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Administration

Conference Schedule

'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, EMA Viola Macolić-Šarinić, HALMED
9.30-10.00	**Welcome note***	Izet Aganović, State representative Luka Vončina, Ministry of Health Andro Vlahušić, Mayor of Dubrovnik Stefano Soro, DG Sanco, EC
10.00-10.30	**HALMED achievements during IPA project period**	Viola Macolić-Šarinić, HALMED
10.30-11.00	**Coffee break**	
11.00-12.45	**Session 1: Pre-accession challenges**	**Chair: Anthony Humphreys, EMA**
	▪ Extension of Commission Decision for CP products in Croatia – expected challenges – EMA perspective and industry perspective	Anthony Humphreys, EMA / Mislav Vučić, PLIVA
	▪ API – the new approach for third countries – what are the consequences – should we expect shortage of medicinal products in the country? Perspectives from an acceding country	Stefano Soro, EC / Anita Filipović Sučić, HALMED
	▪ Pre-accession challenges	Maja Lovrek, HALMED / Vlatka Kartelo, BELUPO / Tatjana Ajhler Đuretek, BELUPO
12.45-14.00	**Lunch**	

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Time	Session	Speaker (Confirmed speakers are in black)
14.00-15.15	**Session 2: Regulatory pathways to new medicines**	**Chair: Anthony Humphreys, EMA**
	▪ Regulatory framework including abridged and borderline applications, case studies	Anthony Humphreys, EMA
	▪ MRP & DCP - step by step instructions how to apply and how the procedures are conducted	Peter Bachmann, BfArM
15.15-15.45	**Coffee break**	
15.45-18.45	**Session 3: PharmacoVigilance**	**Chair: Franck Diafouka, EMA**
	▪ Update on implementation of Pharmacovigilance legislation	Franck Diafouka, EMA
	▪ Good pharmacoVigilance Practice (GVP) modules and European Network of Centres for Pharmacoepidemiology and Pharmacovigilance:	
	➢ Overview of GVP modules I (Pharmacovigilance systems and their quality systems), II (Pharmacovigilance system master file), III (pharmacovigilance inspections) and IV (Pharmacovigilance audits);	Fergus Sweeney, EMA
	➢ Overview of GVP modules V (Risk management systems) and VIII (Post-authorisation safety studies);	Thomas Goedecke, EMA
	➢ Overview of European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)	Thomas Goedecke, EMA
	➢ Overview of GVP modules VI (Management and reporting of adverse reactions to medicinal products), VII (periodic safety update reports), IX (signal management) and X (additional monitoring)	Michael Foy, MHRA
	▪ Patient reporting: Experience of one Member State and experience in Croatia	Michael Foy, MHRA / Jurica Ester, HUPD, Croatia / Marina Dimov Di Giusti, HALMED
20.30-22.45	**Welcome Drink and Conference Dinner**	

Tuesday, 07 May 2013

Time	Session	Speaker
8.30-10.45	**Session 4: Inspections**	**Chair: Fergus Sweeney, EMA**
	▪ Supervision of manufacturers: What is expected of National Competent Authorities?	Fergus Sweeney, EMA
	▪ Cooperation between HALMED and GMP Inspectorate in supervision of manufacturers: Croatia's experience so far	Ana Boban, HALMED
	▪ What do manufacturers and importers have to do to prepare for EU membership?	Vesna Koblar, raPHARM
	▪ Practical implementation of the Falsified Medicines Directive	Belen Escribano, AEMPS
10.45-11.15	**Coffee break**	
11.15-12.45	**Session 5: Going Digital**	**Chair: Olivier Simoen, EMA**
	• From electronic submission to publication: an overview	Olivier Simoen, EMA / Klaus Menges, BfArM
	• Current initiatives	Olivier Simoen, EMA / Andrea Johnson, MHRA
	• Practical aspects of working electronically in the Network	Pieter Vankeerberghen, FAGG / Dubravka Sudić, HALMED
12.45-13.00	**Conference closure**	Sylvie Bénéfice, EMA Viola Macolić-Šarinić, HALMED