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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 27-30 May 2013

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 European Medicines Agency's website under Regulatory/Human/Scientific guidelines. Documents for public consultation will also be available under Document search/Public consultations.

Biologics Working Party (BWP)

Reference number	Document	Status
EMA/CHMP/BWP/151897/2013	Guideline on quality of biological active substances produced by transgene expression in animals • Overview of comments (EMA/CHMP/BWP/151908/2013)	**adopted**
EMA/CHMP/BWP/457920/2013	Guideline on the use of bovine serum in the manufacture of human biological medicinal products • Overview of comments (EMA/CHMP/BWP/596/2013)	**adopted**

Biosimilar Medicinal Product Working Party (BMWP)

Reference number	Document	Status
EMEA/CHMP/BMWP/42832/2005 Rev1	Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues	**6-month public consultation**

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Biostatistics Working Party

Reference number	Document	Status
EMA/295050/2013	Guideline on adjustment for baseline covariates	**6-month public consultation**
EMA/297149/2013	Concept paper on the need for a reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development	**3-month public consultation**

Cardiovascular Working Party (CVWP)

Reference number	Document	Status
EMA/CHMP/281099/2013	Concept Paper to the Guideline on clinical investigation of medicinal products for the treatment of venous thromboembolic disease CPMP/EWP/563/98	**3-month public consultation**
EMA/CHMP/325170/2012 (former CPMP/EWP/707/98 Rev.1 corr.)	Guideline on clinical investigation of medicinal products for prevention of venous thromboembolism (VTE) in patients undergoing high VTE-risk surgery • Overview of comments (EMA/CHMP/47495/2013)	**adopted**

Central Nervous System Working Party (CNSWP)

Reference number	Document	Status
EMA/CHMP/970057/2011	Guideline on the clinical development of medicinal products intended for the treatment of pain	**6-month public consultation**
EMA/CHMP/185423/2010 rev. 2	Guideline on clinical investigation of medicinal products in the treatment of depression	**adopted**

Committee for medicinal products for human use (CHMP)

Reference number	Document	Status
EMA/274183/2012	Position paper on potential medication errors in the context of benefit-risk balance and risk minimisation measures • Overview of comments (EMA/399796/2012)	**adopted**
EMA/283336/2013 Rev. 6	Guideline on the acceptability of names for human medicinal products processed through the centralised procedure	**3-month public consultation**

Oncology Working Party

Reference number	Document	Status
EMA/CHMP/58171/2013	Concept paper on appendix 4 to the guideline on anticancer medicinal products in man	**3-month public consultation**

Quality Working Party (QWP)

Reference number	Document	Status
EMA/CHMP/CVMP/QWP/269743/2013	Q&As on co-operation between assessors and inspectors when RTRT (Real Time Release Testing) is applied	**adopted**