19 December 2013
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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 16-19 December 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.

Quality Working Party

Reference number	Document	Status
EMA/CHMP/CVMP/QWP/ 676913/2013	Annual work programme for 2014	Adopted
EMA/659396/2013	Guideline on Process Validation for finished products. Information and data to be provided in Regulatory Submissions	Adopted
EMA/752676/2013	Revision of Guidelines on the Chemistry of New Active Substances & Guideline on the Chemistry of Active Substances	Adopted for 6-months public consultation

Biologics Working Party

Reference number	Document	Status
EMA/CHMP/BWP/362722/ 2013	Annual work programme for 2014	Adopted

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Blood Products Working Party

Reference number	Document	Status
EMA/CHMP/BPWP/598816/2010	Guideline on core SmPC for plasma-derived fibrin sealant/haemostatic products	Adopted for 3-months public consultation

Cardiovascular Working Party

Reference number	Document	Status
EMA/CHMP/748108/2013	Guideline on clinical investigation of medicinal products in the treatment of lipid disorders	Adopted

Pharmacogenomics Working Party

Reference number	Document	Status
EMA/281371/2013	Draft Guideline on key aspects for the use of pharmacogenomic methodologies in the pharmacovigilance evaluation of medicinal products	Adopted for 6-months public consultation

Infectious Disease Working Party

Reference number	Document	Status
CHMP/EWP/2655/99	Concept paper on revision of the Points to Consider on Pharmacokinetics and Pharmacodynamics in the Development of Antibacterial Medicinal Products and conversion to a CHMP guideline	Adopted for 2-months public consultation

European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations

Reference number	Document	Status
EMA/552003/2013	Annual work programme for 2014	Adopted

European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations

Reference number	Document	Status
EMA/549571/2013	Annual work programme for 2014	Adopted

Radiopharmaceutical Drafting Group

Reference number	Document	Status
EMA/773757/2013	Draft core SmPC Technetium generator	Adopted for 3-months public consultation

Drafting Group on nanomedicines

Reference number	Document	Status
EMA/692195/2013	Reflection paper on block copolymer micelles	Adopted

Joint CVMP/CHMP ad-hoc Expert Group on the application of 3Rs (replacement, reduction and refinement)

Reference number	Document	Status
EMA/CHMP/CVMP/JE-3Rs/704685/2012	Draft concept paper on review and update of EMA guideline to implement best practice with regards to 3Rs in regulatory testing of medicinal products	Adopted for 3-months public consultation

Guideline Consistency Group

Reference number	Document	Status
EMA/690197/2013	New Word Template for clinical and methodological guidelines	Adopted

ICH

Reference number	Document	Status
EMA/CHMP/ICH/752211/2012	ICH guideline S10 – Guidance on photo safety evaluation of pharmaceuticals	Adopted
EMA/CHMP/ICH/645408/2008	ICH guideline Q4B annex 6 to note for evaluation and recommendation of pharmacopoeial text for use in the ICH regions on uniformity of dosage units – general chapter	Adopted
EMA/CHMP/ICH/820/2003	ICH guideline M8 on eCTD – questions and answers	Adopted