25 September 2014
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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 22-25 September 2014

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.

Cardiovascular Working Party

Reference number	Document	Status
EMA/CHMP/559636/2014	Concept paper on the need for revision of the points to consider on the clinical investigation of new medicinal products for the treatment of acute coronary syndrome	Adopted for 3-months public consultation

Quality Working Party

Reference number	Document	Status
EMA/448443/2014	Reflection paper on the Requirements for Selection and Justification of Starting Materials for the Manufacture of Chemical Active Substances	Adopted

Joint CVMP/CHMP ad-hoc expert group on the application of the 3Rs

Reference number	Document	Status
EMA/CHMP/CVMP/JEG-3Rs/450091/2012	Draft Guideline on Regulatory Acceptance of 3R (Replacement, Reduction, Refinement) Testing Approaches	Adopted for 6-months public consultation

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Gastroenterology Drafting Group

Reference number	Document	Status
CPMP/EWP/785/97 Rev. 1	Guideline on the evaluation of medicinal products for the treatment of irritable bowel syndrome	Adopted
EMA/CHMP/328077/2014	Concept paper on the revision of the guideline on the development of new medicinal products for the treatment of Crohn's disease	Adopted for 3-months public consultation
EMA/CHMP/327812/2014	Concept paper on the revision of the guideline on the development of new medicinal products for the treatment of ulcerative colitis	Adopted for 3-months public consultation

Blood Products Working Party

Reference number	Document	Status
EMA/CHMP/BPWP/1625/1999 rev. 2	Guideline on core SmPC for human plasma derived and recombinant coagulation factor IX products	Adopted for 1 month public consultation

Oncology Working Party

Reference number	Document	Status
EMA/CHMP/532800/2014	Guideline on the use of minimal residue disease as an endpoint in chronic lymphocytic leukaemia studies	Adopted for 6-months public consultation