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Press Office

## Guidelines and concept papers

Adopted during the CHMP meeting 23-26 June 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](#).

### Cardiovascular Working Party

Reference number	Document	Status
EMA/CHMP/341363/2014	Draft Guideline on clinical investigation of medicinal products for prevention of stroke and systemic embolic events in patients with non-valvular atrial fibrillation	Adopted
EMA/CHMP/311805/2014	Draft Guideline of medical products used in weight control (previous reference number CPMP/EWP/281/96 Rev.1)	Adopted for 6-month public consultation
EMA/CHMP/283524/2014	Concept paper on the need for revision of the guideline on clinical investigation of medicinal products for the prophylaxis of venous thromboembolic risk in non-surgical patients (previous reference number CPMP/EWP/6235/04)	Adopted for 3-month public consultation



## Pharmacokinetics Working Party

Reference number	Document	Status
EMA/CHMP/211243/2014	Concept paper on Qualification and Reporting of PBPK modelling and analyses	Adopted for 3-month public consultation

## Rheumatology/Immunology Working Party

Reference number	Document	Status
EMA/CHMP/EWP/6054/2010	Guideline on the clinical investigation of medicinal products to slow progression of renal insufficiency	Adopted for 6-month public consultation

## Joint CVMP/CHMP ad-hoc expert group on the application of the 3Rs (replacement, reduction and refinement) in the regulatory testing of medicinal products

Reference number	Document	Status
EMA/CHMP/CVMP/JEG-3Rs/94304/2014	Draft concept paper on product specific validation	Adopted for 3-month public consultation