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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 18-21 February 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/814397/2011	Guideline on the use of porcine trypsin used in the manufacture of human biological medicinal products	**6-month public consultation**
EMA/CHMP/BWP/310834/2012	Guideline on Influenza Vaccines – Quality Module	**6-month public consultation**

Biosimilar Medicinal Product Working Party (BMWP)

Reference number	Document	Status
EMA/CHMP/BMWP/608528/2012	Guideline on similar biological medicinal products containing Interferon Beta	**adopted**
EMA/CHMP/BMWP/671292/2010	Guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant human follicle stimulating hormone (r-hFSH)	**adopted**

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Cardiovascular Working Party (CVWP)

Reference number	Document	Status
EMA/CHMP/87576/2013	Concept paper on the need for revision of the note for guidance on clinical investigation of medicinal products for the treatment of cardiac failure (CPMP/EWP/235/95)	**3-month public consultation**

Central Nervous System Working Party (CNSWP)

Reference number	Document	Status
EMA/CHMP/738756/2011	Guideline on the clinical investigation of medicinal products for the treatment of Duchenne and Becker muscular dystrophy	**6-month public consultation**

Committee for Advanced Therapies (CAT)

Reference number	Document	Status
EMA/CAT/CPWP/686637/2011	Guideline on the risk-based approach according to Annex I, part IV of Directive 2001/83/EC applied to Advanced Therapy Medicinal Products	**adopted**

Committee for Medicinal Products for Human Use (CHMP)

Reference number	Document	Status
EMA/CHMP/779887/2012	Concept paper on the need to revise the Guideline on the clinical development of fixed dose combinations of medicinal products regarding dossier content requirements	**3-month public consultation**

ICH

Reference number	Document	Status
EMA/CHMP/ICH/83812/2013	ICH guideline M7 on assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk, Step 3	**2-month public consultation**

Pharmacokinetics Working Party (PKWP)

Reference number	Document	Status
EMA/CPMP/EWP/280/96 Rev.1	Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms	**6-month public consultation**

Quality Working Party (QWP)

Reference number	Document	Status
EMA/CHMP/CVMP/QWP/57710/2013	Annexes to: CPMP/ICH/283/95 Impurities: Guideline for Residual Solvents & CVMP/VICH/502/99 Guideline on Impurities: Residual Solvents	**adopted**
EMA/CHMP/QWP/70174/2013	Concept paper on the need for a Reflection Paper on quality aspects of medicines for older people	**adopted**

Rheumatology / Immunology Working Party

Reference number	Document	Status
EMA/CHMP/51230/2013	Guideline on clinical investigation of medicinal products for the treatment of systemic lupus erythematosus, cutaneous lupus and lupus nephritis	**6-month public consultation**