



25 September 2015
EMA/38594/2015 Corr*
Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 21-24 September 2015

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](#).

Biosimilar Medicinal Product Working Party

Reference number	Document	Status
EMA/CHMP/BMWP/14327/2006 Rev1	Guideline on Immunogenicity assessment of biotechnology-derived therapeutic proteins	Adopted for 4-months public consultation

Pharmacogenomics Working Party

Reference number	Document	Status
EMA/CHMP/281371/2013	Guideline on key aspects for the use of pharmacogenomics in the pharmacovigilance of medicinal products	Adopted

Committees

Reference number	Document	Status
EMA/494976/2015	Practical guidance on elements required to grant an additional year of marketing protection due to significant clinical benefit	Adopted

* Correction to remove reference to "Guideline on clinical investigation of medicinal products for prevention of venous thromboembolism (VTE) in non-surgical patients", which was included by error in the table.



ICH

Reference number	Document	Status
EMA/CPMP/ICH/2887/1999	ICH guideline M4E(R2) - Common Technical Document for the Registration of Pharmaceuticals for Human Use – Efficacy	Adopted for 6-months public consultation

Cardiovascular Working Party

Reference number	Document	Status
EMA/CHMP/311805/2014	Guideline on clinical evaluation of medicinal products used in weight management	Adopted

Infectious Diseases Working Party

Reference number	Document	Status
EMA/CHMP/594085/2015	Guideline on the use of pharmacokinetics and pharmacodynamics in the development of antibacterial medicinal products	Adopted for 6-months public consultation

Pharmacokinetics Working Party

Reference number	Document	Status
EMA/CHMP/PKWP/151748/2015	Entecavir film-coated tablets 0.5 and 1 mg, oral solution 0.05mg/ml product-specific bioequivalence guidance	Adopted for 3-months public consultation
EMA/CHMP/PKWP/152216/2015	Lenalidomide hard gelatine capsules 2.5, 5, 7.5, 10, 15 and 25mg product-specific bioequivalence guidance	Adopted for 3-months public consultation
EMA/CHMP/PKWP/151340/2015	Rivaroxaban film-coated tablets 2.5, 10, 15 and 20mg product-specific bioequivalence guidance	Adopted for 3-months public consultation
EMA/CHMP/PKWP/36648/2015	Tacrolimus granules for oral suspension 0.2 and 1 mg product-specific bioequivalence guidance	Adopted for 3-months public consultation

Reference number	Document	Status
EMA/CHMP/PKWP/151478/2015	Ticagrelor film-coated tablets 90mg product-specific bioequivalence guidance	Adopted for 3-months public consultation