

19 October 2012
EMA/CHMP/539798/2012
Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 15-18 October 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
EMA/651649/2010	Reflection paper on considerations given to designation of a single stereo isomeric form (enantiomer), a complex, a derivative, or a different salt or ester as new active substance in relation to the relevant reference active substance Overview of comments (EMA/355542/2011)	adopted
EMA/868942/2011	Points to consider on GCP inspection findings and the benefit-risk balance	adopted

Gastroenterology Drafting Group

Reference number	Document	Status
EMA/CHMP/396984/2012	Concept paper on the revision of the guideline on the development of new medicinal products for the treatment of Crohn's Disease (CPMP/EWP/2284/99 Rev. 1)	3-month public consultation
EMA/CHMP/204354/2012	Concept paper on the revision of the guideline on the development of medicinal products for the treatment of ulcerative colitis (CHMP/EWP/18463/2006)	3-month public consultation
EMA/CHMP/462198/2012	Concept paper on the need of a guideline for clinical investigation of medicinal products for the treatment of chronic constipation	3-month public consultation

Rheumatology/Immunology Working Party

Reference number	Document	Status
EMA/CHMP/520786/2012	Concept paper on the need for revision of the guideline on the evaluation of medicinal products in the treatment of primary osteoporosis	3-month public consultation

Safety Working Party (SWP)

Reference number	Document	Status
EMA/CHMP/SWP/647258/2012	Safety Working Party's response to the PDCO regarding the use of PEGylated drug products in the paediatric population	adopted