EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2014
EMA/576846/2014
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 benefit-risk communication

17 September 2014, 09:00hrs to 16:45hrs – meeting room: CP-02-A
European Medicines Agency – 30 Churchill Place, Canary Wharf, London E14 5EU

Background

In a rapidly changing environment where transparency and global mediatisation have become dominant keys, regulators are challenged by the need to avoid unnecessary alarm whilst ensuring users of medicines maintain trust and public confidence in the regulatory system.

As more research in the domain of risk communication continues to emerge, regulators need to consider how to best communicate information on the risks of a medicine (including what is known and not known about it) both at the time of its approval and as its use is extended to real-life conditions, but also, and as importantly, to do so in the context of the benefits of that medicine.

The ultimate goal is to promote the rational, safe and effective use of medicines, by supporting healthcare professionals and patients with balanced information that can facilitate choice of treatment, optimise treatment outcomes and prevent harm from adverse reactions.

Objectives

1. Provide an overview to PCWP and HCWP members of:
    - Current EMA practice regarding benefit-risk communication;
    - On-going initiatives to collect and integrate lessons learnt and research findings into regulatory procedures and communication strategies;
2. Discuss the role of communication in achieving effectiveness of risk minimisation measures;
3. Explore how such communication can support healthcare professionals and patients on their treatment decisions.

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08:30	Registration and reimbursement arrangements		
09:00	Welcome Health and safety information Interests disclosure		I. Moulon (EMA)
	Address by the Executive Director		G. Rasi (EMA)
09:20	Introduction and objectives		I. Moulon (EMA)
1. Communicating risk – myths and reality			
09:30	1.1	Helping doctors and patients make sense of health statistics	W. Gaissmaier (University of Konstanz)
10:15	*Coffee*		
2. How do we communicate today? Chair: I. Moulon (EMA)			
10:30	2.1	Communicating benefits and risks of medicines within the EU regulatory network	J. Garcia Burgos (EMA)
10:50	2.2	Managing media channels	M. Benstetter (EMA)
3. What can we learn from medicines users? Co-Chairs: G. Calvo (HCPWP)/ D. Haerry (PCWP)			
11:10	3.1	Public impact of communication – the example of NSAIDs	F. Bouder (Maastricht University)
11:30	3.1.1	Practical exercise	J. Ahlqvist-Rastad (PRAC)
12:15	*Lunch*		
13:15	3.2	Feedback from practical exercise and discussion	
4. How is research in the field of risk communication supporting regulators? Chair: A. Spooner (PRAC)			
14:00	4.1	Vaccine acceptance or refusal?: Individual choice vs societal needs	H. Larson (London School of Hygiene and Tropical Medicine)
14:20	4.2	Evidence-based guidance for risk communication planning	P. Bahri (EMA)
14:40	4.3	Discussion	

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15:00	*Coffee*		
5. How are regulators responding to the challenges? Co-Chairs: T. Salmonson (CHMP)/ J. Raine (PRAC)			
15:10	5.1	Perspectives from CHMP/PRAC	T. Salmonson (CHMP)/ J. Raine (PRAC)
15:30	5.2	Effectiveness of B/R communication and building capacity between the national agencies: the SCOPE project	D. Montero Corominas (AEMPS/PRAC)
15:50	5.3	Looking forward: building better communications into the optimisation of safe and effective healthcare	J. Garcia Burgos/ M. Benstetter (EMA)
16:10	Final remarks		T. Salmonson (CHMP)/ J. Raine (PRAC)
16:30	Conclusions		I. Moulon (EMA)
16:45	*End of meeting*		