EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Guidelines and concept papers

Adopted during the CHMP meeting 17-20 October 2011

Safety Working Party (SWP)

Reference number	Document	Status[1]
EMA/CHMP/SWP/598303/2011	Concept Paper on the development of toxicological guidance for use in risk identification in the manufacture of different medicinal products in shared facilities	**3-month public consultation**

Infectious Diseases Working Party (IDWP)

Reference number	Document	Status[1]
EMA/802793/2011	Concept paper on the update of guidance on the clinical development of medicinal products for the treatment of HIV	**3-month public consultation**

Radiopharmaceutical Drafting Group

Reference number	Document	Status[1]
EMA/CHMP/167834/2011	Guideline on core SmPC and Package Leaflet for Radiopharmaceuticals • Overview of Comments (EMA/358709/2011)	**adopted**

[1] Adopted or released for consultation documents can be found at the European Medicines Agency website (under "Document library-Public Consultations" or under "Regulatory-Human Medicines").

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ICH

Reference number	Document	Status[1]
EMA/CHMP/ICH/166783/2005	ICH guideline E2B (R3) Electronic transmission of individual case safety reports (ICSRs) - implementation guide - data elements and message specification, Step 3	**6-month public consultation**
EMA/CHMP/ICH/818331/2011	ICH guideline E2B (R3) - appendix - Electronic transmission of individual case safety reports (ICSRs) - backwards and forwards compatibility, Step 3	**6-month public consultation**