2 July 2013
EMA/CHMP/240800/2013
Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 24-27 June 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/729106/2011	Guideline on the use of starting materials-intermediates collected from different sources in the manufacturing of biological medicinal products • Overview of comments (EMA/CHMP/BWP/661511/2012)	**adopted**

Cardiovascular Working Party (CVWP)

Reference number	Document	Status
EMA/CHMP/29947/2013	Guideline on clinical investigations of medicinal products in the treatment of hypertension (EMA/238/1995/Rev. 3)	**6-month public consultation**

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Drafting Group on Nanomedicines

Reference number	Document	Status
EMA/325027/2013	Reflection paper on surface coatings: general issues for consideration regarding parenteral administration of coated nanomedicine products	**adopted**

Gastroenterology Drafting Group

Reference number	Document	Status
(EMEA/CHMP/60337/2013)	Guideline on the evaluation of medicinal products for the treatment of irritable bowel syndrome (CPMP/EWP/785/97 Rev. 1)	**6-month public consultation**

ICH

Reference number	Document	Status
EMA/CHMP/ICH/353369/2013	ICH step 3 guideline Q3D on elemental impurities	**6-month public consultation**
EMA/CHMP/ICH/820/2003	ICH step 5 guideline M8 on eCTD - questions and answers	**adopted**

Inspections

Reference number	Document	Status
EMA/244111/2013	Triggers for inspections of bioequivalence trials	**adopted**
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**
EMA/INS/GCP/908031/2011	Discussion Paper on the Follow-up actions from Inspection Findings	**adopted**
EMA/INS/GCP/588734/2012	Procedure for reporting of GCP inspections requested by the Committee for Medicinal Products for Human Use (CHMP)	**adopted**

Quality Working Party (QWP)

Reference number	Document	Status
EMA/CHMP/QWP/324349/2013	Q&A on change in appearance of tablets during storage	**adopted**
EMA/CHMP/240800/2013	Concept paper on the need for revision of the note for guidance on manufacture of the finished dosage form	**6-month public consultation**

Respiratory Drafting Group

Reference number	Document	Status
CPMP/EWP/2922/01/Rev. 1	Guideline on clinical investigation of medicinal products for the treatment of asthma	**6-month public consultation**

Urology Drafting Group

Reference number	Document	Status
CPMP/EWP/18/01/Rev. 1	Guideline on the clinical investigation of medicinal products for the treatment of urinary incontinence • Overview of comments (EMA/CHMP/197622/2013)	**adopted**