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29 April 2016
EMA/76588/2016
Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 25-28 April 2016

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 Documents for public consultation will also be available under Document search/Public consultations.

Committee/Working Party	Reference number	Document	Status
Safety Working Party	EMA/CHMP/SWP/65429/2016	Concept paper on the revision on the 'Guideline on the environmental risk assessment of medicinal products for human use' (EMEA/CHMP/SWP/4447/00 corr 2)	Adopted for 6-months public consultation
Biologics Working Party	EMA/CHMP/BWP/187338/2014	Guideline on process validation for the manufacture of biotechnology-derived active substances and data to be provided in the regulatory submission	Adopted
Pharmacogenomics Working Party	EMA/CHMP/268544/2016	Guideline on good pharmacogenomic practice	Adopted for 5-months public consultation
Infectious Diseases Working Party	EMA/CPMP/EWP/676857/2015	Guideline clinical development of medicinal products for treatment of HIV	Adopted
Excipients Drafting Group	EMA/CHMP/134648/2015	Information in the package leaflet for aspartame 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
Excipients Drafting Group	EMA/CHMP/460886/2014	Information in the package leaflet for fructose and sorbitol 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

Committee/Working Party	Reference number	Document	Status
Excipients Drafting Group	EMA/CHMP/273718/2014	Information in the package leaflet for fragrances containing allergens 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