Introduction

This Guidance document has been developed to assist sponsors of therapeutic goods and suppliers of Proprietary Ingredient formulations when completing the ‘Notification of a New Proprietary Ingredient’ form.

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.

Before a therapeutic good can be Registered / Listed on the ARTG, the formulation of the therapeutic good must be supplied to the Therapeutic Goods Administration (TGA). This includes the formulation details of Proprietary Ingredients present in the therapeutic good.

Information supplied to the TGA in relation to the inclusion of Proprietary Ingredients on the ARTG is treated as ‘commercial-in-confidence’. The TGA will NOT release formulation information in Proprietary Ingredients, other than in accordance with the Act or as otherwise required or permitted by law.

The ‘Notification of a New Proprietary Ingredient’ form is the mechanism that allows Proprietary Ingredient formulations to be entered onto the ARTG. There is no assessment or evaluation of Proprietary Ingredient formulations, or their ingredients, at the time of application unless toxicological data is required to be evaluated for specific Proprietary Ingredients. During the evaluation or assessment of a finished product which contains a Proprietary Ingredient, the TGA may request additional information on the Proprietary Ingredient, given that the formulation details for a Proprietary Ingredient are supplied in isolation of the finished product formulation.

Proprietary Ingredient suppliers should note the following:

- **It is the supplier’s responsibility to provide complete and accurate formulation details about their Proprietary Ingredient.**

- **It is the supplier’s responsibility to advise the TGA, and sponsor(s) using their Proprietary Ingredient, of any change in formulation, Proprietary Ingredient name, supplier or supplier details.**

Sponsors and other users of Proprietary Ingredients should note the following:

- **The inclusion of a Proprietary Ingredient on the ARTG does not imply any recommendation for its use in either Registered or Listed medicines or medical devices.**

- **It is the sponsor’s responsibility to ensure that the correct Proprietary Ingredient information is provided to TGA in their product formulation.**
Definition of a Proprietary Ingredient

The term ‘Proprietary Ingredient’ means a confidential formulation usually containing two or more ingredients and about which information is not in the public domain. Proprietary Ingredients include, for example, fragrances, flavours, colouring ingredients, adhesives and printing inks.

Note that where a pre-mix of active ingredients is used in a proprietary ingredient formulation, the active ingredients must be disclosed to the sponsor and any other third party.

A single ingredient is not usually acceptable as a proprietary ingredient formulation.

Form Layout

The ‘Notification of a New Proprietary Ingredient’ form consists of the following five parts:

- **Part (A) General Details** - information about the supplier
- **Part (B) Product Details** - information on the intended use
- **Part (C) Formulation Details**
- **Part (D) Additional Information** – information on ingredients that may require toxicological evaluation, on ingredients derived from human/animal origin or from native/endangered species.
- **Part (E) Manufacturer Details** – not mandatory.

TGA processing of a ‘Notification of a New Proprietary Ingredient’ form

A ‘Notification of a New Proprietary Ingredient’ form must be submitted to the TGA by the supplier of the Proprietary Ingredient. However, the sponsor of the finished product may submit a ‘Notification of a New Proprietary Ingredient’ form on the supplier’s behalf provided a letter of authorisation from the supplier is enclosed with the notification.

When a ‘Notification of a New Proprietary Ingredient’ form is lodged with the TGA, the following processing steps occur:

- The eligibility of the Proprietary Ingredient for entry onto the ARTG is established.
- The form is checked to ensure that all required information has been provided including that ingredient names are in the required format.
- All Sub-Proprietary Ingredient information is checked to ensure that the Sub-Proprietary Ingredient can be entered on the ARTG.
- If the information is incomplete or inadequate, a written request will be sent to the supplier requesting further information.
- Once all the required information is received by the TGA, the Proprietary Ingredient is entered onto the ARTG and is allocated a unique ARTG number.
- A letter is sent to the Proprietary Ingredient supplier (and sponsor, if nominated), advising them of the Proprietary Ingredient name, ARTG number, supplier’s name and supplier Client Identification number. Sponsors who wish to include a Proprietary Ingredient in an application to List or Register a product on the ARTG require this information. The Proprietary Ingredient used in a product must match the information supplied by the supplier in their notification to TGA.
Non-acceptance of a Proprietary Ingredient

The TGA may refuse to accept a Proprietary Ingredient formulation for inclusion on the ARTG for the following reasons:

- The Proprietary Ingredient contains a single ingredient and, therefore does not meet the definition of a Proprietary Ingredient.
- The Proprietary Ingredient formulation consists of two or more ingredients and is in the public domain, eg. in a published document such as the International Cosmetic Ingredient Dictionary (ICID). Such a Proprietary Ingredient does not meet the definition of a Proprietary Ingredient.
- An active pre-mix formulation contains only active ingredients with no excipient ingredients. This Proprietary Ingredient does not meet the definition of a Proprietary Ingredient because all the active ingredient information must be declared on product labels (thus not allowing confidentiality).
- The colour in a colouring intended for oral use is not included in the list of Colourings Permitted in Medicines for Oral Use.
- Failure to supply formulation information on Sub-Proprietary Ingredients.
- The Proprietary Ingredient contains a new substance for which toxicological data is required and which, if the Proprietary Ingredient were included on the ARTG, would appear to give tacit approval to the use of the new substance.
- The sole purpose for including the Proprietary Ingredient on the ARTG is to use the Proprietary Name of the Proprietary Ingredient on the product label.
- The request for additional information from a supplier for a Proprietary Ingredient is ignored or the information supplied is such that the Proprietary Ingredient is still unable to be finalised.
- The sponsor of a therapeutic good proposes to include the full excipient formulation details of a product as a Proprietary Ingredient. There are other avenues available to sponsors of Listed or Registered goods, that will ensure the confidentiality of the excipient ingredient formulation.

Public Disclosure of Information about a Proprietary Ingredient

Suppliers should be aware that the following information regarding Proprietary Ingredients is available to third parties:

- The Proprietary Ingredient name, supplier name, supplier’s client detail number and ARTG number of the Proprietary Ingredient.
- 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. 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 ‘Notification of a New Proprietary Ingredient’ form

**Part A – General Details**

Questions 1 - 7 are to be completed by the sponsor of the therapeutic good that will use this Proprietary Ingredient in their product.

Questions 8 - 12 are to be completed by the supplier of the Proprietary Ingredient.

1. **This notification is part of an application for:**

   Indicating the type of therapeutic application for which this notification forms a part, by ticking the appropriate box.

   If unsure or if the notification isn’t part of an application for Listing / Registration, tick the ‘Unknown at the time of application’ box.

2. **Registration / Listing name of goods of which the Proprietary Ingredient is an ingredient:**

   Indicate the name of the therapeutic good exactly as shown in the application for which this notification forms a part.

3. **Route of administration of goods of which the Proprietary Ingredient is an ingredient:**

   Indicate the route(s) of administration using the list in the *TGA Approved Terminology for Medicines*, for example: ‘oral’ or ‘topical’. More than one route of administration can be stated for the use of your Proprietary Ingredient.

4. **Sponsor’s Business Name:**

   Indicate the sponsor’s business name, exactly as shown in the application for which this notification forms a part.

5. **Sponsor’s Business Address:**

   Provide the postal address for the sponsor.

6. **Sponsor’s Contact Person / Agent:**

   Provide the name of the person who is acting on behalf of the sponsor and to whom any correspondence should be referred.

   Contact details such as postal address, e-mail address (if available), phone number and / or facsimile number should be provided.
7 Sponsor’s Client Identification (ID) number:

Provide the sponsor’s Client Identification (ID) (formally Enterprise Detail) number if known, otherwise print ‘Unknown’.

8 Proprietary Ingredient Supplier’s Business Name:

Provide the full name of the person or corporation that supplies the Proprietary Ingredient. 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.

The name of the person or corporation supplying the Proprietary Ingredient 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 Flavours 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 Flavours), or International Wonder Flavours Inc (IWF).

9 Proprietary Ingredient Supplier’s Business Address:

Provide the postal address of the Proprietary Ingredient supplier.

10 Proprietary Ingredient 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.

Contact details such as postal address, e-mail address (if available), phone number and / or facsimile number should be provided.

11 Proprietary Ingredient Supplier’s Client ID number:

The Client Identification (ID) (formally Enterprise Detail) number is a computer-generated code allocated by the TGA when a supplier initially submits a notification of a Proprietary Ingredient. You will have been allocated a Client ID number if you have previously completed a ‘Client Details’ form.
If you have not previously been allocated a Client ID number, leave question 11 blank and complete a separate ‘Client Details’ form.

12 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/about/forms-client-details.htm

If you have been allocated but do not know your Client ID number, please contact the Proprietary Ingredient Coordinator by telephone on (02) 6232 8465 for further information.

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 Proprietary Ingredient 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.

Part B – Product Details

Questions 13 and 14 must be completed by either the supplier or the sponsor.

13 Proprietary Ingredient Name:

The Proprietary Ingredient name is the name (Proprietary or trade name) of the Proprietary Ingredient supplied in Australia. State the Proprietary Ingredient 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 a Proprietary Ingredient, such as:

- the maximum length of a Proprietary Ingredient 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 a Proprietary Ingredient therefore if there is a change in the formulation of a Proprietary Ingredient, 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.

14 This Proprietary Ingredient is intended for use as a... (please tick as appropriate):

Tick one box indicating the role or purpose of the Proprietary Ingredient in the therapeutic good. There are definitions provided in Appendix 1 of these ‘Guidelines’ to assist you in determining the appropriate category for your Proprietary Ingredient.

The type of Proprietary Ingredient nominated will determine the requirements for that Proprietary Ingredient. These requirements are stated at the bottom of the page in the ‘Notification of a New Proprietary Ingredient’ form.
For flavours, fragrances, inks and adhesives (including trans-dermal patch adhesives) the ingredient names are not required to be in Australian Approved Name (AAN) format (see Appendix 2). However, it is preferred that, where possible, these ingredient names be presented in AAN format and that Chemical Abstracts Service (CAS) numbers be provided with each ingredient name. For all other Proprietary Ingredients, ingredient names must be in AAN format.

**Part C – Formulation Details**

Questions 15 - 20 are to be completed by the Proprietary Ingredient supplier.

Note that Questions 17 - 20 are only to be completed if the Proprietary Ingredient contains any Sub-Proprietary Ingredients. Most Proprietary Ingredients will not contain Sub-Proprietary Ingredients.

**15 Total number of ingredients contained in Proprietary Ingredient formulation:**

Include the total number of ingredients in the Proprietary Ingredient formulation.

**16 Please supply information on all ingredients in your Proprietary Ingredient formulation, including details of the role and quantity of each ingredient:**

If the Proprietary Ingredient contains more than ten ingredients, please copy the relevant page and attach to the ‘Notification of a New Proprietary Ingredient’ form as part of your application.

The role of the ingredient must be provided for each ingredient. The role of the ingredient should be:

- an active ingredient, stated as ‘A’, or ‘Active’
- an excipient ingredient, stated as ‘E’ or ‘Excipient’.

It should be noted that all ingredients are classified as excipients unless they are an active ingredient in an active pre-mix or are a Sub-Proprietary Ingredient in a Proprietary Ingredient. If unsure, please check the definitions of these different types of ingredients in Appendix 1.

The active ingredient of an active pre-mix is not confidential in accordance with the Act. 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.

Quantities must be provided for all active, excipient and Sub-Proprietary Ingredients except flavours, fragrances, inks and adhesives. Note that where quantitative information is provided for flavours, fragrances, inks and adhesives, these details will be entered on the ARTG.

- **For active ingredients:**
  - List each ingredient name and nominal quantity on a separate line.
  - State quantities in either metric units or as a percentage.
  - Any overage(s) not included in the nominal quantity.
  - All ingredient names must be in AAN format.
  - Active ingredients to be used in Listed medicines must comply with the requirements of Schedule 4 of the Therapeutic Goods Regulations 1990.
• **For excipient ingredients:**
  - List each ingredient on a separate line.
  - State quantities in either metric units or percentages.
  - Any overage(s) not included in the nominal quantity.

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

This requirement for evaluation applies to 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 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](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 Proprietary Ingredient will not be accepted for inclusion on the ARTG. This document is available on the TGA website at: [http://www.tga.gov.au/industry/cm-colourings-oral-use.htm](http://www.tga.gov.au/industry/cm-colourings-oral-use.htm).

### Number of Sub-Proprietary Ingredients listed for this Proprietary Ingredient:

Indicate the number of Sub-Proprietary Ingredients used in the Proprietary Ingredient.

### Please supply the following information on all Sub-Proprietary Ingredients listed for this Proprietary Ingredient:

It should be noted that it is the responsibility of the Proprietary Ingredient supplier to ensure that all information on Sub-Proprietary Ingredients is either included in the ‘Notification of a New Proprietary Ingredient’ form or has been requested.

Please provide the name of the Sub-Proprietary Ingredient and the supplier. Please include the Supplier’s Client ID number and the Proprietary Ingredient ARTG number, if known. (As many Sub-Proprietary Ingredient formulations are already included on the ARTG, the provision of this information will assist the TGA in identifying the Sub-Proprietary Ingredient on the ARTG and will enable the TGA to finalise your notification form more quickly).

Where the Sub-Proprietary Ingredient is known not to be included on the ARTG, please request the Sub-Proprietary Ingredient supplier to complete and submit a ‘Notification of a New Proprietary Ingredient’ form. Please note that the formulation details of a Sub-Proprietary Ingredient must be provided.

If there are more than three Sub-Proprietary Ingredients in the Proprietary Ingredient, please copy the relevant page and attach to the ‘Notification of a New Proprietary Ingredient’ form as part of your application.
19 Have you sent ‘Client Details’ forms to Sub-Proprietary Ingredient suppliers for which no Client ID number is given?

This question should only be answered ‘No’ if the Client ID numbers for each Sub-Proprietary Ingredient supplier are known and stated in your notification.

20 Have you sent a partially completed ‘Notification of a New Proprietary Ingredient’ form to the suppliers of Sub-Proprietary Ingredients for which no ARTG number is given?

This question should only be answered ‘No’ if all Sub-Proprietary Ingredients are included on the ARTG and the ARTG numbers of all Sub-Proprietary Ingredients have been stated in your notification.

Part D – Additional Information on Proprietary Ingredients

Questions 21 - 23 are to be completed by the Proprietary Ingredient supplier.

21 Are any of the ingredients contained in the formulation not currently included in the ARTG?

This question should only be answered if the proprietary ingredient is NOT to be used as an adhesive, flavour, ink or fragrance.

If any of the ingredients are not currently included in the ARTG, supporting toxicological data will be required. Please contact the Proprietary Ingredient Coordinator on (02) 6232 8465 to arrange submission of data.

If you are unsure as to whether all of the ingredients are currently included in the ARTG please contact the Proprietary Ingredient Coordinator on (02) 6232 8465 to determine whether or not you will be required to submit supporting toxicological data.

Note: Evaluation of toxicological data attracts a fee. If, during the processing of this notification it is discovered that the formulation contains ingredients that are not currently included in the ARTG, you will be required to submit supporting toxicological data for evaluation by the TGA. The proprietary ingredient notification cannot be finalised until the toxicological data has been evaluated and found to be acceptable by the TGA.

22 Are any ingredients derived from human or animal origin?

Complete this question by advising whether or not the Proprietary 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/industry/tse-approach.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/industry/cm-forms-animal-derived-ingredients.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.

23 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/industry/cm-argcm.htm#argcmp4.

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.


Part E – Manufacturer Details

Non-mandatory Question. Only to be completed if multiple manufacturing sites

Questions 24 - 26 are to be completed if the same formulation is manufactured at a number of manufacturing sites. Please indicate all sites of manufacturer. Rather than creating several Proprietary Ingredient numbers for the same formulation please nominate one manufacturing site as the supplier and then include this site and other sites in the manufacturer field.
**24 Manufacturer’s Name:**

Indicate the name of the manufacturer. If there is more than one, please include all manufacturers.

**25 Manufacturer’s Site Address:**

Please provide the site address of the Proprietary Ingredient manufacturer.

**26 Manufacturer’s Client ID number:**

Provide the Manufacture’s Client ID number, if known.

If you have not been allocated a Client ID number, leave this question blank and complete a separate ‘Client Details’ form. To obtain a ‘Client Details’ form, please contact the TGA by phone on (02) 6232 8610 or refer to the TGA website: [http://www.tga.gov.au/about/forms-client-details.htm](http://www.tga.gov.au/about/forms-client-details.htm).

If you do not know your ‘Client ID’ number please contact the Proprietary Ingredient Coordinator by phone on (02) 6232 8465 for further information.

**More Information**

For further assistance, please contact the Proprietary Ingredient Coordinator by telephone on (02) 6232 8465.
Appendix 1

DEFINITIONS

Active ingredient
An ingredient in a medicine’s formulation that is responsible for its therapeutic action. For example, Vitamin E, where it is intended for use as an active ingredient in a vitamin supplement.

Active pre-mix
A formulation that contains one or more active ingredients in combination with one or more excipient ingredients. The excipient ingredients are generally added to stabilise the formulation or to improve the mixing of the Proprietary Ingredient formulation in the final finished product.

Adhesive
A formulation that is used to manufacture a dosage form which is applied to the skin. An example of this is a transdermal patch adhesive.

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 2003.

Capsule shell formulation
A formulation that is used to manufacture a capsule shell.
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.

Coating material
A formulation that is used in the manufacture of a coating for an oral dosage form. This formulation can include a colour or colours.

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.

Cream (or ointment) base
A formulation that is used in the manufacture of a cream or ointment.

Electronic Listing Facility Version 3 (ELF 3)
The electronic Listing application used to List medicines on the ARTG.

Excipient ingredient
An ingredient other than an active ingredient included in a therapeutic good. For example, Vitamin E, where it is intended for use as an antioxidant for the preservation of the Proprietary Ingredient.

Excipient mix
A Proprietary Ingredient formulation comprised of a mixture of excipient ingredients that may be used in a therapeutic good for purposes other than those already stated in question 14 of the form. Examples include emulsifiers and anti-oxidants.

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.

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

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

Ink
A substance whose primary purpose is for printing on a tablet or capsule.

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.

New Substance
An ingredient (Chemical, Herbal or Biological) that is currently not used in a medicine for supply in Australia. This ingredient may or may not have an Australian Approved Name. This criterion for the use of New Substance applies to all Proprietary Ingredients other than flavours, fragrances, printing inks and adhesives.

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

Notification of a New Proprietary Ingredient form
The form submitted by the supplier of the Proprietary Ingredient to the TGA for entry on the ARTG.

Ointment (or cream) base
A formulation that is used in the manufacture of an ointment or cream.

Oral base
The formulation to be used during manufacturer of a base intended to be used in an oral dosage form such as a chewing gum base.

Poisons Schedule
A schedule of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

Preservative mix
A formulation added to therapeutic goods to avoid spoilage of the product by preventing or inhibiting microbial growth.

Proprietary Ingredient
A confidential formulation usually containing two or more ingredients and about which information is not in the public domain. Proprietary Ingredients include fragrances, flavours, colouring ingredients, trans-dermal patch adhesives and printing inks. Note that where a pre-mix of active ingredients is used in a proprietary ingredient formulation, the active ingredients must be disclosed. A single ingredient is not usually acceptable as a proprietary ingredient formulation.

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.

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.

Route of Administration
The intended method by which a therapeutic good is applied onto or introduced into the body. For example, oral, topical or transdermal. A list of these terms is included in the ‘TGA Approved Terminology for Medicines’.
**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.

**Supplier**
A person or company that may be the distributor or manufacturer of the Proprietary Ingredient. 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 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.

**Sweetener**
A substance whose primary purpose is to sweeten the taste of the therapeutic good so that the good is more palatable to consumers.

**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/industry/medicines-approved-terminology.htm](http://www.tga.gov.au/industry/medicines-approved-terminology.htm).

**TGA website**

**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.
AUSTRALIAN APPROVED NAMES (AANS)

General Notes

- Australian Approved Names (AANs) are given in the TGA Approved Terminology for Medicines, which is available from the TGA Publications Office or from the TGA website at http://www.tga.gov.au/industry/medicines-approved-terminology.htm.
- Incomplete names abbreviations or proprietary names should not be used (eg. Ylang Ylang oil instead of Ylang Ylang or ‘butylated hydroxytoluene’ instead of BHT or Dipropylene glycol instead of DPG or Acetaldehyde ethyl phenethyl acetal instead of Hyacinth body.).
- Where two or more forms of a substance appear on the AAN list, provide sufficient detail so that the correct form will be entered onto the database, eg. use ‘Citric acid – anhydrous’ or ‘Citric acid monohydrate’ not ‘Citric acid’.
- Indicate types of starch used in AAN format regardless of the type of Proprietary Ingredient. For example, use a more specific term than ‘modified food starch’.
- If the ingredient name can not be determined to be an Australian Approved Name then a proposal form for a chemical substance must be completed. The proposal form is on the TGA website at http://www.tga.gov.au/industry/medicines-approved-terminology.htm.

Herbal Substances

- 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’.
- Full instructions on how to complete this section of the application with respect to the naming of herbal preparations are included in the preface to the Herbal Substances list.

Biological Substances

- Use an Australian Biological Name (ABN) from the List of Biological Substances in the TGA Approved Terminology for Medicines. The Biological Names section includes approved names for animal parts, animal preparation, biological descriptors and biological substance names. Some ingredient names should be expressed as the Biological name, animal part and animal preparation (eg. ‘Goat horn powder’).
- Full instructions on how to complete this section of the application with respect to the naming of the biological preparations are included in the preface to the Biological Substances List.
- If there is no approved Biological name then please complete a proposal form for biological substance. The proposal form is available on the TGA website at http://www.tga.gov.au/industry/medicines-approved-terminology.htm.