24 July 2014
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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 21-24 July 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.

Safety Working Party

Reference number	Document	Status
EMA/CHMP/704219/2013	Final revised Q&A documents on gluten from the Excipient Drafting group	Adopted for 3-months public consultation
EMA/125393/2014	Questions and Answers on Wheat starch containing gluten in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00 Rev. 1)	Adopted for 3-months public consultation
EMA/CHMP/SWP/415882/2014	SWP position statement on Estragole	Adopted

Vaccines Working Party

Reference number	Document	Status
EMA/CHMP/220181/2013	Non-clinical and clinical module of the new Guideline on Influenza vaccines	Adopted for 6-months public consultation

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Biologics Working Party

Reference number	Document	Status
EMA/CHMP/BWP/295676/2014	Concept paper on revision of Guideline on epidemiological data on blood transmissible infections	Adopted for release for 5-months public consultation

Blood Products Working Party

Reference number	Document	Status
EMA/CHMP/BPWP/572805/2013	Concept paper on 'Guideline and Core SmPC on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)	Adopted for 3-months public consultation

Pharmacogenomics Working Party

Reference number	Document	Status
EMA\CHMP\PGWP\415990\2014	Concept paper on good genomics biomarker practices	Adopted for release for 3-months consultation

Radiopharmaceutical Drafting Group

Reference number	Document	Status
	Adoption of the core SmPC and Package leaflet for sodium fluoride (18F)	Adopted for 3-months public consultation

ICH

Reference number	Document	Status
EMA/CHMP/ICH/820/2003	M8 – Questions and Answers	Adopted
EMA/CHMP/ICH/83812/2013	M7 – Step 4 - Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk	Adopted