16 February 2012
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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 13-16 February 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 website of the European Medicines Agency.

Biologics Working Party (BWP)

Reference number	Document	Status[1]
EMA/CHMP/BWP/729106/2011	Reflection paper on the use of starting materials and intermediates collected from different sources in the manufacturing of biological medicinal products	**6-month public consultation**

Biostatistics Working Party

Reference number	Document	Status[1]
EMA/965150/2011	Concept paper on the need to revise the Points to Consider on Adjustment for Baseline Covariates	**3-month public consultation**

EMA

Reference number	Document	Status[1]
EMEA/CHMP/578661/2010	EMA recommendation on the procedural aspects and dossier requirements for the consultation to the European Medicines Agency by a Notified body on an ancillary medicinal substance or an ancillary human	**adopted**

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Reference number	Document	Status[1]
	blood derivative incorporated in a medical device or active implantable medical device • Overview of comments (EMA/CHMP/92924/2011)	

ICH

Reference number	Document	Status[1]
EMA/CHMP/ICH/902964/2011	ICH quality IWG – points to consider for ICH Q8/Q9/Q10 guidelines	**adopted**
EMA/CHMP/ICH/820/2003	ICH guideline M8 eCTD – questions and answers	**adopted**
EMA/CHMP/ICH/507008/2011	ICH guideline M3 (R2) questions and answers	**adopted**

Pharmacokinetics Working Party (PKWP)

Reference number	Document	Status[1]
EMEA/618604/08 Rev. 4	Questions & Answers: Positions on specific questions addressed to the Pharmacokinetics Working Party	**adopted**

Quality Working Party (QWP)

Reference number	Document	Status[1]
EMA/CHMP/QWP/799402/2011	Reflection Paper on the pharmaceutical development of intravenous medicinal products containing active substances solubilised in micellar systems • Overview of comments (EMA/CHMP/QWP/686808/2011)	**adopted**

Safety Working Party (SWP)

Reference number	Document	Status[1]
EMA/CHMP/SWP/888239/2011	Concept Paper on the need for revision of the Guideline on excipients in the label and package leaflet of medicinal products for human use (CPMP/463/00)	**3-month public consultation**

[1] 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").