26 February 2014
EMA/796225/2013
Stakeholders and Communication Division

Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting
Workshop on regulatory and methodological standards to improve benefit/risk evaluation of medicines

26 February 2014, 09:00hrs to 16:45hrs – meeting room: 4A

European Medicines Agency - 7 Westferry Circus, Canary Wharf, London E14 4HB

Chairs: Isabelle Moulon (EMA), David Haerry (PCWP) and Gonzalo Calvo (HCPWP)

Background:

The continuous need for enhancing transparency and strengthening trust in the regulatory decision-making process associated with the evaluation of medicines have been stimulating the debate on how to further develop methodological standards to support a more structured benefit-risk decision making framework and facilitate benefit-risk communication to the general public.

Results from research in regulatory science and other academic fields in recent years are starting to show some convergence within the global regulatory landscape. The EMA is no stranger to this process, currently playing an active role in specific initiatives and projects, including the generation of data that can also be used by health-technology-assessment (HTA) bodies to determine a medicine's benefit-risk balance and value.

Objectives

1. Provide an overview to PCWP and HCWP members of:
    - Current international benefit-risk initiatives
    - Outcomes of recent EMA/CHMP benefit-risk projects
    - On-going initiatives to capture patient values and preferences in benefit-risk
    - On-going initiatives to translate benefit-risk regulatory decisions into product information
2. Discuss how benefit-risk models in general could support healthcare professionals and patients in the therapeutic decision-making process

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7129
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

26 February 2014			
08:30	Registration and reimbursement arrangements		
09:00	Welcome Health and safety information Interests disclosure		I. Moulon (EMA)
09:05	Introduction and objectives		I. Moulon (EMA) D. Haerry (PCWP) G. Calvo (HCPWP)
1. Where are we today in the benefit-risk debate: from models to real implementation? Chair: David Haerry (PCWP)			
09:25	1.1	How are benefit-risk decisions made in the EU? Where are the challenges today?	H. Enzmann (CHMP)
09:50	1.2	Emerging methodological standards: overview of current international benefit-risk initiatives	H. Hillege (CHMP)
10:15	*Coffee*		
10:30	1.3	How to capture patients values and preferences	A. Beyer (University of Groningen)
11:00		General discussion	
2. Can benefit-risk models support the therapeutic process? Chair: Isabelle Moulon (EMA)			
11:45	2.1	Introduction to breakout sessions Practical examples will be used to aid in understanding how preferences for treatment outcomes can be elicited. The captured preferences will be used to construct value scores and weights which will be subsequently used in a decision model. The differences and/or similarities between preferences of patients and healthcare professionals will be discussed.	A. Beyer (University of Groningen)/ F. Pignatti (EMA)
12:00	*Lunch*		
13:00	2.1.1	Breakout session with patients and consumers (room 4A)	F. Pignatti (EMA)
	2.1.2	Breakout session with healthcare professionals (room 2G)	A. Beyer (University of Groningen)
14:30	*Coffee*		
14:45	2.2	Feedback from breakout sessions and discussion	
	2.3	Address by the EMA Executive Director	G. Rasi (EMA)

26 February 2014		
3. How to explain benefit-risk decisions to stakeholders? Chair: Gonzalo Calvo (HCPWP)		
15:30	3.1 Translating benefit-risk information into product information	L. Brassart (EMA)
15:50	3.2 Outcomes of recent EMA/CHMP benefit-risk project (EPAR)	F. Pignatti (EMA)
16:10	3.3 Benefit-risk assessment throughout the lifecycle of the medicine: what are the future challenges?	H.G. Eichler (EMA)
16:30	Final remarks and conclusions	I. Moulon (EMA) D. Haerry (PCWP) G. Calvo (HCPWP)
16:45	*End of meeting*	