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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 17-20 November 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/169430/2012	Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities	Adopted
EMA/CHMP/SWP/362974/2012	Guideline on the use of phthalates as excipients in human medicinal products	Adopted

Excipients Drafting Group

Reference number	Document	Status
EMA/CHMP/704195/2013	Questions and answers on propylene glycol 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
EMA/CHMP/495747/2013	Questions and answers on cyclodextrins 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



Infectious Diseases Working Party

Reference number	Document	Status
EMA/CHMP/644851/2014	Concept Paper on revision of the Addendum to the note for guidance on evaluation of medicinal products indicated for treatment of bacterial infections to specifically address the clinical development of new agents to treat disease due to mycobacterium tuberculosis	Adopted for 3 months public consultation

Pharmacokinetics Working Party

Reference number	Document	Status
EMA/CHMP/709822/2014	Compilation of individual product-specific guidance on demonstration of bioequivalence	Adopted
EMA/CHMP/669973/2014	Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms	Adopted