18 December 2014
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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 15-18 December 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.

Safety Working Party

Reference number	Document	Status
EMA/CHMP/SWP/362974/2012 corr	Corrigendum of Guideline on the use of phthalates as excipients in human medicinal products	Adopted

Quality Working Party

Reference number	Document	Status
EMA/59240/2014	Questions and Answers on level of detail in the submissions	Adopted

ICH

Reference number	Document	Status
EMA/CHMP/ICH/3943/2003	ICH guideline E2B (R3) - questions and answers	Adopted
EMA/CHMP/ICH/353369/2013	ICH guideline Q3D on elemental impurities	Adopted
EMA/CHMP/ICH/730231/2014	ICH guideline M2 on eCTD - file format criteria	Adopted

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Joint CVMP-CHMP antimicrobial advice ad hoc expert group

Reference number	Document	Status
EMA/381884/2014	Answers to the requests for scientific advice on the impact on public health and animal health of the use of antibiotics in animals	Adopted

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
EMA/CHMP/BPWP/144552/2009 Rev 1	Guideline on clinical investigation of recombinant and human plasma-derived factor IX products	Adopted for 1 month public consultation

Radiopharmaceutical Drafting Group

Reference number	Document	Status
EMA/759393/2014	Guideline on core SmPC and Package Leaflet for (^{99}Mo/^{99}mTc) generator	Adopted

Biosimilar Medicinal Product Working Party

Reference number	Document	Status
EMEA/CHMP/BMWP/42832/2005 Rev1	Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues	Adopted