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4 April 2016
EMA/76588/2016
Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 29 March – 1 April 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.

Committee / Working Party	Reference number	Document	Status
Cardiovascular Working Party	EMA/CHMP/207892/2015	Draft guideline on clinical investigation of new medicinal products for the treatment of acute coronary syndrome	Adopted for 6-months public consultation
Infectious Diseases Working Party	EMA/CHMP/213862/2016	Concept paper on an addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address paediatric-specific clinical data requirements	Adopted for 3-months public consultation
Oncology Working Party	EMA/CHMP/292464/2014	Appendix 2 to the guideline on the evaluation of anticancer medicinal products in man The use of Patient-Reported Outcome (PRO) measures in oncology studies	Adopted
Pharmacokinetics Working Party	EMA/CHMP/PKWP/154772/2016, EMA/CHMP/PKWP/154812/2016, EMA/CHMP/PKWP/162889/2016, EMA/CHMP/PKWP/156358/2016, EMA/CHMP/PKWP/154805/2016	Product specific bioequivalence guidance (generics) – 4th batch, draft: Everolimus, Fingolimod, Levodopa / Carbidopa / Entacapone, Paliperidone, Pazopanib	Adopted for 3-months public consultation
Pharmacokinetics Working Party	EMA/CHMP/158542/2016, EMA/CHMP/160445/2016, EMA/CHMP/158772/2016, EMA/CHMP/160650/2016, EMA/CHMP/158934/2016, EMA/CHMP/159744/2016, EMA/CHMP/159882/2016, EMA/CHMP/177335/2016, EMA/CHMP/177281/2016	Product specific BE guidance (generics) – 2nd batch, final: Asenapine, Entecavir, Prasugrel, Rivaroxaban, Sitagliptin, Tacrolimus, Zonisamide, Lenalidomide, Ticagrelor	Adopted
Quality Working Party	EMA/CHMP/CVMP/QWP/152772/2016	Questions and answers on (active pharmaceutical ingredient) API mixtures	Adopted
Quality Working Party	EMA/CHMP/CVMP/QWP/37330/2016	Reflection paper on the Dissolution specification for generic oral immediate release products	Adopted for 3-months public consultation