

Technical Alert

Reversal of decision regarding *Astragalus membranaceus*

!Members are advised not to change the label name of *Astragalus membranaceus*.

Background

In June 2018, the TGA changed the ingredient name from *Astragalus membranaceus* to *Astragalus mongholicus*, providing an 18 month transition period for sponsors.

The name change and transition period were provided within the *Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2018* on 15 June 2018.

Reversal of Amendment.

Subsequently the TGA received information that the new name is not consistent with the taxonomical classification in the herbal reference naming standard, the Medicine Name Plant Service (MPNS) database, where the botanical species *Astragalus membranaceus* and *Astragalus mongholicus* are not synonymous.

Consequently, the ingredient name AAN will revert back to *Astragalus membranaceus* in the new Permissible Ingredients Determination in early September 2018.

What you need to do:

- If you have a listed medicine with this ingredient and your medicine label(s) read *Astragalus membranaceus*, no action is required.
- If your listed medicine label(s) carry the name *Astragalus mongholicus*, you are required to amend your label as soon as practicable.

The TGA will not pursue any compliance matter regarding related label amendments until after 1 January 2020.

Members are encouraged to forward any identified issues to technical@cmaustralia.org.au for attention by the Committee Secretariat.

ENDS