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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 23-26 February 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.

Quality Working Party

Reference number	Document	Status
EMA/96664/2015	Draft Guideline on the Chemistry of Active Substances	Adopted for 6-months public consultation
EMA/CHMP/CVMP/QWP/776887/2014	Question-and-answer document on plastic containers for eye drops	Adopted
EMA/CHMP/QWP/104928/2015	Question-and-answer document on the calculation of thresholds to set limits for impurities in the finished product specification	Adopted
EMA/CHMP/QWP/558185/2014	Concept paper on the development of a guideline on quality and equivalence of topical products	Adopted for 3-months public consultation
EMA/CHMP/QWP/126334/2015	Concept paper on the need for Revision of the Guideline on the Requirements to the Chemical and Pharmaceutical Quality Documentation concerning Investigational Medicinal Products in Clinical Trials	Adopted for 3-months public consultation
EMA/CHMP/QWP/104223/2015	Reflection paper on the chemical structure and properties criteria to be considered for the evaluation of New Active Substance (NAS) status of chemical substances	Adopted for 3-months public consultation

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Vaccines Working Party

Reference number	Document	Status
EMA/695450/2014	Work plan for the Vaccines Working Party (VWP)	Adopted

Biostatistics Working Party

Reference number	Document	Status
EMA/801811/2014	Work plan for the Biostatistics Working Party	Adopted
EMA/CHMP/295050/2013	Guideline on adjustment for baseline covariates in clinical trials	Adopted

Blood Products Working Party

Reference number	Document	Status
EMA/CHMP/BPWP/517446/2014	CHMP Blood Products Working Party (BPWP) Work programme 2015	Adopted
EMA/CHMP/BPWP/143744/2011 rev. 1	Guideline on core SmPC for human normal immunoglobulin for subcutaneous and intramuscular administration	Adopted

Oncology Working Party

Reference number	Document	Status
EMA/130525/2015	Concept paper on the need to revise the “Guideline on the evaluation of anticancer medicinal products in man” in order to provide guidance on the reporting of safety data from clinical trials	Adopted for 3-months public consultation

Biosimilar Medicinal Product Working Party

Reference number	Document	Status
EMEA/CHMP/BMWP/32775/2005 Rev. 1	Guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant human insulin and insulin analogues	Adopted

Cardiovascular Working Party

Reference number	Document	Status
EMA/CHMP/41230/2015 Rev.1	Draft Guideline on clinical investigation of medicinal products for the treatment of venous thromboembolic disease	Adopted for 6-months public consultation
EMA/CHMP/206815/2013	Paediatric Addendum to the Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Hypertension	Adopted

Rheumatology / Immunology Working Party

Reference number	Document	Status
EMA/CHMP/80184/2015	Concept paper on clinical investigation of medicinal products for the treatment of Axial Spondyloarthritis	Adopted for 3-months public consultation
EMA/CHMP/51230/2013	Guideline on clinical investigation of medicinal products for the treatment of systemic lupus erythematosus and lupus nephritis	Adopted

Excipients Labelling Drafting Group

Reference number	Document	Status
EMA/CHMP/495737/2013	Questions and answers on benzalkonium chloride in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'	Adopted

Modelling and Simulation Working Group

Reference number	Document	Status
EMA/91751/2015	EMA Modelling and Simulation Working Group Plan 2015	Adopted