



12 June 2013
EMA/164503/2013
ENCEPP Secretariat

Draft agenda - 11th ENCePP Plenary Meeting

18 June 2013, 09.30 to 16.30, room 2A

Chairperson: Peter Arlett

Time	Item	Name
09.30	1. General Matters	
	1.1 Welcome and introductory remarks / Adoption of Agenda	Chair
09.40	2. Report from the Steering Group & Working Groups	
	2.1 Announcement of Steering Group Election 2013	Peter Arlett
	2.2 Report from the ENCePP Steering Group	Morten Andersen
	2.3 Updates from ENCePP Working/Drafting Group Chairs <ul style="list-style-type: none"> ➤ <i>Reports on activities and mandates/scopes of the more recently established groups on health technology assessment and data integration</i> 	Alejandro Arana, WG1 Laura Yates, WG2 Miriam Sturkenboom, WG3 Marlene Sinclair, WG HTA Nawab Qizilbash, DG DIG
	2.4 Q & A	ENCEPP Plenary
~ 11.00	COFFEE BREAK (30 minutes)	
	Break-out session: Special Interest Group 'Drug Safety in Pregnancy' (Room 1B)	
11.30	3. Session on Special Populations - Paediatrics	
	3.1 European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA) ¹ <ul style="list-style-type: none"> ➤ <i>Exploring commonalities between the networks</i> 	Irmgard Eichler
	3.2 Global Research in Paediatrics (GRiP) ² <ul style="list-style-type: none"> ➤ <i>Including call for participation in the network of excellence</i> 	Miriam Sturkenboom & Jan Bonhoeffer
	3.3 PHARMacovigilance for Adverse effects in Childhood arthritis focussing on Immune modulatory Drugs (PHARMACHILD) ³ <ul style="list-style-type: none"> ➤ <i>Another example of collaborative paediatric research</i> 	Nicola Ruperto
	3.4 Discussion <ul style="list-style-type: none"> ➤ <i>Including consideration of an ENCePP paediatric SIG (Special Interest Group)</i> 	ENCEPP Plenary

¹ http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000303.jsp&mid=WCOB01ac05801df74a

² <http://www.grip-network.org/index.php/cms/en/home>

³ http://www.printo.it/project_ongoing_detail.asp?ProjectID=15



Time	Item	Name
~12.30	LUNCH (60 minutes)	
13.30	4. Session on Methodology	
	4.1 Case-population strategy in pharmacovigilance <ul style="list-style-type: none"> ➤ <i>Description of an approach aimed at providing early estimates of the magnitude of the risk of rare ADRs</i> 	Joan-Ramon Laporte
	4.2 Discussion <ul style="list-style-type: none"> ➤ <i>Putting the case-population approach and use of sales data into context</i> 	Susana Perez-Gutthann & ENCePP Plenary
14.00	5. ENCePP Best Evidence	
	5.1 Experience so far <ul style="list-style-type: none"> ➤ <i>Examples how ENCePP has helped with data and expertise in supporting regulatory decision making</i> 	Kevin Blake
	5.2 Discussion <ul style="list-style-type: none"> ➤ <i>How ENCePP can continue to help</i> 	ENCEPP Plenary
~14.30	COFFEE BREAK (20 minutes)	
14.50	6. Interface ENCePP and industry	
	6.1 Results of ENCePP survey of industry <ul style="list-style-type: none"> ➤ <i>Key findings from survey conducted April 2013</i> 	Kevin Blake
	6.2 Report from ENCePP meeting with industry associations <ul style="list-style-type: none"> ➤ <i>Key messages from meeting held 22 May 2013</i> 	Morten Andersen
	6.3 Discussion <ul style="list-style-type: none"> ➤ <i>Optimising ENCePP collaboration with pharmaceutical industry and the use of ENCePP outputs to benefit public health including the Code of Conduct and Study Seal</i> 	ENCEPP Plenary
16.00	Summary of discussions & next steps	Chair
16.15	A.O.B	Chair
16.30	Close of meeting	