**Technical Alert**

**Call for comment – Proposal to adopt European Union Guidelines relating to herbal medicinal products**

Dear member,

CMA is calling for your feedback on two European Union guidelines proposed for adoption by the TGA. Comments can be made via a prepopulated form within this alert and sent to submissions@cmaustralia.org.au by **Friday 27 March 2015**.

Consultation documents are:

* Guideline on specifications: [Test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products. CPMP/QWP/2820/00 Rev.2, 2011](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/09/WC500113210.pdf)
* [Guideline on quality of herbal medicinal products/traditional herbal medicinal products CPMP/QWP/2819/00 Rev. 2, 2011](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/09/WC500113209.pdf)

These updates takes into account new and revised guidelines, the European Pharmacopeia revised general monograph ‘herbal drugs’, as well as new requirements for impurities.

Where possible, the TGA aligns its regulatory approach to therapeutic products with those of comparable international regulatory counterparts. The previous 2006 versions of the above guidelines were adopted and it is timely to consider if the 2011 revisions to these guidelines should be adopted as guidance material.

The EU Guidelines listed above provide guidance to applicants on the data required to establish the quality of herbal materials, compliance of which expedites the application processes for new listable herbal ingredients and registered CMs with herbal ingredients.

[Attachment A](https://www.tga.gov.au/node/288795) and [Attachment B](https://www.tga.gov.au/node/288796) list the changes between the 2006 and 2011 documents. While the changes appear minor and unlikely to result in additional regulatory burden, your feedback about their adoption is important to us.

Note: *The EU legislation references in these guidelines are not applicable to therapeutic goods regulated by Australian legislation. Additionally, should these guidelines be adopted, all Australian legislative requirements remain applicable.*

Your comments can be included in this form an emailed to submissions@cmaustralia.org.au

**Questions in relation to the Guideline on specifications (CPMP/QWP/2820/00 Rev.2, 2011)**

1. Do you support the adoption of the Guideline on specifications? Y/N
	1. If not, please provide information on why you do not support it and describe any alternatives that may be acceptable. For example, should the guidelines be adopted only in part or with annotations?

Click here to enter text.

1. Will the adoption of the guidelines positively or negatively impact you? If it will negatively affect you, please include an estimate of the potential cost impact of the changes compared with the likely benefits of implementation.

Click here to enter text.

1. Do you have any other comments on the adoption of the Guideline on specifications?

Click here to enter text.

**Questions in relation to the Guideline on quality of herbal medicinal products/traditional herbal medicinal products CPMP/QWP/2819/00 Rev. 2, 2011**

1. Do you support the adoption of the Guideline on specifications Y/N
	1. If not, please provide information on why you do not support it and describe any alternatives that may be acceptable. For example, should the guidelines be adopted only in part or with annotations?

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1. Do you have any other comments on the adoption of the Guideline on specifications?

Click here to enter text.

If you have any questions or require further information please contact Emma Burchell on
02 6260 4022 or email emma.burchell@cmaustralia.org.au