EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 October 2013
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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 21-24 October 2013

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.

Quality Working Party

Reference number	Document	Status
EMA/603905/2013	Questions-and-Answers on Design Space Verification	adopted

Cardiovascular Working Party

Reference number	Document	Status
EMA/CHMP/623942/2013	Draft Guideline on clinical investigation of medicinal products for prevention of stroke and systemic embolic events in patients with non-valvular atrial fibrillation	2-month public consultation

Central Nervous System Working Party

Reference number	Document	Status
EMA/CHMP/617734/2013	Concept Paper on the need for revision of the note for guidance on the clinical investigation of medicinal products for the treatment of Alzheimer's disease and other dementias	3-month public consultation

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Infectious Disease Working Party

Reference number	Document	Status
EMA/CHMP/351889/2013	Addendum to Note of Guidance on evaluation of medicinal products indicated for treatment of bacterial infection	adopted

Pharmacokinetics Working Party

Reference number	Document	Status
EMA/653473/2013	Erlotinib product-specific bioequivalence guideline	3-month public consultation
EMA/653473/2013	Dasatinib product-specific bioequivalence guideline	3-month public consultation
EMA/653473/2013	Posaconazole product-specific bioequivalence guideline	3-month public consultation
EMA/653473/2013	Emtricitabine/tenofovir disoproxil product-specific bioequivalence guideline	3-month public consultation
EMA/653473/2013	Sorafenib product-specific bioequivalence guideline	3-month public consultation
EMA/653473/2013	Sirolimus product-specific bioequivalence guideline	3-month public consultation
EMA/653473/2013	Capecitabine product-specific bioequivalence guideline	3-month public consultation
EMA/653473/2013	Repaglinide product-specific bioequivalence guideline	3-month public consultation
EMA/653473/2013	Imatinib product-specific bioequivalence guideline	3-month public consultation
EMA/423735/2013	Tadalafil product-specific bioequivalence guideline	3-month public consultation
EMA/653473/2013	Oseltamivir product-specific bioequivalence guideline	3-month public consultation
EMA/423734/2013	Memantine product-specific bioequivalence guideline	3-month public consultation
EMA/653473/2013	Voriconazole product-specific bioequivalence guideline	3-month public consultation
EMA/653473/2013	Miglustat product-specific bioequivalence guideline	3-month public consultation
EMA/653473/2013	Telithromycin product-specific bioequivalence guideline	3-month public consultation
EMA/653473/2013	Carglumic acid product-specific bioequivalence guideline	3-month public consultation

Radiopharmaceuticals Drafting Group

Reference number	Document	Status
EMA/653473/2013	Core SmPC for Technetium (99mTc) for sestamibi	adopted