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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 18-21 June 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
EMEA/CHMP/2990/00 Rev.4	Guideline on the processing of renewals in the centralised procedure • Overview of comments (EMA/257975/2012)	**adopted**

Biosimilar Medicinal Product Working Party (BMWP)

Reference number	Document	Status
EMA/CHMP/BMWP/403543/2010	Guideline on similar biological medicinal products containing monoclonal antibodies – non-clinical and clinical issues • Overview of comments (EMA/205886/2012)	**adopted**

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Blood Products Working Party (BPWP)

Reference number	Document	Status
EMA/CHMP/BPWP/494462/2011	Guideline on core SmPC for human albumin solution-rev.3	**2-month public consultation**

Central Nervous System Working Party (CNSWP)

Reference number	Document	Status
EMA/CHMP/330418/2012 rev. 2	Guideline on clinical investigation of medicinal products in the treatment of Parkinson's disease	**adopted**
EMA/351466/2012	Questions and answers on additional clarification for inclusion criteria in the "Guideline on clinical investigation of medicinal products in the treatment of Parkinson's disease"	**adopted**

Infectious Diseases Working Party (IDWP)

Reference number	Document	Status
	Addendum to the note for guidance on evaluation of medicinal products indicated for treatment of bacterial infections (CPMP/EWP/558/95 rev 2) to address indication-specific clinical data requirements	**adopted**

Pharmacokinetics Working Party (PKWP)

Reference number	Document	Status
EMA/CHMP/EWP/125211/2010	Guideline on the investigation of drug interactions	**adopted**

Quality Working Party (QWP)

Reference number	Document	Status
CHMP/QWP/227/02 Rev 3	Guideline on Active Substance Master File procedure • Overview of comments (EMA/314313/2012)	**adopted** Publication of this guideline is subject to adoption by CVMP.