



26 February 2016
EMA/76582/2016
Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 22-25 February 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](#).

Committees (CHMP)

Reference number	Document	Status
EMA/CHMP/697051/2014 Rev. 1	Guideline on the scientific application and the practical arrangements necessary to implement the procedure for accelerated assessment pursuant to article 14(9) of regulation (EC) No 726/2004	Adopted
EMA/CHMP/57760/2015	Enhanced early dialogue to facilitate accelerated assessment of priority medicines (PRIME)	Adopted
EMA/CHMP/509951/2006 Rev.1	Guideline on the scientific application and the practical arrangements necessary to implement Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004	Adopted



Cardiovascular Working Party

Reference number	Document	Status
EMA/CHMP/41230/2015	Guideline on clinical investigation of medicinal products for the treatment of venous thromboembolic disease	Adopted
EMA/CHMP/50549/2015	Reflection paper on assessment of cardiovascular safety profile of medicinal products	Adopted

Oncology Working Party

Reference number	Document	Status
EMA/CHMP/205/95/Rev.5	Guideline on evaluation of anticancer medicinal products in man	Adopted for 6-months public consultation

Respiratory Drafting Group

Reference number	Document	Status
EMA/CHMP/RDG/765422/2015	Work plan for the CHMP Respiratory Drafting Group for 2016	Adopted

Blood Products Working Party

Reference number	Document	Status
EMA/CHMP/BPWP/94767/2016	Work plan for the CHMP Blood Products Working Party (BPWP) for 2016	Adopted

Biologics Working Party

Reference number	Document	Status
EMA/CHMP/BWP/548524/2008. rev 1	Guideline on epidemiological data on blood transmissible infections	Adopted

Central Nervous System Working Party

Reference number	Document	Status
EMA/CHMP/598082/2013	Guideline on the clinical development of medicinal products for the treatment of Autism Spectrum Disorder (ASD)	Adopted for 6-months public consultation

International Council on Harmonisation (ICH)

Reference number	Document	Status
EMA/CHMP/ICH/536328/2013	ICH guideline S1 Regulatory notice on changes to core guideline on rodent carcinogenicity testing of pharmaceuticals Step 5	Adopted