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Press Office

## Guidelines and concept papers

Adopted during the CHMP meeting 23-26 May 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/44609/2010 Rev. 1	Questions and answers on 'Guideline on the environmental risk assessment of medicinal products for human use'	Adopted
ICH	EMA/CHMP/ICH/320985/2016	ICH Guideline S3A: Note for guidance on toxicokinetics: the assessment of systemic exposure in toxicity studies - questions and answers - Step 2b	Adopted for 3-months public consultation
Radiopharmaceutical Drafting Group	EMA/CHMP/337681/2016	Guideline on core SmPC and Package Leaflet for (68Ge/68Ga) generator	Adopted for 4-months public consultation
Radiopharmaceutical Drafting Group	EMA/CHMP/337958/2016	Guideline on core SmPC and Package Leaflet for fluorodopa (18F)	Adopted for 4-months public consultation
Radiopharmaceutical Drafting Group	EMA/CHMP/337820/2016	Guideline on core SmPC and Package Leaflet for gadoteric acid	Adopted for 4-months public consultation
Antimicrobial Advice ad hoc Expert Group (AMEG)	EMA/231573/2016	Updated advice on the use of colistin products in animals 3 within the European Union: development of resistance 4 and possible impact on human and animal health	Adopted for 1 month public consultation