

**ANNEX B****NAMING AND LABELLING CONVENTIONS FOR  
ACTIVE INGREDIENTS IN COMPLEMENTARY MEDICINES****PREAMBLE**

Complementary medicines cover a wide range of potential active ingredients from various sources, uses, preparations, disciplines, and traditional names. As a result the many potential active ingredients may vary significantly in their nomenclature. This often leads to situations in which the same active ingredients may be labelled / named in different ways. In order for stakeholders to provide sufficient identifying information of specific active ingredients that would provide sufficient insight into its origin and intention, a standardised approach to naming and labelling active ingredients in CMs is necessary. This will provide for standardised reference and evaluation of applications for registration of CMs and will enhance prescriber and patient choice when selecting a CM best for their purposes. This guidance takes into account the challenge associated with limited space available on product labels while stipulating the standard requirements for Professional Information (PIs) and Patient Information Leaflets (PILs).

**1 INTRODUCTION****1.1 Objectives of the Guideline**

The guideline seeks to standardise the presentation of naming of active ingredients used in these medicines. It represents mechanisms for all labelling that would be deemed most appropriate, however, alternative approaches can be used when there are justifiable reasons.

**1.2 Scope of the Guideline**

This guideline is applicable to all Complementary Medicines (Category D).

The guideline addresses the format of naming information for active ingredients in CMs and pertains to the labelling of products available for sale, those products yet to be made available for sale and for applications submitted to the SAHPRA in consideration of their registration based on quality, safety or efficacy.

**1.3 General Principles**

The requirements for approved and common names in relevant specified guideline should also be considered. The correct intended layout should make use of square and round brackets and italicisation of Latin binomial, where appropriate. The use of the Accepted Name is required while the use of the Common Name is optional.

Active ingredients should be included in order of the highest quantity to least quantity. Any active ingredients of the same quantity should be presented in alphabetical order.

The accepted name may / may not be in italics which is determined by the origin of the name. Accepted names should be checked such that they are precisely representative of the ingredient used with attention to detail of lettering style and spacing in the required areas critical.

Descriptor use is mandatory if not already described by the approved / common names.

In sections 2 and 3 bracketed text indicated by <blue> brackets represents text that would be inserted. Any black text that appears in the tables represents standard text.

**2 NAMING CONVENTIONS FOR PROFESSIONAL INFORMATION (PI) AND PATIENT INFORMATION LEAFLETS (PIL)**

**2.1 General Ingredients in Complementary Medicines**

<Accepted Name> (<Common / Pharmacopoeial Name>) ..... <X> <unit>

e.g. Niacinamide (Vitamin B3).....30 mg

**2.2 Labelling of Biological Substances and Animal Substances**

<Accepted Name> (<Common / Pharmacopoeial Name>) ..... <X> <unit>  
 [<part, preparation and / or biological descriptor>]

e.g. *Taraxacum campylodes* G.E. Haglund (Dandelion) ..... 200 mg  
 [root powder]

e.g. Chondroitin sulphate..... 800 mg  
 [porcine]

e.g. *Perna canalicula* (Green Lipped Mussel) ..... 100 mg

2.3 Labelling of Herbal Extracts

**Option 1**

Where: X = Dried herb equivalent

<Accepted name> (<Common Name / Pharmacopoeial Name>) ..... <X> <unit>  
 [<part, preparation and / or biological descriptor> as <ABC> <unit> of a <D:E> extract / standardised to <Herbal Component Name> <FGH> %]

e.g. *Hypericum perforatum* L. (St. John's Wort) ..... 300 mg  
 [flowering tops, as 30 mg of a 10:1 extract standardised to hypericin 0,3 %]

OR:

**Option 2**

Where: X = Amount included in formulation

<Accepted name> (<Common Name / Pharmacopoeial Name>) ..... <X> <unit>  
 [<part, preparation and / or biological descriptor>, <D:E> extract / standardised to <Herbal Component Name> <FGH> %  
 providing <ABC> unit of dried herb equivalent]

e.g. *Hypericum perforatum* L. (St. John's Wort) ..... 30 mg  
 [flowering tops, 10:1 extract standardised to hypericin 0,3 % providing 300 mg of dried herb equivalent]

2.4 Labelling of Herbal Ingredients with mixed sources

**Option 1**

<Genus> species (<Shared Common / Pharmacopoeial name>) ..... <X> <unit>  
 [<parts, preparation or biological descriptor>]  
 from: <Accepted name(s)>

e.g. *Euphrasia* species (Eyebright) ..... 1 ml  
 [aerial portions, 1:10]  
 from: *Euphrasia officinalis* L., *Euphrasia rostkoviana* Hayne, *Euphrasia stricta* D. Wolff

OR:

**Option 2**

<Preparation description> of <Genus> species (<Shared Common / Pharmacopoeial name>) from:  
 <Accepted name>  
 [<parts, preparation of descriptor>]  
 <Accepted name>  
 [<parts, preparation of descriptor>]  
 ...

e.g. Tincture of *Crataegus* species (Hawthorn) from:  
*Crataegus monogyna* Jacq.  
*Crataegus rhipidophylla* Gand. (*Crataegus oxyacantha* L.)  
 [fruits]

2.5 Labelling of Health Supplements

**Option 1**

<Accepted Name> (<Common/ Pharmacopoeial Name>) ..... <X> <unit>  
 providing <descriptor> ..... <X> <unit>

e.g. Chromium polynicotinate..... 200 mg  
 providing Chromium (elemental)..... 20 mg

OR:

**Option 2**

<Accepted Name> (<Common/ Pharmacopoeial Name>) ..... <X> <unit>

e.g. L-Ascorbic acid (Vitamin C) ..... 100 mg

**3 NAMING CONVENTIONS FO CONTAINER OR PACKAGING LABELS**

The same principles may apply in the application of the conventions described in sections 2 and 3. However, due to restrictions and space on the label, it shall be sufficient to use a simple Latin binomial or pharmacopoeial name of herbal ingredients that are fully characterised in a monograph of an accepted pharmacopoeia, provided it is clear to the consumer exactly which herb (or part thereof) is being used. The common name may also be stipulated and the summarised information regarding the part, preparation and / or biological descriptor must be supplied.

**Option 1**

<Accepted Name> (<Common / Pharmacopoeial Name>) ..... <X> <unit>  
 [<brief description of part, preparation and / or biological descriptor, extract / standardisation>]

OR:

**Option 2**

Where space limitation on the label may prevent listing of the name as per option 1.

<Accepted Name> (<Common / Pharmacopoeial Name>, <brief description of part/preparation>) ..... <X> <unit>  
 [extract / standardisation>]

OR:

<Common / Pharmacopoeial Name>, <brief description of part/preparation>..... <X> <unit>  
 [extract / standardisation>]

OR:

<Preparation description> mix of:  
 <Common / Pharmacopoeial Name, part> ..... <X> <unit>  
 <Common / Pharmacopoeial Name, part> ..... <X> <unit>  
 <Common / Pharmacopoeial Name, part> ..... <X> <unit>

**4 ADDITIONAL EXAMPLES**

The examples below are not intended to be examples of real formulas but are intended to guide the principles of naming active ingredients only.

**4.1 Aromatherapy**

<u>PI and PIL:</u>	
Volatile oil mix of:	
<i>Lavandula angustifolia</i> Mill. (Lavender) [flowers and leaves]	..... 3 ml
<i>Melaleuca alternifolia</i> (Maiden & Betche) Cheel (Tea Tree)	..... 2 ml
<i>Rosmarinus officinalis</i> L. (Rosemary)	..... 1 ml
<u>Container Label:</u>	
Same as for PI and PIL unless space is restricted:	
Volatile oil mix of:	
Lavender, flowers and leaves	..... 3 ml
Tea tree	..... 2 ml
Rosemary	..... 1 ml

4.2 Ayurveda

**Example 1:**

PI and PIL:

*Withania somnifera* (L.) Dunal (Asvangandha) ..... 500 mg  
 [root powder]

Container Label:

Same as for PI and PIL unless space is restricted:

*Withania somnifera* (L.) Dunal ..... 500 mg  
 [root powder]

**OR:**

Asvangandha, root powder ..... 500 mg

**Example 2:**

PI and PIL:

*Withania somnifera* (L.) Dunal (Asvangandha) ..... 1 000 mg  
 [root, as 0,5 ml of a 2:1 ethanolic extract standardised to withanolides 5 %]

Container Label:

Same as for PI and PIL unless space is restricted:

*Withania somnifera* (L.) Dunal ..... 1 000 mg  
 [root, as 0,5 ml of a 2:1 ethanolic extract standardised to withanolides 5 %]

**OR:**

Asvangandha, root ..... 1 000 mg (DHE)\*

\* Dried Herb Equivalent

4.3 Homeopathy

**Example 1:**

PI and PIL:

<i>Sepia officinalis</i> (Common cuttlefish)	4 cH	.....	0,3 ml
<i>Astacus astacus</i> ( <i>Astacus fluviatilis</i> )	6 cH	.....	0,3 ml
<i>Lycopodium clavatum</i> L. ( <i>Lycopodium clavatum</i> )	6 cH	.....	0,3 ml
<i>Strychnos nux-vomica</i> L. ( <i>Nux vomica</i> )	12 cH	.....	0,3 ml
<i>Citrullus colocynthis</i> (L.) Schrad. ( <i>Colocynthis</i> )	30 cH	.....	0,3 ml
Potassium carbonate ( <i>Kalium carbonicum</i> )	30 cH	.....	0,3 ml

Container Label:

Same as for PI and PIL unless space is restricted:

<i>Sepia officinalis</i>	4 cH	.....	0,3 ml
<i>Astacus fluviatilis</i>	6 cH	.....	0,3 ml
<i>Lycopodium clavatum</i>	6 cH	.....	0,3 ml
<i>Nux vomica</i>	12 cH	.....	0,3 ml
<i>Colocynthis</i>	30 cH	.....	0,3 ml
<i>Kalium carbonicum</i>	30 cH	.....	0,3 ml

**Example 2:**

PI and PIL:

*Sepia officinalis* (Common cuttlefish) D4 ..... 0,3 ml

*Astacus astacus* (*Astacus fluviatilis*) D6 ..... 0,3 ml

Container Label:

Same as for PI and PIL unless space is restricted:

*Sepia officinalis* D4 ..... 30 mg

*Astacus fluviatilis* D6 ..... 30 mg

**Example 3:**

PI and PIL:

*Calendula officinalis* L. (*Calendula officinalis*) Mother Tincture ..... 30 ml

[HAB 3A: 60 % alcohol]

Container Label:

Same as for PI and PIL unless space is restricted:

*Calendula officinalis* MT..... 30 ml

[HAB 3A: 60 % alcohol]

## 4.4 Traditional Chinese Medicine

**Example 1:**PI and PIL:

*Poria cocos* (Schwein.) F. A. Wolf (Fú líng) ..... 500 mg  
[sclerotium powder]

Container Label:

Same as for PI and PIL unless space is restricted:

*Poria cocos* (Schwein.) F. A. Wolf (Fú líng) ..... 500 mg  
[sclerotium powder]

**Example 2:**PI and PIL:

*Reynoutria multiflora* (Thunb.) Moldenke (Polygoni multiflori radix preparata) ..... 1 000 mg  
[root, as 50 mg of a 20:1 extract]

**OR:**

*Reynoutria multiflora* (Thunb.) Moldenke (zhì hé shǒu wū) ..... 1 000 mg  
[root, as 50 mg of a 20:1 extract]

Container Label:

Same as for PI and PIL unless space is restricted:

Polygoni multiflori radix preparata ..... 1 000 mg  
[root, as 50 mg of a 20:1 extract]

**OR:**

zhì hé shǒu wū ..... 1 000 mg  
[root, as 50 mg of a 20:1 extract]

4.5 Unani

PI and PIL:  
*Nardostachys jatamansi* (D.Don) DC. (Sumbul-ut-teeb) ..... 300 mg  
[rhizome powder]

Container Label:  
Same as for PI and PIL unless space is restricted:  
Sumbul-ut-teeb ..... 300 mg  
[rhizome powder]

4.6 Western Herbal Medicine

**Example 1:**

PI and PIL:  
*Inula helenium* L. (Elecampane) ..... 250 mg  
[root powder]

Container Label:  
Same as for PI and PIL unless space is restricted:  
*Inula helenium* L. .... 250 mg  
[root powder]

**OR:**  
Elecampane ..... 250 mg  
[root powder]

**Example 2:**

PI and PIL:

*Ginkgo biloba* L. (Ginkgo) ..... 120 mg

[leaf, 50:1 extract standardised to ginkgo flavone glycosides 24 % and terpenoids 6 % providing 6 000 mg of dried herb equivalent]

Container Label:

Same as for PI and PIL unless space is restricted:

*Ginkgo biloba* L. (Ginkgo, leaf) ..... 6 000 mg (DHE)\*

\* Dried Herb Equivalent