

## Technical Alert

### Changes to Herbal Component Names

The TGA have announced changes to the regulation of herbal component names, as they will no longer be assessing component names as a regular administrative activity:

- Without a TGA pre-approved name this means that many components of herbal ingredients will no longer be available for selection in the eBS listed medicine application system.
- The changes apply to all **non-mandatory** herbal components.
- There are no changes to herbal components that are **mandatory** for safety related purposes. Mandatory components are those subject to any kind of restriction - for example, inclusion in the Poisons Standard or Permissible Ingredients Determination.
- Herbal components that are not mandatory will no longer be available for inclusion on new listings of medicines on the Australian Register of Therapeutic Goods (ARTG) from 1 October 2018.
- Sponsors will still be able to use herbal component names on medicine labels as quality markers and/or therapeutic markers of activity, even though they are not included on ARTG records.
- Sponsors are not required to make changes to existing listings, which will remain unaffected.

#### Can Herbal Component Names still be used on medicine labels?

Yes, component names and quantity claims can be made on labels as part of the medicine content and therapeutic activity, provided the sponsor can provide evidence.

If questioned at post market review, sponsors may be asked to verify the label information by providing the following. It is advisable to hold all of this information at the time of listing:

- evidence that the component occurs in the herbal species, such as published scientific literature or original scientific analysis showing the presence of the component;
- details of the method of analysis used to identify and/or quantify the individual component declared on the label;
- if therapeutic activity is claimed against the component, evidence supporting the indications relating to that component, as per usual evidence expectations.

#### TGA's Frequently Asked Questions on Changes to Herbal Components

The outcomes of the public consultation on this matter, and a number of frequently asked questions are available [here](#).

**Members are encouraged to forward any further questions or identified issues to [technical@cmaustralia.org.au](mailto:technical@cmaustralia.org.au) for attention by the Committee Secretariat.**

**ENDS**