24 May 2012
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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 21-24 May 2012

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.

CHMP

Reference number	Document	Status
EMA/151751/2010 Rev 1	Revised procedural advice on CHMP/CAT Rapporteur/Co-Rapporteur appointment principles, objective criteria and methodology in accordance with Article 62 (1) of Regulation (EC) No 726/2004	**adopted**
EMA/274183/2012	Position paper on considerations addressing the benefit risk balance and risk reduction measures in the context of potential medication errors	**6-month public consultation**

Biologics Working Party (BWP)

Reference number	Document	Status
EMA/CHMP/BWP/247713/2012	Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues (revision)	**6-month public consultation**
EMA/CHMP/BWP/238098/2012	Revised guideline on quality of biological active substances	**6-month public consultation**

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Reference number	Document	Status
	produced by transgene expression in animals	

Biosimilar Medicinal Product Working Party (BMWP)

Reference number	Document	Status
EMA/CHMP/BMWP/86289/2010	Guideline on immunogenicity assessment of monoclonal antibodies intended for in vivo clinical use • Overview of comments (EMA/420188/2011)	**adopted**

Biostatistics Working Party

Reference number	Document	Status
EMA/286914/2012	Concept paper on the need for a guideline on multiplicity issues in clinical trials	**3-month public consultation**

Blood Products Working Party (BPWP)

Reference number	Document	Status
EMA/CHMP/BPWP/1619/1999	Guideline on core SmPC for human plasma derived and recombinant coagulation factor VIII products-Rev. 1	**adopted**
EMA/CHMP/BPWP/1925/1999	Guideline on core SmPC for human plasma derived and recombinant coagulation factor IX products-Rev. 1	**adopted**

Cardiovascular Working Party (CVWP)

Reference number	Document	Status
EMA/312040/2012	Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus	**adopted**
CPMP/EWP/707/98 Rev.2 corr.	Guideline on clinical investigation of medicinal products for prophylaxis of high intra- and post-operative venous thromboembolic risk	**6-month public consultation**

Central Nervous System Working Party (CNSWP)

Reference number	Document	Status
EMA/CHMP/705940/2011	Revised Work Plan 2012	**adopted**

Gastroenterology Drafting Group

Reference number	Document	Status
EMA/294134/2012	Concept paper on the revision of the CHMP points to consider on the evaluation of medicinal products for the treatment of irritable bowel syndrome (CPMP/EWP/785/97)	**3-month public consultation**

ICH

Reference number	Document	Status
EMA/CHMP/ICH/507008/2011	ICH guideline M3 (R2) – Questions and answers – Step 5	**adopted**
EMA/CHMP/ICH/310133/2008	ICH guideline E14 – Questions and answers – Step 5	**adopted**
EMA/CHMP/ICH/425213/2011	ICH guideline Q11 on development and manufacture of drug substances (chemical entities and biotechnological/ biological entities) – Step 4	**adopted**

Pharmacokinetics Working Party (PKWP)

Reference number	Document	Status
EMA/CHMP/EWP/125211/2010	Guideline on the investigation of drug interactions • Overview of comments (EMA/55111/2011)	**adopted**
EMA/CHMP/203926/2012	Concept paper on the need for revision of the note for guidance on the evaluation of the pharmacokinetics of medicinal products in patients with impaired renal function	**2-month public consultation**

Quality Working Party (QWP)

Reference number	Document	Status
EMA/CHMP/CVMP/QWP/199250/2009	Guideline on setting specifications for related impurities in antibiotics • Overview of comments (EMA/CHMP/CVMP/QWP/310350/2012)	**adopted** Publication of this guideline is subject to adoption of CVMP.
EMA/CHMP/CVMP/QWP/310440/2012	Revised Questions and Answers on harmonisation of policies on setting specifications for potentially genotoxic impurities, heavy metal catalysts residues and class 1 solvents residues	

Rheumatology/Immunology Working Party

Reference number	Document	Status
EMA/937321/2011	Concept paper on the need of the guideline on clinical investigation of medicinal products for the treatment of gout	**3-month public consultation**