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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 19-22 September 2011

Biologics Working Party (BWP)

Reference number	Document	Status ²
EMA/CHMP/BWP/367751/2011	Concept paper for a guideline on the quality of porcine trypsin used in the manufacture of human biological medicinal products	3-month public consultation

Biosimilar Medicinal Product Working Party (BMWP)

Reference number	Document	Status ²
EMA/CHMP/BMWP/572828/2011	Concept paper on the revision of the guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues	3-month public consultation

Blood Products Working Party (BP WP)

Reference number	Document	Status ²
EMA/CHMP/BPWP/598816/2010 Rev. 1	Guideline on core SmPC for plasma-derived fibrin sealant / haemostatic products	3-month public consultation

¹ The document has been revised to include additional information on the Concept paper on the need for revision of the Appendix to the Note for Guidance on the clinical investigation of medicinal products in the treatment of schizophrenia EMA/CHMP/457223/2011 (page 2).

² 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").



Central Nervous System Working Party (CNS WP)

Reference number	Document	Status ²
EMA/CHMP/185423/2010, previously CPMP/EWP/518/97 Rev. 1	Guideline on clinical investigation of medicinal products in the treatment of depression	6-month public consultation
EMA/CHMP/457223/2011	Concept paper on the need for revision of the Appendix to the Note for Guidance on the clinical investigation of medicinal products in the treatment of schizophrenia – methodology of clinical trials concerning the development of depot preparations of approved medicinal products in schizophrenia	adopted No revision is required. The appendix will be integrated into the Guideline on clinical investigation of medicinal products in the treatment of schizophrenia (CHMP/40072/2010) which is currently under revision.
EMA/CHMP/CNSWP/257565/2011	Concept paper on the need for revision of Note for Guidance on Clinical Medicinal Products for Treatment of Nociceptive Pain and Guideline on clinical investigation of products intended for the treatment of neuropathic pain	3-month public consultation

Cardiovascular Working Party (CVS WP)

Reference number	Document	Status ²
CPMP/EWP/1080/00 Rev.1	Guideline on clinical investigation of medicinal products in the treatment of diabetes mellitus	2-month public consultation

Infectious Diseases Working Party (IDWP)

Reference number	Document	Status ²
CPMP/EWP/558/95 Rev 2	Concept paper on an addendum to the note for guidance on evaluation of medicinal products indicated for treatment of bacterial infections to address indication-specific clinical data requirements	3-month public consultation

Vaccine Working Party (VWP)

Reference number	Document	Status ²
EMA/CHMP/VWP/703340/2011	Concept paper on the revision of guidelines for influenza vaccines	3-month public consultation

Committees

Reference number	Document	Status ²
EMA/HMPC/201116/2005 Rev. 2	Guideline on quality of herbal medicinal products/traditional herbal medicinal products	adopted Publication of this guideline is subject to adoption by the CVMP.
EMA/HMPC/162241/2005 Rev. 2	Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products	adopted Publication of this guideline is subject to adoption by the CVMP.

Radiopharmaceutical Drafting Group

Reference number	Document	Status ²
EMA/547466/2011	Guideline on core SmPC and Package Leaflet for fludeoxyglucose	3-month public consultation