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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 10-13 December 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.

Biosimilar Medicinal Product Working Party (BMWP)

Reference number	Document	Status
EMEA/CHMP/BMWP/32775/2005 Rev. 1	Guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant human insulin and insulin analogues	**6-month public consultation**

Blood Products Working Party (BPWP)

Reference number	Document	Status
EMA/CHMP/BPWP/94038/2007	Guideline on core SmPC for human normal immunoglobulin for intravenous administration (IVIg)	**adopted**

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
An agency of the European Union

Cardiovascular Working Party (CVWP)

Reference number	Document	Status
EMA/CHMP/718840/2012	Guideline on clinical investigation of medicinal products in the treatment of lipid disorders (CPMP/EWP/3020/03/Rev. 1/Rev. 2)	**3-month public consultation**
EMA/CHMP/778582/2012	Concept paper on the need for a paediatric addendum to the Guideline on clinical investigation of medicinal products for the treatment of acute heart failure (CHMP/EWP/2986/03 Rev. 1)	**3-month public consultation**

GCP Inspectors Working Group

Reference number	Document	Status
EMA/INS/GCP/167386/2012	Points to consider for assessors, inspectors and EMA inspection coordinators on the identification of triggers for the selection of applications for “routine” and/or “for cause” inspections, their investigation and scope of such inspections	**adopted**

ICH

Reference number	Document	Status
EMA/CHMP/ICH/820/2003	ICH guideline M8 eCTD Step 5 – questions and answers	**for information**
EMA/CHMP/ICH/544553/1998	ICH guideline E2C(R2) Step 4 – Periodic benefit-risk evaluation report (PBRER)	**adopted**
EMA/CHMP/ICH/752211/2012	ICH guideline S10 Step 3 – Guidance on photosafety evaluation of pharmaceuticals	**6-month public consultation**
EMA/CHMP/ICH/166783/2005	ICH guideline E2B(R3) Step 4 - Electronic transmission of individual case safety reports (ICSRs) - implementation guide - data elements and message specification	**adopted**

Reference number	Document	Status
EMA/CHMP/ICH/818331/2011	ICH guideline E2B(R3) Step 4 – Appendix I (B) to the Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs): Backwards and Forwards Compatibility Recommendations	**adopted**
EMA/CHMP/ICH/752486/2012	ICH guideline S1 – Regulatory notice on changes to core guideline on rodent carcinogenicity testing of pharmaceuticals	**4-month public consultation**

Oncology Working Party

Reference number	Document	Status
EMA/CHMP/205/95/rev.4	Guideline on the evaluation of anticancer medicinal products in man • SAG Oncology answers on the revision of the guideline (EMA/768937/2012)	**adopted**
EMA/CHMP/27994/2008	Appendix 1 to the guideline on the evaluation of anticancer medicinal products in man (EMA/CHMP/205/95/rev.4)	**adopted**
EMA/CHMP/703715/2012	Appendix 4 to the guideline on the evaluation of anticancer medicinal products in man (EMA/CHMP/205/95/rev.4)	**adopted**

Safety Working Party (SWP)

Reference number	Document	Status
EMA/CHMP/ CVMP/ SWP/169430/2012	Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities	**6-month public consultation**