15 December 2011
EMA/CHMP/941885/2011
Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 12-15 December 2011

The guidelines and concept papers which have been adopted during this meeting of the Committee for Medicinal Products for Human Use (CHMP) will be published shortly on the website of the European Medicines Agency.

Biologics Working Party (BWP)

Reference number	Document	Status[1]
EMA/CHMP/BWP/360642/2010	Guideline on the warning on transmissible agents in summary of product characteristics (SmPCs) and package leaflets for plasma-derived medicinal products • Overview of comments received (EMA/CHMP/BWP/552021/2011)	**adopted**

Biosimilar Medicinal Product Working Party (BMWP)

Reference number	Document	Status[1]
EMA/CHMP/BMWP/652000/2010	Guideline on similar biological medicinal products containing interferon beta	**6-month public consultation**

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Cardiovascular Working Party (CVWP)

Reference number	Document	Status[1]
EMA/CHMP/EWP/213972/2010	Paediatric addendum to CHMP guideline on the clinical investigations of medicinal products for the treatment of pulmonary arterial hypertension	**adopted**

ICH

Reference number	Document	Status[1]
EMA/CHMP/ICH/126642/2008	ICH guideline S2 (R1) Genotoxicity testing and data interpretation for pharmaceuticals intended for human use, Step 4	**adopted**

Infectious Diseases Working Party (IDWP)

Reference number	Document	Status[1]
CPMP/EWP/558/95 Rev. 2	Guideline on Evaluation of Medicinal Products Indicated for Treatment of Bacterial Infections	**adopted**

Oncology Working Party

Reference number	Document	Status[1]
CPMP/EWP/205/95/Rev. 4	Guideline on Evaluation of Anticancer Medicinal Products in Man	**6-month public consultation**
EMEA/CHMP/EWP/267575/2006/ Corr.	Appendix 1 to the Guideline on the Evaluation of Anticancer Medicinal Products in Man	**6-month public consultation**

Pharmacogenomics Working Party (PGWP)

Reference number	Document	Status[1]
EMA/917570/2011	Concept Paper on the key aspects on the use of pharmacogenomic methodologies in the pharmacovigilance evaluation of medicinal products	**3-month public consultation**

Quality Working Party (QWP)

Reference number	Document	Status[1]
CHMP/QWP/227/02 Rev 3	Guideline on Active Substance Master File Procedure	**2-month public consultation** Publication of this guideline is subject to adoption by CVMP foreseen in January 2012.

Rheumatology/Immunology Working Party

Reference number	Document	Status[1]
CPMP/EWP/556/95 Rev 2	Guideline on Clinical Investigation of Medicinal Products other than NSAIDs for Treatment of Rheumatoid Arthritis	**6-month public consultation**

[1] Adopted or released for consultation documents can be found at the European Medicines Agency website (under "Document library-Public Consultations" or under "Regulatory-Human Medicines").