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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 16-19 September 2013

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 (SWP)

Reference number	Document	Status
EMA/CHMP/SWP/539410/2013	Concept paper on the need for a reflection paper on the regulatory acceptability of a Cell Transformation Assay for <i>in vitro</i> prediction of carcinogenic potential	3-month public consultation
EMA/CHMP/ICH/752486/2012	ICH guideline S1 – Regulatory notice on changes to core guideline on rodent carcinogenicity testing of pharmaceuticals	adopted

Biologics Working Party (BWP)

Reference number	Document	Status
EMA/CHMP/BWP/64982/2012	Pancreatin viral safety and need for warning statement: BWP report for publication	adopted



Cardiovascular Working Party

Reference number	Document	Status
EMA/CHMP/206815/2013	Draft Paediatric Addendum to the Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Hypertension	6-month public consultation

Infectious Diseases Working Party

Reference number	Document	Status
EMA/403021/2013 rev 3	Revised Guideline on the clinical development of medicinal products for the treatment of HIV infection	6-month public consultation

Pharmacokinetics Working Party

Reference number	Document	Status
EMA/CHMP/558326/2013	Concept paper on the development of a guideline on the demonstration of therapeutic equivalence for locally applied and locally acting products in the gastrointestinal tract	3-month public consultation