

19 April 2012 EMA/CHMP/213033/2012 Press Office

Guidelines and concept papers

Adopted during the CHMP meeting 16-19 April 2012

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 <u>Regulatory/Human/Scientific guidelines</u>. Documents for public consultation will also be available under <u>Document search/Public consultations</u>.

ICH

Reference number	Document	Status
EMA/CHMP/ICH/544553/1998	ICH guideline E2C (R2) –	1-month public consultation
	Periodic benefit-risk evaluation	
	report (PBRER) Step 3	

Quality Working Party (QWP)

Reference number	Document	Status
EMA/CHMP/CVMP/QWP/185278/ 2012	Revised Q&A on how to demonstrate compliance with the Ph. Eur. with regard to uniformity of dosage units	adopted



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