



Australian Government
Department of Health
Therapeutic Goods Administration

European Union guidelines used by the Office of Complementary Medicines

European Union guidelines adopted in Australia

13 March 2006

Please note: Where European Union (EU) guidelines adopted in Australia include references to EU legislation (including EC Directives and Regulations), the requirements contained in the referenced EU legislation are not applicable to the evaluation of prescription medicines by the TGA. The Australian legislative requirements applying to prescription medicines are contained in the *Therapeutic Goods Act 1989* and the Therapeutic Goods Regulations 1990, as well as in various legislative instruments such as Therapeutic Goods Orders, Notices and Determinations, see [Legislation \(//www.tga.gov.au/legislation-legislative-instruments\)](http://www.tga.gov.au/legislation-legislative-instruments).

Herbal medicinal products

[CPMP/QWP/2819/00 \(pdf,73kb\) \(//www.tga.gov.au/sites/default/files/qwp281900en01.pdf\)](http://www.tga.gov.au/sites/default/files/qwp281900en01.pdf)

Note For Guidance on Quality of Herbal Medicinal Products

Published: TGA Internet Site: 7 April 2003

This guideline has been included for the reference of complementary medicine sponsors seeking guidance in addition to that provided in the Australian Regulatory Guidelines for Complementary Medicines (ARGCM).

[CPMP/QWP/2820/00 \(pdf,159kb\) \(//www.tga.gov.au/sites/default/files/qwp282000en01_0.pdf\)](http://www.tga.gov.au/sites/default/files/qwp282000en01_0.pdf)

Note For Guidance on Specifications: Test Procedures and Acceptance Criteria for Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products

Published: TGA Internet Site: 7 April 2003

This guideline has been included for the reference of complementary medicine sponsors seeking guidance in addition to that provided in the [Australian Regulatory Guidelines for Complementary Medicines \(ARGCM\) \(//www.tga.gov.au/publication/australian-regulatory-guidelines-](http://www.tga.gov.au/publication/australian-regulatory-guidelines-complementary-medicines)

[How to access a pdf document \(//www.tga.gov.au/accessing-documents-website\)](http://www.tga.gov.au/accessing-documents-website)

[complementary-medicines-argcm](#)).

Category: Complementary medicines

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