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Press Office

## Guidelines and concept papers

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

### Biologics Working Party

Reference number	Document	Status
EMA/CHMP/BWP/187338/2014	Guideline on process validation for the manufacture of biotechnology-derived active substances and data to be provided in the regulatory submission	Adopted for 6-months public consultation
EMA/CHMP/BWP/310834/2012	Guideline on Influenza Vaccines – Quality Module	Adopted
EMA/CHMP/BWP/78086/2014	Concept paper on Viral safety of blood products with respect to hepatitis E	Adopted for 3-months public consultation

### Safety Working Party

Reference number	Document	Status
EMA/CHMP/SWP/187944/2014 Rev. 1	Guideline on non-clinical local tolerance testing of medicinal products	Adopted for 3-months public consultation
EMA/CHMP/SWP/191104/2014	Questions and answers on the withdrawal of the 'Guideline on pharmacokinetics and metabolic studies in the safety evaluation of new medicinal products in animals	Adopted



Reference number	Document	Status
	(3BS11A)'	
EMA/CHMP/SWP/743862/2013	Revised SWP Work plan 2014	Adopted

### **Rheumatology-Immunology Working Party**

Reference number	Document	Status
EMA/CPMP/422/04	Guideline on treatment of Juvenile Idiopathic Arthritis	Adopted for 6-months public consultation

### **Biosimilar Medicinal Product Working Party**

Reference number	Document	Status
EMA/CHMP/BMWP/32775/2005_Rev. 1	Guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant human insulin and insulin analogues	Adopted for 3-months public consultation (2 <sup>nd</sup> consultation)