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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 20-23 July 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.

Respiratory Drafting Group

Reference number	Document	Status
CHMP/EWP/2922/01 Rev.1	Guideline on the Clinical Investigation of Medicinal Products for the Treatment of Asthma	Adopted

Biosimilar Medicinal Product Working Party

Reference number	Document	Status
EMA/CHMP/BMWP/214262/2015	Concept paper on the revision of the guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant granulocyte-colony stimulating factor	Adopted for 3-months public consultation

Oncology Working Party

Reference number	Document	Status
EMA/CHMP/151853/2014	Guideline on the role of pathological complete response as an endpoint in neoadjuvant breast cancer studies	Adopted

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Committees

Reference number	Document	Status
EMA/CHMP/76150/2015	Guideline on the scientific application and the practical arrangements necessary to implement Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004	Adopted for 2-months public consultation
EMA/CHMP/697051/2014-Rev. 1	Revision of the Guideline on the scientific application and the practical arrangements necessary to implement the procedure for accelerated assessment pursuant to article 14(9) of regulation (EC) No 726/2004 – Rev 1	Adopted for 2-months public consultation
EMA/CHMP/742633/2014	Peer Review – Best Practice	Adopted

Blood Products Working Party

Reference number	Document	Status
EMA/CHMP/BPWP/410415/2011 rev 1	Guideline on the clinical investigation of human normal immunoglobulin for subcutaneous and/or intramuscular administration (SCIg/IMIg)	Adopted
EMA/CHMP/BPWP/585257/2009	Guideline on the clinical investigation of hepatitis B immunoglobulins	Adopted
EMA/CHMP/BPWP/691754/2013 Rev 1	Guideline on core SmPC for Human Fibrinogen Products	Adopted

Excipients Drafting Group

Reference number	Document	Status
EMA/CHMP/619104/2013	Questions and answers on boron (boric acid and borates) in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'	Adopted for 3-months public consultation

Reference number	Document	Status
EMA/CHMP/606830/2014	Questions and answers on Sodium laurilsulfate in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'	Adopted for 3-months public consultation

ICH

Reference number	Document	Status
EMA/CHMP/ICH/135/1995	Guideline for good clinical practice E6(R2)	Adopted for 6-months public consultation
EMA/CHMP/ICH/458894/2015	Application of the principles of the ICH M7 guideline to calculation of compound-specific acceptable intakes	Adopted for 6-months public consultation
EMA/CHMP/ICH/820/2003	ICH guideline M8 on eCTD – questions and answers	Adopted
EMA/CHMP/ICH/468930/2015	ICH guideline Q7 on good manufacturing practice for active pharmaceutical ingredients – questions and answers	Adopted
EMA/CHMP/ICH/82260/2006	Q3C (R6): Impurities: guideline for residual solvents	Adopted for 3-months public consultation