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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 23-26 March 2015

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.

Safety Working Party

Reference number	Document	Status
EMA/CHMP/SWP/620008/2012	Reflection paper on the data requirements for intravenous iron-based nano-colloidal products developed with reference to an innovator medicinal product	Adopted
EMA/CHMP/SWP/44609/2010 Rev. 1	Questions and answers on 'Guideline on the environmental risk assessment of medicinal products for human use'	Adopted for 3-months public consultation

Central Nervous System Working Party

Reference number	Document	Status
EMA/CHMP/771815/2011 Rev. 2	Guideline on clinical investigation of medicinal products for the treatment of Multiple Sclerosis	Adopted

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Committee for Advanced Therapies

Reference number	Document	Status
EMA/CAT/80183/2014	Guideline on the quality, non-clinical and clinical aspects of gene therapy medicinal products	Adopted for 4-months public consultation

Pharmacokinetics Working Party

Reference number	Document	Status
EMA/CHMP/736403/2014	Compilation of individual product-specific guidance on demonstration of bioequivalence	Adopted

Rheumatology / Immunology Working Party

Reference number	Document	Status
CPMP/EWP/556/95 Rev. 2	Guideline on clinical investigation of medicinal products other than NSAIDs for treatment of rheumatoid arthritis	Adopted for 5-months public consultation