EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 22-25 June 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.

Safety Working Party

Reference number	Document	Status
EMA/CHMP/CVMP/JEG-3Rs/243112/2015	Recommendation to marketing authorisation holders, highlighting recent updates for 3Rs methods described in the European Pharmacopoeia	Adopted

Quality Working Party

Reference number	Document	Status
EMA/CHMP/CVMP/QWP/390257/2015	Questions and Answers What is understood by "manufactured by complex manufacturing processes" in change code B.II.b.4 (change in batch size of the finished product) or in change code B.II.b.1 (replacement or addition of a manufacturing site)? H+V	Adopted

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Biologics Working Party

Reference number	Document	Status
EMA/CHMP/BWP/723009/2014	Reflection paper on viral safety of plasma-derived medicinal products with respect to hepatitis E virus	Adopted for 3-months public consultation

Gastroenterology Drafting Group

Reference number	Document	Status
EMA/CHMP/336243/2013	Guideline on the evaluation of medicinal products for the treatment of chronic constipation (including opioid induced constipation) and for bowel cleansing	Adopted

Pharmacokinetics Working Party

Reference number	Document	Status
EMA/618604/2008 Rev. 12	Questions & Answers: positions on specific questions addressed to the Pharmacokinetics Working Party (PKWP)	Adopted
EMA/CHMP/PKWPEMA/CHMP/36761/2015	Prasugrel film-coated tablets 5 and 10 mg Product-Specific Bioequivalence Guidance	Adopted for 6-months public consultation
EMA/CHMP/PKWP/269533/2015	Asenapine sublingual tablets 5 and 10 mg Product-Specific Bioequivalence Guidance	Adopted for 6-months public consultation
EMA/CHMP/PKWPEMA/CHMP/36869/2015	Sitagliptin film-coated tablets 25, 50 and 100 mg Product-Specific Bioequivalence Guidance	Adopted for 6-months public consultation
EMA/CHMP/PKWPEMA/CHMP/253507/2015	Zonisamide hard capsules 25, 50 and 100 mg, orodispersible tablets 25, 50, 100 and 300 mg Product-Specific Bioequivalence Guidance	Adopted for 6-months public consultation

Radiopharmaceutical Drafting Group

Reference number	Document	Status
EMA/212874/2015	Guideline on core SmPC and Package Leaflet for sodium fluoride (18F)	Adopted

Committees

Reference number	Document	Status
EMA/PDCO/71162/2014	Paediatric investigation plan: Expected key elements and requirements for a new DTaP-containing combination vaccine for primary and booster vaccination in infants and toddlers	Adopted

Blood Products Working Party

Reference number	Document	Status
EMA/CHMP/BPWP/598816/2010 rev. 1-1	Guideline on core SmPC for plasma-derived fibrin sealant/ haemostatic products	Adopted