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Guidelines and concept papers

Adopted during the CHMP meeting 12-15 September 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
ICH	EMA/CPMP/ICH/2711/1999	Addendum (R1) to International Council for Harmonisation (ICH E11) Guideline 'Clinical Investigation of Medicinal Products in Paediatric Population'	Adopted
Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)	EMA/422206/2016	The worksharing procedure for the assessment of active substance master file (ASMF): Competent Authority version	Adopted
Blood Products Working Party	EMA/CHMP/BPWP/319619/2005 Rev. 2	Guideline on the core SmPC for human Anti-D immunoglobulin for intravenous use	Adopted
Blood Products Working Party	EMA/CHMP/BPWP/29205/2005	Guideline on the core SmPC for human Anti-D immunoglobulin for intramuscular use	Adopted
Rheumatology/Immunology Working Party	EMA/CHMP/500825/2016	Guideline on the clinical investigation of medicinal products to prevent development/slow progression of chronic renal insufficiency	Adopted
Biologics Working Party	EMA/CHMP/BWP/596747/2016	BWP report: Viral safety of plasma-derived and urine-derived medicinal products with respect to Zika virus	Adopted
Quality Working Party	EMA/514583/2016	Q/A on deletion of a non-significant specification parameter	Adopted