Member Alert

Herbal Ingredients and Active Proprietary Ingredients – changes to sponsor and public ARTG records to display more accurate information.

The TGA are implementing an update to ARTG summaries for listed medicines for both sponsors and the public. This update will ensure that when proprietary ingredients are used in listed medicines, including herbal ones, the information about the active ingredient will be displayed more clearly.

This has occurred in response to feedback that there are inconsistencies in the information displayed between documents that sponsors and the public are able to access on the ARTG. The changes are set to be implemented over the next few weeks are likely to be released by the end of December at which time the TGA will publish a TBS News alert.

For **consumers**, **practitioners**, and **retailers**, this means that there will be a far clearer display of information on the public record that more closely reflects the labelled content. For some products, this will occur as soon as the change in implemented in December, for others, it will occur more gradually as individual products become update.

For **sponsors** and **manufacturers**, they will also have a greater access to the information contained in their listing to have as part of their ARTG records. There is no requirement for sponsors to make an update to their medicine as the formulation information that will display in the documents is already stored in TGA's electronic systems. Information on herbal ingredients which are not Proprietary ingredients will display the new information as soon as the change is implemented in December. However, the information about the active PIs (proprietary ingredients with an active ingredient) will not appear on either the sponsor or public records until the next time that a sponsor submits an application to change or vary a medicine. This action will automatically trigger a refresh of the ARTG information. At this time it is recommended for sponsors to verify that the information in the proprietary ingredient formulation is correct.

Note for sponsors: CMA recommends checking with your proprietary ingredient suppliers over the accuracy of the content of any proprietary ingredients, especially when making new certifications under the Act when doing a new listing or a grouping application.

A summary of changes to these documents are outlined below. The level of detail that will be displayed is dependent on the document's purpose The attachments demonstrating the changes can be found at the end of this member alert:

ARTG Record Summary - available to the Sponsor (Attachment A)

Currently when a proprietary ingredient with the purpose of 'active pre-mix' or 'active herbal extract' is included in a listed medicine, the active ingredient name is displayed without the additional information typically included for standard ingredients. After the update is released, the following additional information from ***active proprietary ingredients (active herbal extracts and active premixes)*** will **be** displayed:

- The equivalent herbal starting material used in a herbal preparation, including the equivalent preparation (e.g. fresh, dry, juice) and equivalent quantity.
- Component name and quantity for herbal ingredients.
- Equivalent ingredient name and quantity for non-herbal ingredients.

This information is already entered and visible to the sponsor at the time of the medicine application (in both the TBS portal and the application Print Preview).

ARTG Certificate (Attachment B)

The ARTG Certificate currently displays the proprietary ingredient identifier adjacent to the active ingredient name in brackets (e.g. PI 12345). Following the update, the proprietary ingredient identifier will be removed. The active ingredient derived from a proprietary ingredient formulation will now appear in a format consistent with standard ingredients.

The ARTG Certificate will display the following ***herbal ingredient*** details for the active ingredient when the ingredient is either: a standard active; or an active ingredient derived from a proprietary ingredient formulation:

- Plant part and plant preparation.
- The equivalent herbal starting material used in a herbal preparation such as the equivalent preparation (e.g. fresh, dry, juice) and equivalent quantity.

Public Summary (Attachment C) (consumers, practitioners, retailers)

The Public Summary will display the following ***herbal ingredient*** details for the active ingredient when the ingredient is either: a standard active; or an active ingredient derived from a proprietary ingredient formulation:

- Plant part and plant preparation

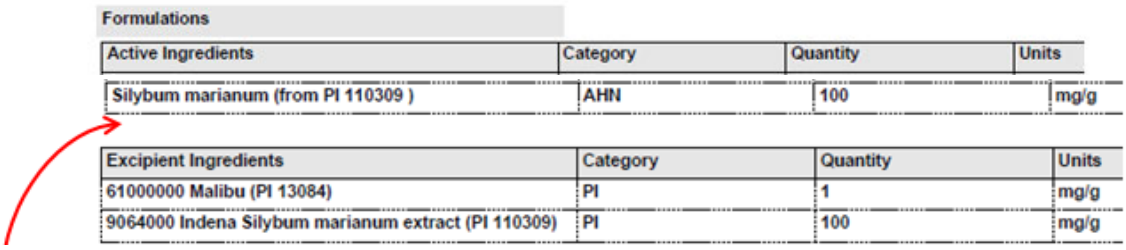
The Public Summary will also display the following ***herbal ingredient*** details when the ingredient is an active ingredient derived from a proprietary ingredient formulation (this information is already displayed for standard active herbal ingredients):

- The equivalent herbal starting material used in a herbal preparation such as the equivalent preparation (e.g. fresh, dry, juice) and equivalent quantity.

Attachment A

Record Summary

Figure 1: Current Record Summary



Formulations

Active Ingredients	Category	Quantity	Units
Silybum marianum (from PI 110309)	AHN	100	mg/g

Excipient Ingredients	Category	Quantity	Units
61000000 Malibu (PI 13084)	PI	1	mg/g
9064000 Indena Silybum marianum extract (PI 110309)	PI	100	mg/g

Figure 2: Additional information on the Record Summary

Silybum marianum (from PI 110309)	**AHN**	**100**	**mg/g**
Plant Details (origin)	**Part**	**Preparation**	
	fruit	Extract dry concentrate standardised	
Equivalent			
Silybin		29.7	mg/g
Silybum marianum (Dry)		4000	mg/g

Attachment B

ARTG Certificate

Figure 3: Current ARTG Certificate

Product Formulation(s)

Active Ingredients

	Quantity	Units
Canola Oil	100	mg/g
Fish oil - natural	100	mg/g
Petroselinum crispum	100	mg/g
Pyridoxine hydrochloride	100	mg/g
Silybum marianum ~~(from PI 110309)~~	100	mg/g

Figure 4: Additional information on ARTG Certificate

Product Formulation(s)

Active Ingredients

	Quantity	Units
Pyridoxine hydrochloride	100	mg/g
Canola Oil	100	mg/g
Petroselinum crispum leaf Extract dry concentrate	100	mg/g
Equivalent: Petroselinum crispum (Fresh)	1	g/g
Silybum marianum fruit Extract dry concentrate standardised	100	mg/g
Equivalent: Silybum marianum (Dry)	4000	mg/g
Fish oil - natural	100	mg/g
Canola Oil	100	mg/g

Attachment C

Public Summary

Figure 5: Current Public Summary

Active Ingredients	
Canola Oil	**100 mg/g**
Fish oil - natural	**100 mg/g**
Equivalent: docosahexaenoic acid	20 mg/g
Petroselinum crispum	**100 mg/g**
Equivalent: Petroselinum crispum (Fresh)	1 g/g
Pyridoxine hydrochloride	**100 mg/g**
Equivalent: Pyridoxine	83 mg/g
Silybum marianum	**100 mg/g**

Figure 6: Additional information on Public Summary

Active Ingredients	
Canola Oil	**100 mg/g**
Fish oil - natural	**100 mg/g**
Equivalent: docosahexaenoic acid	20 mg/g
Petroselinum crispum leaf Extract dry concentrate	**100 mg/g**
Equivalent: Petroselinum crispum (Fresh)	1 g/g
Pyridoxine hydrochloride	**100 mg/g**
Equivalent: Pyridoxine	83 mg/g
Silybum marianum fruit Extract dry concentrate standardised	**100 mg/g**
Equivalent: Silybum marianum (Dry)	4000 mg/g