- comply with the requirements for their use in listed medicines

All formulation details must be provided in your submission dossier.

Refer to the table below for the information required for active and excipient ingredients.

Field	Description
Active ingredients **Excipient ingredients**	Enter the name of the ingredient as listed in 'Ingredient Name' in the Ingredient Summary sheet. **(Enter the ingredient equivalent details, if required)** **Equivalent:** There are two instances where equivalents are used: • Equivalent dry or fresh herb where the preparation is an extract. • Where a component of a substance is declared on the label or mandated due to regulatory requirements.
Category	Enter the appropriate ingredient category acronym from the following: **AAN** – Australian Approved (Chemical Substance) Name **ABN** – Australian Biological Name **AFN** – Australian Food Name **AHN** – Australian Herbal Name **AHS** – Australian Herbal Substance **HCN** – Herbal Component Name
Quantity	Ingredient quantities are required for all active ingredients. Excipient ingredient quantities are currently not required unless they are **AHNs or have restrictions**. Enter the ingredient quantity (for **homeopathic ingredients**, enter potency)

Field	Description
Units	Enter the units for the ingredient (for **homeopathic ingredients**, enter diluent details)
Restrictions	Tick yes or no to indicate whether the ingredient has any restrictions for use.

Requirements for Australian Herbal Name (AHN) ingredients details (if applicable)

Further information is required to support your application if the product contains an AHN ingredient.

If your product contains an AHN ingredient, refer to the table below for the information required to support your application.

AHN Only	Description
Plant part	Enter the plant part.
Plant preparation	Enter the plant preparation.
Equivalent preparation	Enter the appropriate equivalent preparation, if required.
Equivalent quantity	Enter the amount of equivalent preparation to be used in the ingredient, including the units.
Final preparation ratio	Enter the final preparation ratio.
Remaining Restricted Solvent	Required if solvents are restricted. The solvent to be added must be the same as those used in preparation steps previously completed. **Residue Quantity:** The upper limit (maximum amount) of solvent allowed in the specifications for the ingredient.
Carrier	A carrier is an excipient ingredient which may be included in a herbal ingredient. Press the 'Add' button to add a carrier to the ingredient. Multiple carriers can be added.

Proprietary ingredients details (if applicable)

Additional information is required to support your application if the product contains a proprietary ingredient.

Formulation details of 'Proprietary Ingredients' are not released and usually contain either multiple excipient ingredients or a single active preparation which may also include excipient ingredients.

'Active Proprietary Ingredients' require ingredient quantities to be entered. Some excipient 'Proprietary Ingredients' such as flavours, fragrances and printing inks also require quantities to be entered, as the following limits apply to the final formulation:

- Flavour - 5%
- Fragrance - 1%
- Printing Ink - 0.1%

If your product contains a proprietary ingredient, refer to the table below for the information required to support your application.

Proprietary ingredient	Description
Proprietary ingredient name	Enter the name of the ingredient as listed in 'Ingredient Name' in the Ingredient Summary sheet.
Proprietary ingredient ID	Enter the proprietary ingredient ID as listed in 'Ingredient Name' in the Ingredient Summary sheet.
Formulation type	Enter the formulation type as listed in 'Ingredient Name' in the Ingredient Summary sheet.
Ingredient role	Enter the ingredient role as listed in 'Ingredient Name' in the Ingredient Summary sheet.
Ingredient type	Enter the ingredient type as listed in 'Ingredient Name' in the Ingredient Summary sheet.
Quantity	Enter the ingredient quantity. Ingredient quantities are required for all active ingredients. Excipient ingredient quantities are currently not required unless they are AHNs or have restrictions.
Units	Select the appropriate unit.
Equivalent	There are two instances where equivalents are used: • Equivalent dry or fresh herb where the preparation is an extract. • Where a component of a substance is declared on the label or mandated due to regulatory requirements.

Ingredients of human or animal origin details (if applicable)

This is applicable to AAN or ABN ingredients.

Ingredients with potential viral and Transmissible Spongioform Encephalopathies (TSE) risks must be approved before their inclusion in listed medicines. Refer to the TGA's website for the Transmissible Spongiform Encephalopathies (TSE): TGA approach to minimising the risk of exposure. Information on clearance of risk for TSE must be held by the sponsor in support of your application.

Tick 'yes' or 'no' to indicate whether all ingredients in the medicine formulation contain ingredients of human or animal origin.

Complete the fields below with information about the human or animal origin ingredients in the product.

Ingredients of Human or Animal Origin	Description
Name of ingredient	Applicable to AAN or ABN ingredients. Note: A preclearance certificate issued by the TGA's Scientific Evaluation Branch may be required. Include the pre-clearance code here also, if applicable.
Animal species	Enter the animal the ingredient is derived from.
Animal part	Enter the part of the animal from which the ingredient is derived.
Country of origin	Enter the country, or countries, of origin for the ingredient from the drop down list.

3.2 Manufacturer details

What to include:

- download the separate Module 1.2.1 Assessed listed medicine general application information
- complete the form as instructed below
- include the form in Module 1.2.1 of your submission dossier.

The applicant should ensure that their manufacturing licence or GMP Clearance covers the manufacturing steps of the product type and dosage forms that are to be performed by each of the manufacturing sites.

Tick yes or no to indicate whether:

- All Australian manufacturers involved in the manufacture of the product have a current Good Manufacturing Practice (GMP) licence which is suitable for the product type and dosage form.
- All overseas manufacturers involved in the manufacture of the product have current GMP clearance which is suitable for the product type and dosage form.

All details of Australian and overseas manufacturers must be provided in your submission dossier.

Complete the field below with information about the manufacturer(s) of the product.

Field	Description
Name	Enter the full name of the manufacturer.
Licence/clearance number	If the manufacturer is **Australian** enter the Good Manufacturing Practice (GMP) licence number. If the manufacturer is **overseas**, the clearance ID number, if available.
Address	Enter the full address of the manufacturing site.
Manufacturing steps	Enter the steps performed by this manufacturer Note: the manufacturer **must be licensed** to carry out the manufacturing steps listed in the application.

Part 4 – Indication(s) details

An indication means the specific therapeutic use of the medicine. There are two types of indications which can be added to an assessed listed medicine: 'Intermediate level' and 'Low level' indications. Advertising claims are not indications and do not need to be entered in the application and will not appear in the ARTG entry.

Field	Description
Intermediate level indications	For your application to progress, it must contain at least one intermediate level indication. These indications exceed the criteria for low level indications but are still appropriate for listed medicines. Refer to the Assessed listed medicines evidence guidelines for more information on intermediate level indications.
Low level indications	Inclusion of low level indications is optional for assessed listed medicines. These indications are those appropriate for listed medicines, such as those specified in the list of permitted indications. You can access and search the list of permitted indications on the TGA Business Services website.

Restricted representations

Tick 'yes' or 'no' to indicate whether your product indications refer to a restricted representation.

Part 5 – Submission details

Tick 'yes' or 'no' to indicate whether you have had a pre-submission meeting with the TGA concerning this application.

Part 6 – Fees

Ensure the fee paid is based on the application category.

Visit the following pages on the TGA website for more information about fees and payments:

- Fees & Payments – current fees
- Fees & payments – payment options

Check a box to select your payment method.

Part 7 – Certification

The medicine that is the subject of the application must meet the requirements for each of the matters referred to in subsection 26AB(2) of the Act.

Check the box to certify that your medicine meets these requirements.

Part 8 – Declaration

What you need to do:

- Read the statements and conditions;
- Check the corresponding boxes; and
- Complete all remaining fields.

An application form will not be accepted unless it has been completed and is accompanied by a submission dossier.

Submitting an application form provides a declaration of understanding and agreement to satisfy the requirements for an effective submission.

Ensure the submission dossier contains the full data set to be evaluated.

Submission

Once you have finalised your application and are ready to submit the application to the TGA, press 'submit' to submit the electronic application form. Do not close your browser until the electronic application form has been fully submitted (this may take several minutes).

Once the electronic application form has been submitted in TGA Business Services, e-mail your application dossier/s to complementary.medicines@health.gov.au. Include the TGA Business Services electronic submission reference number in your e-mail.

The electronic upgrades to support the electronic submission of assessed listed medicines applications will be implemented late 2018.

Attachment 1: Dosage forms accepted for listed medicines

Bar, soap
Block
Capsule, enteric
Capsule, hard
Capsule - modified release
Capsule, soft
Collodion
Cream
Capsule soft enteric
Enema
Ear Drops, emulsion
Ear Drops, powder for
Ear Drops, solution
Ear Drops, suspension
Essential Oil
Gel
Granules
Granules, effervescent
Granules, enteric-coated
Granules, modified release
Gum - chewing
Herb, dried
Inhalation
Inhalation, conventional
Inhalation, pressurised
Inhalation, powder for
Insufflation
Liniment
Liquids
Liquid, multipurpose
Lotion
Lotion, powder for
Lozenge
Mouthwash
Nasal Drops, emulsion
Nasal Drops, powder for
Nasal Drops, solution
Nasal Drops, suspension
Ointment
Oral Liquid
Oral Liquid, emulsion
Oral Liquid, powder for
Oral Liquid, solution
Oral Liquid, suspension
Pad - impregnated
Paste
Pastille
Pessary
Pessary, compressed
Pessary, moulded
Pessary, modified release
Pessary, shell
Pill
Paint
Paint, concentrated
Paint, powder for
Powder
Powder, dusting
Powder, oral
Patch, dermal
Solution
Solution, powder for
Spray
Spray, pressurised
Spray, solution
Spray, suspension
Spray - nasal
Stick
Stick, lip
Suppository
Suppository, compressed
Suppository, moulded
Suppository, shell
Suspension
Suspension, powder for
Tablet, chewable
Tablet, dispersible
Tablet, enteric coated
Tablet, effervescent
Tablet, film coated
Tablet, gelatin coated
Tablet, multilayer
Tablet - modified release
Tablet - orally disintegrating
Tablet - sugar coated
Tablet - soluble
Tablet - uncoated
Wafer

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Complementary and OTC Medicines Branch, TGA	March 2018
V1.1	Minor text update	Complementary and OTC Medicines Branch, TGA	April 2018
V1.2	Minor text update – Submission process clarification	Complementary and OTC Medicines Branch, TGA	August 2018

Therapeutic Goods Administration

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