

Meeting agenda

Introductory meeting on the participation of candidate and potential candidate countries in activities of the European Medicines Agency (EMA)

1-2 February 2010 — EMA, London — Meeting room 4A

This meeting is being held as part of the Instrument for Pre-accession Assistance (IPA) programme.

Chairs: Andreas Pott / Sylvie Bénédice.

Monday, 1 February 2010		
09.00 – 09.10	Opening note	Andreas Pott
09.10 – 09.25	Welcome address	Thomas Lönngren
09.25 – 09.35	Project description	Sylvie Bénédice
09.35 – 09.55	The European Medicines Agency: Overview and structure	Martin Harvey Allchurch
09.55 – 10.35	EU authorisation procedures	Zaide Frias + Melanie Leivers
10.35 – 11.00	Role of the European Commission	Sabine Atzor, EC – DG Enterprise and Industry
11.00 – 11.30	Coffee break	
11.30 – 13.00	Candidate countries and potential candidate countries – presentations and discussions	Croatia former Yugoslav Republic of Macedonia Turkey Albania
13.00 – 14.30	Lunch in room 3B (function room)	
14.30 – 16.00	Potential candidate countries – presentations and discussions	Bosnia & Herzegovina Kosovo Montenegro Serbia
16.00 – 16.30	Coffee break	



Monday, 1 February 2010		
16.30 – 17.10	Centralised procedure – Human/veterinary	George Wade + Jill Kieffer
17.10 – 17.30	Human medicines special areas: • Paediatrics • Orphan drugs • Scientific advice • SMEs	Jordi Llinares Garcia
17.30 – 17.50	Consumer safety and establishment of maximum residue limits (MRLs)	Isaura Duarte
17.50 – 18.10	GxP inspections and related Inspectors Working Groups	Ana Rodriguez
18.10 – 18.30	Discussions – closing remarks	
19.00 – 22.00	Networking dinner at the Hotel Marriott (West India Quay)	

Tuesday, 2 February 2010		
09.00 – 09.20	Biologicals/vaccines/advanced therapies/biosimilars	Glenda Silvester
09.20 – 09.40	Pharmacovigilance	Henry Fitt
09.40 – 10.00	Authorisation of generic products in the EU	George Wade
10.00 – 10.20	Interactions with stakeholders – Communication at the Agency	Juan Garcia Burgos
10.20 – 10.40	Linguistic aspects and preparatory steps before accession to the EU	Alexios Skarlatos
10.40 – 11.00	Coffee break	
11.00 – 11.30	EU telematics implementation plan	Hans-Georg Wagner
11.30 – 11.45	IPA selected activities	Sylvie Bénédice
11.45 – 12.15	Closing remarks	Andreas Pott + Sylvie Bénédice