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Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 17-20 March 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.

Quality Working Party

Reference number	Document	Status
EMA/CHMP/QWP/95328/2014	Q&A on stability of generics versus the innovator product	Adopted
EMA/CHMP/QWP/95348/2014	Q&A on acceptability of two different appearances (shape, dimensions, colour) for a single strength tablet in a single MA	Adopted
EMA/CHMP/QWP/95316/2014	Q&A on particles originated from the container closure system	Adopted
EMA/CHMP/QWP/428693/2013	Guideline on quality of oral modified release products	Adopted
EMA/CHMP/CVMP/QWP/128000/2014	Concept Paper on the establishment of a guideline on the Selection of Sterilisation Processes for Drug Products	Adopted for 3-month public consultation
EMA/CHMP/CVMP/QWP/136250/2014	Reflection paper on the use of Cocrystals and other solid state forms of active substances in medicinal product	Adopted for 3-month public consultation

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Oncology Working Party

Reference number	Document	Status
EMA/CHMP/42527/2014	Guideline on the role of the Pathological Complete Response as an endpoint in neoadjuvant Breast Cancer studies	Adopted for 3-month public consultation

Infectious Disease Working Party

Reference number	Document	Status
EMA/CHMP/IDWP/735916/ 2013	Work Programme for 2014	Adopted

Blood Products Working Party

Reference number	Document	Status
EMA/CHMP/BPWP/297895/ 2013	Work Programme for 2014	Adopted

Gastroenterology Drafting Group

Reference number	Document	Status
EMA/CHMP/723944/2013	Revised Gastroenterology Drafting Group Work Programme for 2014	Adopted