

## Technical Alert

### TGA Consultation: Herbal Component Names

As flagged in our recent newsletters, the TGA has today released a public consultation: Discontinuing pre-market evaluation of Herbal Component Names (HCNs). Submissions close **12 January 2018**.

Reasons provided by the TGA for the proposal is that assessing HCNs:

- requires significant TGA resources;
- is not underpinned by legislation; and
- importantly, does not provide consumers with an assurance that HCNs are applied consistently across products.

In consultation with industry stakeholders, the proposal in summary is that:

- The TGA will no longer pre-assess herbal component names.
- Standardised component claims on medicine labels can remain, provided the sponsor holds acceptable evidence. However, the consultation also raises the question of whether products should be able to claim “standardisation”, when there would be no real indication of what “standardised” means.
- The quantity of mandatory HCNs will still be required to be declared in eBS for new listed medicines.
- Non-mandatory HCNs will no longer be available in eBS for new listed medicines.
- Groupings/Variations for existing listed medicines with a non-mandatory HCN will not be affected by any system changes.

#### Option 1

Maintain the status quo. Consistent with the cost recovery arrangements in place, a fee for such HCN applications may be considered in the future.

#### Option 2

Industry and the TGA to work together to produce a workable mechanism that allows for discontinuing pre-market evaluation of HCN applications.

- Do you support Regulatory Option 1 or 2 as outlined in this paper or would you like to propose an additional option for consideration?
- Do you have any specific concerns regarding discontinuation of the HCN evaluation process?

The consultation is available on the [TGA website here](#). CMA encourages all members to provide a submission to the TGA on this issue and to express your views to CMA via [technical@cmaustralia.org.au](mailto:technical@cmaustralia.org.au) to inform our industry-wide submission.

**ENDS**