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Guidelines and concept papers

Adopted during the CHMP meeting 20-23 June 2016

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 Documents for public consultation will also be available under Document search/Public consultations.

Committee / Working Party	Reference number	Document	Status
Biologics Working Party	EMA/CHMP/BWP/723009/2014	Reflection paper on viral safety of plasma-derived medicinal products with respect to Hepatitis E virus	Adopted
Biologics Working Party	EMA/CHMP/BWP/534898/2008 rev. 1	Guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials	Adopted for 6-months public consultation
Cardiovascular Working Party	EMA/317855/2016	Concept paper on the need for revision of the Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus	Adopted for 3-months public consultation
Cardiovascular Working Party	EMA/CHMP/748108/2013, Rev. 3	Guideline on clinical investigation of medicinal products in the treatment of lipid disorders	Adopted
Cardiovascular Working Party	EMA/CHMP/311805/2014	Guideline on clinical evaluation of medicinal products used in weight management	Adopted
Cardiovascular Working Party	EMA/CHMP/29947/2013/Rev. 4	Guideline on clinical investigation of medicinal products in the treatment of hypertension	Adopted
Infectious Diseases Working Party	EMEA/CHMP/EWP/30039/2008 Rev 1	Guideline on the clinical evaluation of direct acting antivirals for the treatment of chronic hepatitis	Adopted for 6-months public consultation
Quality Working Party	EMA/404489/2016	Implementation of ICH Q3D	Adopted for 1 month public consultation
Quality Working Party	EMA/CHMP/CVMP/QWP/404276/2016	Question-and-answer on product specific active substance information	Adopted
Rheumatology/Immunology Working Party	CPMP/EWP/4891/03 Rev.1	Guideline on the clinical investigation of medicinal products for the treatment of Axial Spondyloarthritis	Adopted for 6-months public consultation