European Commission

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Reference documents

English (en)

EudraLex - Volume 7 Scientific guidelines for medicinal products for veterinary use

Volume 7 of the publications "The rules governing medicinal products in the European Union" contains scientific guidelines prepared by the Committee for Medicinal Products for Human Use (CHMP) in consultation with the competent authorities of the EU Member States, to help applicants prepare marketing-authorisation applications for medicinal products for human use.

Guidelines are intended to provide a basis for practical harmonisation of the manner in which the EU Member States and the EMEA interpret and apply the detailed requirements for the demonstration of quality, safety and efficacy contained in the Community directives. They also help to ensure that applications for marketing authorisation are prepared in a manner that will be recognised as valid by the EMEA.

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