15 March 2012
EMA/CHMP/162992/2012
Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 12-15 March 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/534898/2008	Guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials	**adopted**

Central Nervous System Working Party (CNSWP)

Reference number	Document	Status[1]
EMA/CHMP/59352/2012	Concept paper on the need for revision of the points to consider on clinical investigation of medicinal products for the treatment of amyotrophic lateral sclerosis	**3-month public consultation**
EMA/CHMP/60715/2012	Concept paper on need for revision of the guideline on medicinal products for the treatment of Alzheimer's disease and other dementias	**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

Reference number	Document	Status[1]
EMA/140721/2012	Guideline on the processing of renewals in the centralised procedure	**1-month public consultation**

Quality Working Party (QWP)

Reference number	Document	Status[1]
EMA/CHMP/CVMP/QWP/70278/2012-Rev1	Guideline on process validation	**6-month public consultation**
EMA/CHMP/QWP/811210/2009 Rev 1	Guideline on real time release testing (formerly guideline on parametric release) • Overview of comments	**adopted**
EMA/CHMP/CVMP/QWP/586330/2010	Q&A on the use of post approval change management protocols	**adopted**

Vaccine Working Party (VWP)

Reference number	Document	Status[1]
EMA/CHMP/VWP/923610/2011	Concept paper on guidance for DNA vaccines	**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").