



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 January 2016
EMA/67199/2016
Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 25-28 January 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 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/850 374/2015	Guideline on the sterilisation of the medicinal product, active substance, excipient and primary container	Adopted for 6-months public consultation
EMA/CHMP/CVMP/QWP/826 799/2015	Q/A on sterilisation of primary packaging	Adopted

Blood Products Working Party

Reference number	Document	Status
EMA/CHMP/BPWP/29205/20 05 Rev. 2	Guideline on the core SmPC for Human Anti-D Immunoglobulin for Intramuscular Use	Adopted for 3-months public consultation
EMA/CHMP/BPWP/319619/2 005 Rev. 2	Guideline on the Core SmPC for Human Anti-D Immunoglobulin for Intravenous Use	Adopted for 3-months public consultation
EMA/CHMP/BPWP/1619/199 9 rev. 2	Guideline on core SmPC for human plasma derived and recombinant coagulation factor VIII products	Adopted
EMA/CHMP/BPWP/144533/2 009 rev 1	Guideline on the clinical investigation of recombinant and human plasma-derived factor VIII products	Adopted



Central Nervous System Working Party

Reference number	Document	Status
EMA/CHMP/539931/2014	Guideline on the clinical investigation of medicines for the treatment of Alzheimer's disease and other dementias	Adopted for 6-months public consultation

Radiopharmaceuticals Drafting Group

Reference number	Document	Status
EMA/CHMP/765387/2015	Work plan for the CHMP Radiopharmaceuticals Drafting Group for 2016	Adopted
EMA/CHMP/39163/2016	Guideline on core SmPC and Package Leaflet for gadopentetate dimeglumine	Adopted for 3-months public consultation
EMA/CHMP/39283/2016	Guideline on core SmPC and Package Leaflet for nanocolloidal technetium (99mTc) albumin	Adopted for 3-months public consultation

Oncology Working Party

Reference number	Document	Status
EMA/CHMP/707548/2015	Work plan for the CHMP Oncology Working Party for 2016	Adopted

Cardiovascular Working Party

Reference number	Document	Status
EMA/392958/2015	Guideline on clinical investigation of medicinal products for the treatment of chronic heart failure	Adopted for 6-months public consultation

International Council on Harmonisation

Reference number	Document	Status
EMA/CHMP/ICH/310133/2008	ICH guideline E14: The clinical evaluation of QT/QTc interval prolongation and proarrhythmic potential for non-antiarrhythmic drugs (R3) - questions and answers	Adopted

Reference number	Document	Status
EMA/CHMP/ICH/11623/2016	ICH guideline E18 on genomic sampling and management of genomic data - Step 3	Adopted for 4-months public consultation