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Guidelines and concept papers

Adopted during the CHMP meeting 18-21 July 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 Documents for public consultation will also be available under Document search/Public consultations.

Committee / Working Party	Reference number	Document	Status
Safety Working Party	EMA/CHMP/SWP/242917/2016	Questions and answers on the withdrawal of the CPMP Note for guidance on preclinical pharmacological and toxicological testing of vaccines	Adopted
Safety Working Party	EMA/CHMP/CVMP/JEG-3Rs/677407/2015	Review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products – report on actions taken	Adopted
Safety Working Party	EMA/CHMP/CVMP/JEG-3Rs/94436/2014	Guidance for individual laboratories for transfer of quality control methods Validated in Collaborative Trials with a view to implementing 3Rs	Adopted for 6-months public consultation
Biologics Working Party	EMA/CHMP/BWP/532517/2008 Rev 1	Guideline on development, production, characterisation and specification for monoclonal antibodies and related products	Adopted
Biologics Working Party	EMA/CHMP/BWP/271475/2006 Rev 1	Guideline on potency testing of cell based immunotherapy medicinal products for the treatment of cancer	Adopted
Biologics Working Party	EMA/CHMP/BWP/3354/1999 Rev 1	Guideline on production and quality control of animal immunoglobulins and immunosera for human use	Adopted
Biologics Working Party	EMA/CHMP/BWP/109166/2014	Guideline on production and quality control of cytokine products derived by biotechnological processes	Adopted

Committee / Working Party	Reference number	Document	Status
Blood Products Working Party	EMA/CHMP/BPWP/383118/2016	Concept paper on revision of guidelines on the clinical investigation and core SmPC of recombinant and human plasma-derived factor VIII products	Adopted for 2-months public consultation
Central Nervous System Working Party	EMA/CHMP/318360/2015	Concept paper on the need for revision of the Note for Guidance on Clinical Investigation of Medicinal Products for the Treatment and Prevention of Bipolar Disorder	Adopted for 3-months public consultation
Infectious Diseases Working Party	EMA/CHMP/594085/2015	Guideline on the use of pharmacokinetics and pharmacodynamics in the development of antimicrobial medicinal products	Adopted
Infectious Diseases Working Party	EMA/CHMP/EWP/14377/2008 Rev 1	Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address the clinical development of new agents to treat disease due to Mycobacterium tuberculosis	Adopted for 6-months public consultation
Pharmacokinetics Working Party	EMA/CHMP/458101/2016	Guideline on the qualification and reporting of Physiologically Based Pharmacokinetic (PBPK) Modelling and Simulation	Adopted for 6-months public consultation
Pharmacokinetics Working Party	EMA/CHMP/156998/2016	Abiraterone - substance characteristics important for assessment of generics (oral use, immediate release)	Adopted for 3-months public consultation
Pharmacokinetics Working Party	EMA/CHMP/157419/2016	Exenatide - substance characteristics important for assessment of generics (parenteral use, modified release)	Adopted for 3-months public consultation
Pharmacokinetics Working Party	EMA/CHMP/157302/2016	Paliperidone palmitate - substance characteristics important for assessment of generics (parenteral use, modified release)	Adopted for 3-months public consultation
Pharmacokinetics Working Party	EMA/CHMP/157500/2016	Vandetanib - substance characteristics important for assessment of generics (oral use, immediate release)	Adopted for 3-months public consultation
Pharmacokinetics Working Party	EMA/CHMP/157360/2016	Vemurafenib - substance characteristics important for assessment of generics (oral use, immediate release)	Adopted for 3-months public consultation
Gastroenterology Drafting Group	EMA/CHMP/457879/2016	Guideline on the development of new medicinal products for the treatment of Crohn's Disease	Adopted for 6-months public consultation
Gastroenterology Drafting Group	EMA/CHMP/457994/2016	Guideline on the development of new medicinal products for the treatment of Ulcerative Colitis	Adopted for 6-months public consultation
Excipients Drafting Group	EMA/CHMP/619104/2013	Questions and answers on boric acid in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'	Adopted

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Excipients Drafting Group	EMA/CHMP/495747/2013	Questions and answers on cyclodextrins in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'	Adopted
Excipients Drafting Group	EMA/CHMP/338679/2014	Questions and answers on sodium in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'	Adopted
Excipients Drafting Group	EMA/CHMP/606830/2014	Questions and answers on Sodium laurilsulfate in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use'	Adopted
Respiratory Drafting Group	EMEA/CHMP/EWP/9147/2008	Concept Paper for the revision of the Guideline on the clinical development of medicinal products for the treatment of cystic fibrosis	Adopted for 3-months public consultation
Antimicrobial Advice ad hoc Expert Group (AMEG)	EMA/231573/2016	Updated advice on the use of colistin products in animals within the European Union: development of resistance and possible impact on human and animal health	Adopted
Quality Working Party	EMA/454576/2016	Guideline on the Chemistry of Active Substances	Adopted
ICH	EMA/CHMP/ICH/453276/2016	ICH guideline E17: general principles for planning and design of multi-regional clinical trials - Step 3	Adopted for 6-months public consultation
ICH	EMA/CPMP/ICH/2887/1999	M4E(R2) - Common technical document for the registration of pharmaceuticals for human use – Efficacy - Step 4	Adopted
ICH	EMA/CHMP/ICH/453684/2016	ICH S9 guideline on nonclinical evaluation for anticancer pharmaceuticals - questions and answers - Step 3	Adopted for 6-months public consultation
Committees (CHMP)	EMA/CHMP/446302/2016	Concept paper on the revision of the 'Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products'	Adopted for 2-months public consultation
Committees (CHMP)	EMEA/CHMP/2990/00 Rev.5	Guideline on the processing of renewals in the centralised procedure	Adopted
Vaccines Working Party	EMA/CHMP/VWP/92675/2016	Guideline on influenza vaccines. Non-clinical and clinical module	Adopted