



Guide to the Completion of the 'Application for Selective Non-Disclosure of Active Herbal Extract Details' form

Introduction

This Guidance document has been developed to assist sponsors of therapeutic goods and suppliers of Active Herbal Extracts when completing the 'Application for Selective Non-Disclosure of Active Herbal Extract Details' form. This form should be used to request the Therapeutic Goods Administration (TGA) to keep selective details regarding an 'Active Herbal Extract' (eg. solvent type, concentration extract ratio and extract excipient details) confidential from the sponsor. Please note that information such as herb species, plant part, basic preparation details (eg concentrated extract), ratio of equivalent dry weight to extract amount, and component percentage (if relevant) may not be confidential from the sponsor.

The *Therapeutic Goods Act 1989* (the Act) requires that therapeutic goods supplied in Australia, unless specifically exempted or excluded, be Registered or Listed on the Australian Register of Therapeutic Goods (ARTG), before they can be supplied in, or exported from, Australia.

Information supplied to the TGA in relation to the inclusion of an Active Herbal Extract on the ARTG is treated as 'commercial-in-confidence'. The TGA will NOT release formulation information of Active Herbal Extracts, other than in accordance with the Act or as otherwise required or permitted by law.

The '*Application for Selective Non-Disclosure of Active Herbal Extract Details*' form is the mechanism that allows confidential Active Herbal Extract details to be entered onto the ARTG, following an assessment process by the TGA Laboratories to ensure that the herbal ingredient and manufacturing process comply with the definition of a herbal substance (as defined in Regulation 2 of the *Therapeutic Goods Regulations 1990*).

'Active Herbal Extract' suppliers should note the following:

- ***It is the supplier's responsibility to provide complete and accurate formulation details about their Active Herbal Extract.***
- ***It is the supplier's responsibility to advise the TGA, and sponsor(s) using their Active Herbal Extract, of any change in formulation, Active Herbal Extract name, supplier or supplier details.***

Sponsors and other users of Active Herbal Extracts should note the following:

- ***It is the sponsor's responsibility to ensure that the correct Active Herbal Extract information eg. the name and number, is provided to TGA in their product formulation.***

Definition of an Active Herbal Extract

An 'Active Herbal Extract' for the purposes of this document, is a herbal extract or concentrate for which a supplier intends specific commercial in confidence information on the extraction method, steps and/or solvent details, to remain confidential from sponsors who include the extract as an active ingredient in a therapeutic product. The formulation may also contain excipient ingredients.

It is mandatory for Active Herbal Extracts to contain at least one active ingredient and for all ingredients (active and excipients) to use valid names consistent with the Australian Approved Terminology for Medicines (i.e. Australian Approved Name or AAN). Note that the name of the active ingredient in an Active Herbal Extract is not confidential, in accordance with the Act.

Form Layout

The '*Application for Selective Non-Disclosure of Active Herbal Extract Details*' form consists of the following three parts:

Part (A) General Details - information about the supplier

Part (B) Product/Formulation Details - information on the composition of the Active Herbal Extract

Part (C) Information Regarding Ingredients of Human or Animal Origin

TGA processing of the '*Application for Selective Non-Disclosure of Active Herbal Extract Details*' form

An '*Application for Selective Non-Disclosure of Active Herbal Extract Details*' form must be submitted to the TGA by the supplier of the Active Herbal Extract, or an agent acting on behalf of the supplier of the Active Herbal Extract. However, the sponsor of the finished product may submit an '*Application for Selective Non-Disclosure of Active Herbal Extract Details*' form on the supplier's behalf, provided a letter of authorisation from the supplier is enclosed with the notification.

When an '*Application for Selective Non-Disclosure of Active Herbal Extract Details*' form is lodged with the TGA, the following processing steps occur:

- The form is checked to ensure that all required information has been provided, including that all ingredient names are in the required format.
- The eligibility of the Active Herbal Extract for entry onto the ARTG is established. All active and excipient ingredients, including any residual solvents and Sub-Proprietary Ingredient information are checked to ensure that all ingredients are eligible for inclusion on the ARTG.
- The application is then assessed by the TGA to ensure that the herbal ingredient and manufacturing process comply with the definition of a herbal substance (as defined in Regulation 2 of the *Therapeutic Goods Regulations 1990*).
- If the information is incomplete or inadequate, a written request will be sent to the supplier requesting further information.
- Once the application has been assessed by the TGA, the Active Herbal Extract is allocated a specific name and Active Herbal Extract reference number and is entered onto the ARTG. The name and reference number will be used in ARTG entries.
- A letter is sent to the Active Herbal Ingredient supplier (and sponsor, if nominated), advising of the Active Herbal Extract name, number, supplier's name and supplier Client Identification number. Sponsors who wish to include an Active Herbal Extract in an application to List or Register a product on the ARTG require this information. The Active Herbal Extract used in a product must match the information supplied by the supplier in their notification to the TGA.

Non-acceptance of a Active Herbal Extract

The TGA may refuse to accept an Active Herbal Extract formulation for inclusion on the ARTG for the following reasons:

- If any of the active ingredient names, excipient or solvent names of the Active Herbal Extract are not in an AAN format, or are not eligible for inclusion on the ARTG.
- The TGA determines that the Active Herbal Extract does not meet the definition of a herbal substance.
- The colour in a colouring intended for oral use is not included in the list of '*Colourings Permitted in Medicines for Oral Use*'.
- The request for additional information from a supplier for an Active Herbal Extract is ignored or the information supplied is such that the Active Herbal Extract is still unable to be finalised.

Public Disclosure of Information about an Active Herbal Extract

Suppliers should be aware that the following information regarding Active Herbal Extract is available to third parties:

- The Active Herbal Extract name, number, supplier name, and supplier's client detail number.
- Details of the active ingredient, including herb species, plant part, basic preparation details (eg. concentrated extract), ratio of equivalent dry weight to extract amount, and component percentage.
- The active ingredient is not confidential in accordance with the Act, but selective information on solvent and extraction methods are confidential. Information on an active ingredient is in the public domain and must be displayed on the label in accordance with Therapeutic Goods Order No. 69. All active ingredients, regardless of the source of these ingredients (chemical, biological or herbal), must be displayed on the label of a therapeutic good.
- The name and quantity of any restricted ingredients. This information will be available through the Electronic Listing Facility (ELF 3).
- Compliance with relevant Regulations or Therapeutic Goods Orders (TGOs). The requirements for public disclosure of excipient ingredients or active ingredients are contained in:
 - Schedule 1 of the Therapeutic Goods Order No. 69 (TGO 69) lists 'Excipients required to be declared on the label of medicines'. This includes ingredients such as ethanol, hydroxybenzoic acid esters, peanut and peanut products and sodium salts.
 - Item 3(2) of TGO 69 'Particulars to be included on a label' Section b) states that the name(s) of all active ingredients in the goods.
 - Section 46 of the Regulations 'Release of information' states that the information which can be released to the public are the name and quantities of therapeutically active substances in the good, and/or the presence or absence of any specific excipient in the goods.

Specific instructions for completing the ‘Application for Selective Non-Disclosure of Active Herbal Extract Details’ form

Questions 1-13 are to be completed by the **supplier** of the Active Herbal Extract, or an agent acting on behalf of the supplier of the Active Herbal Extract. A sponsor using the Active Herbal Extract in a finished product may submit an ‘Application for Selective Non-Disclosure of Active Herbal Extract Details’ form on the supplier’s behalf, provided a letter of authorisation from the supplier is enclosed with the notification.

Part A – General Details

1 Active Herbal Extract Supplier’s Business Name:

Provide the full name of the person or corporation that supplies the Active Herbal Extract. This must be identical to that supplied in the ‘Client Details’ form (formally ‘Enterprise Details’ form). A completed ‘Client Details’ form must be submitted with this notification unless one has already been submitted and there have been no changes to the information contained in that form (including authorised contacts for the organisation).

The name of the person or corporation supplying the Active Herbal Extract may include the trading name, but **MUST** include either:

- the registered company name under the companies code, if the supplier is an Australian company, or
- the equivalent company name registered under overseas legislation, if the supplier is an overseas company, or
- the name of the person who conducts the business.

Provide the supplier’s business name as follows:

- for corporations: the registered company name, eg. Wonder Herbs Australia Pty Ltd;
- for individual traders: the full name of the person conducting the business, eg. John Canberra Smith;
- for partnerships: the full names of all partners, eg. John Canberra Smith and Mary Melbourne Brown; or
- if trading under another business name: if appropriate, give any other trading name or abbreviated name in brackets after the above name, eg. John Canberra Smith (Wonder Herbs), or International Wonder Herbs (IWH).

2 Active Herbal Extract Supplier’s Business Address:

Provide the postal address of Active Herbal Extract supplier.

3 Active Herbal Extract Supplier’s Client Identification (ID) number:

Provide the supplier’s Client Identification (ID) (formally Enterprise Detail) number if known. If the supplier does not have an ID number, please leave this Item blank, and either complete and submit a ‘Client Details’ form with this notification, or ensure Item 4 is completed in full.

4 Active Herbal Extract Supplier's Contact Officer:

Provide the name of the person who is acting on behalf of the supplier and to whom any correspondence should be referred. This person should be an authorised contact for the organisation, with details included on the TGA's Client ID database.

Contact details such as postal address, e-mail address (if available), phone number and/or facsimile number should be provided, except where Item 3 has been completed.

5 Have you attached a completed 'Client Details' form for this information?

To obtain a 'Client Details' form please contact the TGA by telephone on (02) 6232 8610 or refer to the TGA website at: <http://www.tga.gov.au/docs/html/forms/clientdt.htm>.

Additional information regarding Client Details:

- The TGA requires accurate information regarding your postal and street addresses, e-mail addresses (if available), telephone and fax numbers and the persons to contact regarding the 'Application for Selective Non-Disclosure of Active Herbal Extract Details' form that you have submitted. A separate 'Client Details' form should be used to provide this information. You do not need to complete this form if the TGA already holds current information for your company and all authorised persons.
- If your contact details change, please advise the TGA of such changes as soon as possible, by submitting a new 'Client Details' form.

6 Active Herbal Extract Manufacturer's Client Identification (ID) number:

Provide the Manufacturer's Client ID number, if known.

If you have not been allocated a Client ID number, leave this question blank and either complete and submit a separate 'Client Details' form, or ensure Item 7 is completed in full.

If you do not know your 'Client ID' number please contact the Proprietary Ingredient Coordinator by phone on (02) 6232 8648 for further information.

7 Active Herbal Extract Manufacturer's Name and Site Address

Where Item 6 has not been completed, please provide the name and site address of the manufacturer. Please include all manufacturers if there is more than one manufacturer.

Part B – Product / Formulation Details

8 Proposed Active Herbal Extract Name:

The Active Herbal Extract name is the name (Proprietary or trade name) of the Active Herbal Extract supplied in Australia. State the Active Herbal Extract name exactly as the supplier has stated or as the name appears on the product label or product specification sheet.

There are some computer limitations which should be considered in the naming of an Active Herbal Extract, such as:

- the maximum length of a Active Herbal Extract name available on the ARTG is 150 characters;
- the use of certain punctuation symbols (eg. comma and full stop) is limited because the computer system cannot search on these symbols;
- the computer will not accept duplicate names for an Active Herbal Extract therefore if there is a change in the formulation of a Active Herbal Extract, a new number is required. As such, either the old or the new name must be modified to allow the new formulation to be entered on the database.

9 Please supply the following information for the active ingredient:

The following information must be provided for all active ingredients in the Active Herbal Extract. If there is more than one active ingredient, copy page 3 of the '*Application for Selective Non-Disclosure of Active Herbal Extract Details*' form and attach to your application.

- **Botanical name**

Please provide the botanical name (Genus, species) of the active herbal ingredient, eg. *Ginkgo biloba*. This must be an Approved Herbal Name (AHN), as listed in the TGA's '*Approved Terminology for Medicines*'. The herbal ingredient must also be eligible for inclusion in Listed Medicines on the ARTG.

- **Plant part used:**

The plant part nominated must use botanically correct terminology and must use an appropriate Australian Approved Name (AAN), as listed in the TGA '*Approved Terminology for Medicines*'. Examples of plant-part AANs include "leaf", "stem bark" and "whole plant".

- **Type of preparation:**

Details of the plant preparation should accurately describe the preparation used. The preparation must be a Preparation AAN as listed in the TGA's '*Approved Terminology for Medicines*' eg. "Extract dry concentrate".

- **Physical appearance (optional):**

The final physical form of the preparation may be described. eg. "Pale yellow powder".

- **Equivalent weight of herb (specify fresh or dry):**

Where the substance is processed, the equivalent dry of fresh weight of the herbal material should be provided.

- **Standardised activity:**

If the active herbal ingredient has been standardised to a herbal component, either a single chemical entity or a component group, this must be nominated, using an approved Herbal Component Name (HCN) as listed in the TGA's '*Approved Terminology for Medicines*' eg. 22% theanine. It may be necessary to apply for a HCN if one is not available.

If the standardised quantity is expressed as a range, the midpoint of the range will be selected to express the quantity eg. if the standardised component is 20-24% theanine, this will be expressed as 22% theanine. In some cases suppliers may not wish to use the midpoint value. If this is the case, justification should be provided to the Coordinator and approval will be considered on a case by case basis. Please contact the Active Herbal Extract Coordinator by phone on (02) 6232 8648 for further information.

- **Equivalent amount of standard component:**

The quantity of the standardised active component/s must be stated eg. Equivalent cascarioside A 240mg.

- **Method of analysis:**

The method of analysis used to identify the herbal substance must be provided eg. HPLC.

- **Native plant/Extract ratio:**

The Native plant/extract ratio is to be stated. This is the ratio of the weight of herbal material in a given amount of the final extract, to the weight of herbal material initially used to make that amount of extract (this is sometimes called the 'native extraction ratio').

- **Final plant/ Extract ratio:**

The Final plant/extract ratio is to be stated. This is the ratio of the weight of the final amount of extract used, to the weight of the dried herbal material used to make this amount of extract. This may be the same as the native plant extract ratio if there are no excipients included in the final extract.

- **Number of extraction steps:**

The number of extraction steps used in processing the herbal material must be provided.

- **Details of each extraction step used, including solvent details and extraction ratios for each step:**

The name and relative proportion of solvent (s) used in each extraction must be provided. The solvent must be in AAN format or an accepted abbreviation (but written at least once in full) and approved for use as a solvent in products on the ARTG. The relative solvent concentrations should be stated as percentages. If there is more than one solvent the percentage figure refers to the proportion of the first named solvent. For example, one solvent "in 100% Water", or two solvents "in 45% Ethanol:Water". Any residual solvents must be named and quantified as excipient ingredients. For more information refer to '*The extraction Ratio- AAN and Solvent- AAN*' in the '*TGA Approved Terminology for Medicines*'.

If there is more than one extraction step in the processing of the herbal material, the extraction ratios of the weight of the raw herbal material should be provided for each extraction step eg.

1. Extract (5:1) in 40% E:W
2. Extract (10:1) in 100% glycerol

If the active ingredient has more than two extraction steps, please copy the relevant page and attach to the '*Application for Selective Non-Disclosure of Active Herbal Extract Proprietary Ingredient Details*' form as part of your application.

- **Additional Preparation steps (if any):**

Additional preparation steps (if any) - If there are any other processing steps involved in the preparation of the herbal material these must be stated eg. filtration, separation.

10 Please list all excipient/s used in the formulation including the purpose and quantity of each ingredient. Attach additional pages if required.

Please include all residual solvents in the list of excipient ingredients. Appendix VIII L to the British Pharmacopoeia (BP) provides guidance on the acceptability of residual solvents. Where applicable, compliance with the BP is required.

Each excipient ingredient, including any residual solvents and any Sub-Proprietary ingredients, must be listed and the amount must be nominated. All excipient ingredients must be in AAN format and be eligible for inclusion on the ARTG. State the quantities of each excipient ingredient in either metric units or percentages.

Appendix VIII L to the British Pharmacopoeia (BP) provides guidance on the acceptability of residual solvents. Where applicable, compliance with the BP is required.

The role of the ingredient should be provided for each ingredient eg. Antioxidant, residual solvent. Where the ingredient is a residual solvent which complies with the limits outlined in the BP, under 'Quantity/Units' state 'Complies with BP'.

If the Active Herbal Extract contains more than five excipient ingredients, please copy the relevant page and attach to the '*Application for Selective Non-Disclosure of Active Herbal Extract Proprietary Ingredient Details*' form as part of your application.

If the excipient ingredients have not been currently used in a medicine, then toxicological data will be required to be submitted and approved prior to the use of the ingredient (see below).

Toxicological evaluation:

Evaluation of toxicological data is required when an excipient ingredient has not previously been used in therapeutic goods supplied in Australia, or is used at a higher quantity, or is via a different route of administration, to that currently used in Australia.

This requirement for evaluation applies to excipient ingredients that are used in Proprietary Ingredients classified as active pre-mixes, capsule formulations, coating materials, colours, cream or ointment bases, excipient mixes, oral bases, preservative mixes or sweeteners.

Where an excipient ingredient is identified as a new substance, the supplier (or manufacturer) is required to provide toxicological data to the TGA for evaluation and approval.

Guidance on the toxicological data required to support a new substance application is contained in the Australian Regulatory Guidelines for Complementary Medicines (ARGCM), the Australian Regulatory Guidelines for Prescription Medicines (ARGPM) and the Australian Regulatory Guidelines for OTC Medicines (ARGOM). These guidelines are all available on the TGA website: <http://www.tga.gov.au>.

Colours:

Colours to be used in Proprietary Ingredients intended for oral preparations are restricted to those included in the '*Colourings Permitted in Medicines for Oral Use*', otherwise the Active Herbal Extract will not be accepted for inclusion on the ARTG. This document is available on the TGA website at: <http://www.tga.gov.au/meds/colourings.htm>.

11 Total number of ingredients contained in Active Herbal Extract formulation:

Include the total number of ingredients in the Active Herbal Extract formulation.

12 Product specification sheet provided:

Attach the product specification sheet to this notification form. This information is required by the TGA to process this application.

13 Manufacturing details (including flow chart of manufacturing process):

Attach the manufacturing details, including a flow chart of the manufacturing details to this notification. This information is necessary for the TGA to determine whether the herbal extract meets the definition of a herbal substance, as per Regulation 2 of the Regulations.

Part C– Information Regarding Ingredients of Human or Animal Origin

14 Are any ingredients derived from human or animal origin?

Complete this question by advising whether or not the Active Herbal Ingredient or any Sub-Proprietary Ingredients contains an ingredient of human or animal origin.

Note that the TGA has developed a policy to minimise the potential risk of exposure to Transmissible Spongiform Encephalopathy (TSE), in particular Bovine Spongiform Encephalopathy (BSE), and through the use of medicines and medical devices in Australia. A copy of this policy is available from the TGA website at: <http://www.tga.gov.au/docs/html/tsepolicy.htm>.

The TGA requires that all new products included on the ARTG contain, or use in their manufacture, only animal or human products which are sourced from BSE-free countries, or where this is not possible, that there is an assessment of the evidence as to the TSE safety of the material used.

Examples of ingredients of animal origin include gelatin derived from bovine, civet derived from the Civet cat (*Civettictis civetta* or *Viverra zibetha*) and lecithin derived from eggs.

If the “Yes” box is ticked, you may be required to complete and attach a ‘Pre-clearance application for animal-derived ingredients’ form. If you are unsure of your obligation in this regard, please contact the Proprietary Ingredient Coordination Unit on (02) 6232 8465. A copy of the form is available on the TGA website at <http://www.tga.gov.au/docs/html/forms/animder.htm>.

If the material is of human origin, sponsors should first contact the Head of the Therapeutic Goods Administration Laboratories’ Immunobiology Section for details of data requirements.

15 Are any ingredients derived from endangered species?

Complete this question by indicating whether any ingredients are derived from endangered or native species. Information on endangered or native species is available in Part IV, Section 9 of the Australian Regulatory Guidelines for Complementary Medicines (ARGCM). This document is available on the TGA website at <http://www.tga.gov.au/docs/html/argcmp4.htm>.

While the TGA does not play a role in the administration or enforcement of Environment Protection and Biodiversity Conservation legislation, the TGA is obligated to take reasonable steps to prevent the illegal trade of endangered and Australian native species. In order to meet these obligations, the TGA will release to Environment Australia, information about therapeutic goods that contain substances derived from endangered or Australian native species.

While the TGA will continue to treat commercial-in-confidence information in accordance with legislated requirements, Section 61(6) of the *Therapeutic Goods Act 1989* allows the release of therapeutic goods information. Regulation 46 of the *Therapeutic Goods Regulations 1990* describes the kinds of therapeutic goods information that the Secretary may release. As described in Regulations 46(2)(b) and 46(2)(e)(v-vi) this information may include:

- the name of the therapeutic goods;
- the name and address of the sponsor of the goods;
- the names and quantities of therapeutically active substances in the goods;
- the presence or absence of any specific excipient in the goods.

Further information regarding the identification of endangered and Australian native species is available on the Department of the Environment and Heritage website at <http://www.deh.gov.au/biodiversity/trade-use/index.html>.

More Information:

For further assistance, please contact the Active Herbal Extract Coordinator by telephone on (02) 6232 8648.

DEFINITIONS

Active ingredient

An ingredient in a medicine's formulation that is responsible for its therapeutic action. For example, *Hypericum perforatum*, leaf extract.

Active Herbal Extract

An 'Active Herbal Extract', is a herbal extract or concentrate for which a supplier intends specific commercial in confidence information on the extraction method, steps and/or solvent details, to remain confidential from sponsors who include the extract as an active ingredient in a therapeutic product. The formulation may also contain excipient ingredients.

Animal

An invertebrate or vertebrate member of the animal kingdom.

ARTG

Australian Register of Therapeutic Goods.

ARTG number

The unique number assigned to a Proprietary Ingredient after it is entered on the Australian Register of Therapeutic Goods (ARTG).

Australian Approved Name (AAN)

The approved name applied to a therapeutic substance, as outlined in the '[TGA Approved Terminology for Medicines](#)', which includes:

- Approved Chemical Substance Names;
- Approved Biological Substance Names (ABNs);
- Approved Herbal Names (AHNs); and
- Approved Herbal Substances (AHSs).

Approved Biological Substance Name (ABN)

The approved name of a substance of biological origin that is not an antibiotic and is not derived from plant material.

Approved Herbal Name (AHN)

The approved botanical name of a species of a plant, eg. "*Allium sativum*", where the first word is the genus and the second word is the specific epithet. A complete AAN for a herbal substance is formed with the AHN, the plant part-AAN (eg. "fruit"), and the preparation-AAN (eg. "dry").

Approved Herbal Substance Name (AHS)

The approved name of a substance derived from plants or other organisms that are treated as plants, such as fungi and blue-green algae. AHSs are the only type of herbal AANs that are complete AANs. For example, "liquorice powder", as defined in the British Pharmacopoeia 2004.

Herbal Component Name (HCN)

The approved name for a constituent of an herbal ingredient. The herbal component is usually used as the marker for when an ingredient is claimed to be standardised e.g hyperforin (of *Hypericum perforatum*).

If a particular botanical name does not appear in the '[TGA Approved Terminology for Medicines](#)', please complete a proposal form for an herbal substance. The proposal form is on the TGA website at <http://www.tga.gov.au/docs/html/aanamend.htm#forms>.

Client Identification number or Client (ID) number

The unique number assigned by the TGA to a sponsor or supplier of products included on the ARTG.

Colourings Permitted in Medicines for Oral Use

A list of colours, approved by the TGA, for inclusion in medicines intended for oral use.

Colour

A substance whose primary purpose is to visually alter the appearance of a therapeutic good by imparting a definite colour or shade.

Electronic Listing Facility Version 3 (ELF 3)

The electronic Listing system used to List medicines on the ARTG.

Excipient ingredient

An ingredient other than an active ingredient included in a therapeutic good eg. maltodextrin.

Export only medicine

A medicine that:

- is manufactured in Australia for export only, or imported into Australia for export only
- is Listable goods only because it is so manufactured or imported (and not for any other reason).

Flavour

A substance whose primary purpose is to alter the taste of a therapeutic good.

Herbal substance

A herbal substance, as defined in Regulation 2 of the Regulations, means all or part of a plant or substance (other than a pure chemical or a substance of bacterial origin):

- 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.

Use an Approved Herbal Name (AHN) or Approved Herbal Substance Name (AHS) from the list of herbal substances in the '*TGA Approved Terminology for Medicines*'. The order in which herbal substances are presented is botanical name (genus and species), plant part and plant preparation and other relevant details if required (such as solvent details and ratio of dry herb to extract). For example "*Glycyrrhiza glabra* root extract liquid" not "Liquorice extract".

Ingredient of animal or human origin

An ingredient that is derived directly from a human or animal source.

Listed medicines

Therapeutic goods required to be included in the part of the ARTG for Listed goods. See Schedule 4 of the *Therapeutic Goods Regulations 1990*.

Name of an active ingredient

The name of the active ingredient that is that which is approved for inclusion in an Australian Approved Names List included in the '[TGA Approved Terminology for Medicines](#)'.

Name of an excipient ingredient

The name of the excipient ingredient that is approved for inclusion in an Australian Approved Names List included in the '*TGA Approved Terminology for Medicines*'.

Nominal quantity

The quantity stated by the supplier or manufacturer as the amount contained in the Proprietary Ingredient.

Plant preparation

Plant preparations can be a single term such as “fresh”, “dry”, “powder” and “oil essential”. In contrast, non-oil extracts have three or four parts that make the complete preparation name, as follows:

- a. the type of preparation, eg. “extract dry concentrate”
- b. the extract ratio and solvent details, eg. “(3:1 in 55% E:W)”
- c. the type of raw material used eg. “dry” or “fresh” (preceded by “EQUIV.”, the species AHN and the plant part AAN)
- d. where standardised, the name of the component against which the preparation is standardised eg. “EQUIV hypericin...”

Poisons Schedule

A schedule of the ‘*Standard for the Uniform Scheduling of Drugs and Poisons*’ (SUSDP).

Registered medicines

Therapeutic goods required to be included in the part of the ARTG for Registered goods. See Schedule 3 of the *Therapeutic Goods Regulations 1990*. Some examples include: prescription medicines, cough and flu preparations and paracetamol preparations.

Residual solvent

Solvent remaining in final product.

Restricted ingredients

Ingredients to which certain restrictions and conditions apply when used in Listed medicines. These restrictions may be the result of the ingredient being included in a poisons schedule, or Schedule 1 of the Therapeutic Goods Order No. 69. A list of restricted ingredients is published on the TGA website at the following address: <http://www.tga.gov.au/docs/html/restingr.htm>.

Sub-Proprietary Ingredient

A sub-formulation that is used in a master formulation of a Proprietary Ingredient and is usually supplied by another supplier. The Sub-Proprietary Ingredient formulation is usually confidential from the supplier of the Proprietary Ingredient or Active Herbal Extract.

Supplier

A person or company that may be the distributor or manufacturer of the Proprietary Ingredient or Active Herbal Extract. This person or company is responsible for ensuring that the Proprietary Ingredient information supplied to TGA is accurate, true and correct and that changes in the Proprietary Ingredient or Active Herbal Extract name, formulation, or supplier are notified to the TGA as soon as possible.

Sponsor

A person who exports, imports or manufactures a therapeutic good, or who arranges the exportation, importation or manufacture of the goods for supply. It does not include a person who exports, imports or manufactures the goods or arranges the exportation, importation or manufacture of the goods on behalf of another person who, at the time of the exportation, importation or manufacture or arrangements, is a resident of, or is carrying on business in Australia.

‘TGA Approved Terminology for Medicines’

The document that contains lists of approved names for chemical substances, biological substances, herbal substances, units and expressions of proportion, routes of administration, etc., explanatory notes and proposal forms for approved names. This document is updated and amended from time to time. Available at: <http://www.tga.gov.au/docs/pdf/aan/aan.pdf>.

TGA website

<http://www.tga.gov.au>.

The Act

The *Therapeutic Goods Act 1989*.

Therapeutic Goods Administration (TGA)

The Australian regulatory authority responsible for the regulation of therapeutic goods supplied in and/or exported from Australia.

Therapeutic Goods Order No. 69 ‘General requirements for labels for medicines’

The legislative requirements for the labelling of medicines in Australia. Generally referred to as TGO 69.

Therapeutic Goods Regulations 1990

The Regulations referred to in the *Therapeutic Goods Act 1989*.

Toxicological data

Data provided to the TGA to determine the safety of an ingredient of a medicine. This information is required for all ingredients that have not previously been used in therapeutic goods supplied in Australia or those ingredients supplied at a higher quantity or via different routes of Administration to those previously supplied in Australia.