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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 14-17 December 2015

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/735015/2015	Work plan for the CHMP Safety Working Party for 2016	Adopted

Cardiovascular Working Party

Reference number	Document	Status
EMA/CHMP/728676/2015 rev 0	Work plan for the CHMP Cardiovascular Working Party for 2016	Adopted

Pharmacokinetics Working Party

Reference number	Document	Status
EMA/CHMP/83874/2014	Guideline on the evaluation of the pharmacokinetics of medicinal products in patients with decreased renal function	Adopted
EMA/CHMP/PKWP/671542/2015	Work plan for the CHMP Pharmacokinetics Working Party for 2016	Adopted



Modelling and Simulation Working Group

Reference number	Document	Status
EMA/811070/2015	Work plan for the Modelling and Simulation Working Group 2016	Adopted

Biostatistics Working Party

Reference number	Document	Status
EMA/CHMP/BSWP/799281/2015	Work plan for the CHMP Biostatistics Working Party for 2016	Adopted

Biosimilar Medicinal Products Working Party

Reference number	Document	Status
EMA/CHMP/BMWP/694728/2015	Work plan for the CHMP Biosimilar Medicinal Products Working Party for 2016	Adopted
EMA/CHMP/BMWP/693108/2015	Concept paper on the revision of the Reflection Paper on non-clinical and clinical development of similar biological medicinal products containing recombinant interferon alpha or pegylated recombinant interferon alpha	Adopted for 3-months public consultation

Central Nervous System Working Party

Reference number	Document	Status
EMA/CHMP/CNSWP/236981/2011	Guideline on the clinical investigation of medicinal products for the treatment of Duchenne and Becker muscular dystrophy	Adopted
EMA/CHMP/970057/2011	Guideline on the clinical development of medicinal products intended for the treatment of pain	Adopted for 3-months public consultation
EMA/CHMP/735080/2015	Work plan for the CHMP Central Nervous System Working Party for 2016	Adopted

Gastroenterology Drafting Group

Reference number	Document	Status
EMA/CHMP/GDG/702053/2015	Work plan for the Gastroenterology Drafting Group for 2016	Adopted

Infectious Diseases Working Party

Reference number	Document	Status
EMA/CHMP/701775/2015	Work plan for the CHMP Infectious Diseases Working Party for 2016	Adopted

Vaccines Working Party

Reference number	Document	Status
EMA/CHMP/VWP/833298/2015	Work plan for the CHMP Vaccines Working Party for 2016	Adopted

Quality Working Party

Reference number	Document	Status
EMA/834816/2015	Guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials	Adopted for 4-months public consultation
EMA/CHMP/CVMP/QWP/763085/2014	Question and answer on the use of powders and granules in medicinal products composed of 100% active substance	Adopted
EMA/CHMP/QWP/104223/2015	Reflection paper on the chemical structure and properties criteria to be considered for the evaluation of New Active Substance (NAS) status of chemical substances	Adopted

Geriatric Expert Group

Reference number	Document	Status
EMA/CHMP/778709/2015	Points to Consider on Frailty: Evaluation Instruments for Baseline Characterisation of Clinical trial populations	Adopted for 5-months public consultation

Pharmacogenomics Working Party

Reference number	Document	Status
EMA/CHMP/PGWP/707191/2015	Work plan for the CHMP Pharmacogenomics Working Party for 2016	Adopted

Rheumatology/Immunology Working Party

Reference number	Document	Status
EMA/CHMP/RIWP/649551/2015	Work plan for the CHMP Rheumatology-Immunology Working Party for 2016	Adopted

Biologics Working Party

Reference number	Document	Status
EMA/CHMP/BWP/454652/2015	Work plan for the CHMP Biologics Working Party for 2016	Adopted

Excipients Drafting Group

Reference number	Document	Status
EMA/CHMP/833588/2015	Work plan for the CHMP Excipients Drafting Group for 2016	Adopted

Oncology Working Party

Reference number	Document	Status
EMA/629967/2014	Guideline on the use of minimal residual disease as an endpoint in chronic lymphocytic leukaemia studies	Adopted