

**Technical Alert: Notification of update to listed medicines validation rules
Coumarin requirements for herbal ingredients and
Thujone content of *Artemisia spp.***

Dear member,

The Therapeutic Goods Administration will update the listed medicine validation rules for herbal ingredients containing the component 'coumarin'. An update will also be made for 'thujone' as a herbal component of *Artemisia spp.*

The validation rules for medicines containing these ingredients have been tightened to reflect SUSMP limits. These limits are also reflected in the 26BB [Permissible Ingredients Determination](#), which commenced 1 January 2016.

Coumarin as a component of herbal ingredients used in listed medicines

The TGA will update the listed medicine validation rules for herbal ingredients containing the component coumarin to reflect SUSMP limits, effect 1 January 2016.

Coumarin is a naturally occurring component of several herbal species including *Cinnamomum spp.* This component is currently subject to Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) for active therapeutic use and the maximum daily dose of coumarin in a medicine must be no more than 10mg/kg or 0.001% in order to be eligible for listing.

To ensure that listed medicines in Australia containing these ingredients are not subject to a schedule of the SUSMP; and are of acceptable safety and quality, the following update will be made to the TGA Business Services (TBS) System effective 1 January 2016.

- the presence and quantity of coumarin will be required to be declared in the application and on the ARTG for all medicines containing the abovementioned active ingredient.

Implementation plan

The TGA has commenced sending letters to affected sponsors advising them of the update to the TGA business Services system to mandate the presence and quantity of coumarin in listed medicines containing *Cinnamomum spp.* ingredients. A statement to this effect is also included on the TGA Business Services website [here](#).

What sponsors will need to do

By the **1 February 2016**, sponsors will need to update their ARTG listings which contain herbal ingredients requiring coumarin content to be declared. The component details can be included in the ARTG entry via an application in TGA Business Services with no associated fee.

Sponsors must ensure that other coumarin containing herbal ingredients are also compliant with the maximum daily dose requirements mentioned above.

Notification of update to TGA Business System- SUSMP limits for thujone as a herbal component of *Artemisia spp.* ingredients used in listed medicines

The TGA will update the listed medicine validation rules for herbal ingredients containing the component thujone, effective 1 January 2016.

Thujone is a naturally occurring component of *Artemisia spp.* ingredients. This component is currently subject to Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) for active therapeutic use and the maximum daily dose of thujone in a medicine must be no more than 4% w/w in order to be eligible for listing.

To ensure that listed medicines in Australia containing these ingredients are not subject to a schedule of the SUSMP; and are of acceptable safety and quality, the following update will be made to the TGA Business Services (TBS) System effective 1 January 2016.

- the presence and quantity of thujone will be required to be declared on the ARTG for all medicines containing the abovementioned active ingredient.

Implementation plan

The TGA has commenced sending letters to affected sponsors advising them of the update to the TGA business Services system to mandate the presence and quantity of thujone for the ingredients identified above. A statement to this effect is also included on the TGA Business Services website [here](#).

What sponsors will need to do

By the **1 February 2016**, sponsors will need to update their ARTG listings which contain herbal ingredients requiring thujone content to be declared. The component details can be included in the ARTG entry via an application in TGA Business Services with no associated fee.

For any questions in relation to the TBS updates, the listed medicines helpdesk can be contacted on ph. 02 6232 8818 or email: listed.medicines@tga.gov.au

Alternatively, please contact Emma Burchell on 02 6260 4022 or email: emma.burchell@cmaustralia.org.au