



20 February 2014  
EMA/54973/2014  
Press Office

## Guidelines and concept papers

Adopted during the CHMP meeting 17-20 February 2014

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/QWP/40776/2014	Q&A on expression/declaration of potency in quantitative and qualitative composition for Vancomycin products	Adopted for 3-month public consultation
EMA/CHMP/CVMP/QWP/40811/2014	Guideline on Stability Testing for Applications for Variations to a Marketing Authorisation	Adopted
EMA/CHMP/CVMP/QWP/63700/2014	Guideline on the use of Near Infrared Spectroscopy (NIRS) by the pharmaceutical industry and the data requirements for new submissions and variations	Adopted
EMA/CHMP/CVMP/QWP/80360/2014	Quality Person declaration concerning GMP compliance of active substance manufacture and verification of its supply chain: template and guidance	Adopted

### Biosimilar Medicinal Product Working Party

Reference number	Document	Status
EMA/CHMP/BMWP/275542/2013	Concept paper on the revision of the guideline on Immunogenicity	Adopted for 3-month public consultation



Reference number	Document	Status
	Assessment of Biotechnology-derived Therapeutic Proteins	
EMA/CHMP/BMWP/736496/2013	Biosimilar Medicinal Products Working Party Work Program for 2014	Adopted

### Biologics Working Party

Reference number	Document	Status
EMA/CHMP/BWP/814397/2011	Guideline on the use of porcine trypsin used in the manufacture of human biological medicinal products	Adopted
EMA/CHMP/BWP/85290/2012	Guideline on the declaration of the quantitative composition/labelling of biological medicinal products that contain modified proteins as active substance	Adopted

### Vaccines Working Party

Reference number	Document	Status
EMA/CHMP/VWP/95156/2014	Vaccines Working Party Work Program for 2014	Adopted

### Blood Products Working Party

Reference number	Document	Status
EMA/CHMP/BPWP/691754/2013	Guideline on core SmPC for human fibrinogen products	Adopted for 3-month public consultation

### Cardiovascular Working Party

Reference number	Document	Status
EMA/CHMP/50673/2014	Reflection paper on the wording of indication for medicinal products for treatment of type 2 diabetes	Adopted for 3-month public consultation

### Central Nervous System Working Party

Reference number	Document	Status
EMA/54973/2014	Central Nervous System Working	Adopted

Reference number	Document	Status
	Party Work Program for 2014	

### Oncology Working Party

Reference number	Document	Status
EMA/CHMP/68747/2014	Guideline on the clinical development of medicinal products intended for the treatment of chronic primary immune thrombocytopenia	Adopted
EMA/54973/2014	Oncology Working Party Work Program for 2014	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 for 6-month public consultation

### Biostatistic Working Party

Reference number	Document	Status
EMA/CHMP/469174/2013	Biostatistics Working Party Work Program 2014	Adopted

### Gastroenterology Drafting Group

Reference number	Document	Status
EMA/CHMP/336243/2013	Guideline on the evaluation of Medicinal Products for the treatment of Chronic Constipation	Adopted for 6-month public consultation

### Radiopharmaceutical Drafting Group

Reference number	Document	Status
EMA/CHMP/39557/2014	Radiopharmaceutical Drafting Group Work Program 2014	Adopted