EU 28: science, medicines, health
A regulatory system fit for the future
6–7 May 2013, Dubrovnik, Croatia

HALMED
Agency for Medicinal Products and Medical Devices of Croatia

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

05 February 2013
EMA/74857/2013
Administration

Draft conference programme

'EU28: science, medicines, health — a regulatory system fit for the future'

6–7 May 2013, Dubrovnik, Croatia

Monday, 6 May 2013

Time	Session	Speaker (Confirmed speakers are in black)
9.00–9.30	**Welcome address**	Andreas Pott, European Medicines Agency (EMA) Viola Macolic Sarinic, HALMED Croatia
9.30–10.00	**Welcome note**	DG Sanco, EC State representation Ministry of Health Mayor of Zagreb
10.00–10.30	**HALMED achievements during IPA project period**	HALMED
10.30–11.00	Coffee break	
11.00–12.45	**Pre-accession challenges** ▪ Extension of Commission Decision for CP products in Croatia – expected challenges – EMA perspective and industry perspective ▪ API – the new approach for third countries – what are the consequences – should we expect shortage of medicinal products in the country? Perspectives from a new Member State ▪ Pre-accession challenges	**Chair: Anthony Humphreys, EMA** Anthony Humphreys, EMA / Industry EC / HALMED HALMED / Industry
12.45–14.00	Lunch	

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8501
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Time	Session	Speaker (Confirmed speakers are in black)
14.00–15.15	**Regulatory**: ***Regulatory pathways to new medicines*** ▪ Regulatory framework, including abridged and borderline applications, case studies ▪ MRP & DCP - step by step instructions how to apply and how the procedures are conducted	**Chair: Anthony Humphreys, EMA** Anthony Humphreys, EMA Peter Bachmann, BfArM
15.15–15.45	Coffee break	
15.45–18.45	**Pharmacovigilance** ▪ New PhV legislation (including a status update regarding implementation and experience to date – ex: PRAC) ▪ GVP: ➢ Module V-RMPs (Brief overview); ➢ Module VI-ADR reporting; ➢ Module VII–PSURs; ➢ Module VIII-PASS (role of small MS vs larger MS in terms of sample sizes, explaining the role and significance of the ENCePP network) ➢ Quality systems and audit + GVP Module II- PSMF ▪ Patient reporting: Current status of EU implementation + experience of patient reporting in Croatia	**Chair:** EMA Michael Foy, MHRA Thomas Goedecke, EMA Michael Foy, MHRA Michael Foy, MHRA Thomas Goedecke, EMA Fergus Sweeney, EMA Michael Foy, MHRA / Patient org.
20.30–23.30	Welcome drink and conference dinner	

Tuesday, 7 May 2013

Time	Session	Speaker
8.30–10.45	**Inspections** ▪ Supervision of manufacturers: What is expected of national competent authorities? ▪ Supervision of manufacturers: Croatia's experience so far ▪ What do manufacturers and importers have to do to prepare for EU membership?	**Chair: Fergus Sweeney, EMA** Fergus Sweeney, EMA HALMED / Ministry of Health Vesna Koblar, raPHARM, Slovenia

	▪ Practical implementation of the Falsified Medicines Directive	Belen Escribano, AEMPS, Spain
10.45–11.15	Coffee break	
11.15–12.45	**Going Digital** • From electronic submission to publication: An overview • Current initiatives • Practical aspects of working electronically in the network	**Chair: EMA** Klaus Menges, BfArM / Olivier Simoen, EMA Alison Davies, MHRA / Olivier Simoen, EMA MS
12.45–13.00	Conference closure	Sylvie Benefice, EMA Viola Macolic Sarinic, HALMED, Croatia