8 March 2016
EMA/856049/2015
Stakeholders and Communication Division

Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting
Session on communication and information on medicines

08 March 2016, 09:00hrs to 16:45hrs – meeting room: 3E

Chair: I. Moulon (EMA)

Background

The European Medicines Agency has over the past 20 years produced a wealth of information on medicines. A number of tools have been developed and adapted in order to best respond to patients and healthcare professionals' information needs albeit within the remit of the Agency's responsibilities and in the context of current legislation.

Throughout this time frame several aspects related with how information is produced and how it is used by different stakeholders have emerged; both at organisation and individual levels. The PCWP and HCPWP have engaged in numerous discussions, which have paved the way to better understand the needs and expectations of patients, consumers and healthcare professionals as well as regulators. Patients, consumers and healthcare professionals are systematically involved in the review of information produced by EMA. In addition, their European representative organisations are heavily engaged in serving as multipliers of that information.

As discussions matured over the years, it became apparent that there is a need for flexibility to adapt to a changing environment. Whilst the continuous interaction between regulators and interested parties allows for the identification of areas where adjustments may be recommended, this will need to be supported by specific research and evidence-based practice. Therefore, the PCWP and HCPWP would like to promote an open discussion that can provide indicative lines of research to experts in the field of communication and information on medicines that could support future advancements.

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Objectives

1. Discuss findings emerging from recent information-related surveys;
2. Recognise the challenges and opportunities that can shape the production and use of medicines information and assess the role of different actors;
3. Identify potential areas that would benefit from further research.

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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)
09:15	Opening remarks	D. Haerry (PCWP) G. Calvo Rojas (HCPWP)
1. Information and communication: where are we today?		
09:30	1.1 EMA's perception survey	J. Garcia Burgos (EMA)
	1.2 Drug information by public health institutions: Results of an 8-country survey in Europe	G. Formoso (ISDB)
	1.3 Findings from the HCPWP topic group on information on medicines survey	J. Peppard (EAHP) / L. Brassart (EMA)
	1.4 Update on SCOPE activity on risk communication	D. Montero Corominas (AEMPS)
	1.5 Findings from a patient/ doctor survey on pharmaceutical transparency in Europe	D. Way (King's College London) / F. Bouder (Maastricht University)
	1.6 Assessment of current shortcomings in the summary of product characteristics and the package leaflet	M. Dorazil (EC)
11:15	*Coffee*	

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2. Issues around 'Producing', 'Disseminating' and 'Using information' This session will be organised as a breakout session where participants will be distributed in smaller groups and asked to discuss the three questions bellow. During the discussion participants will be asked to consider the questions through the lens of 'as is today' and 'as needs to be in the next decade', bearing in mind the communication avenues between regulators and healthcare professionals/ patients, other sources of information to patients/healthcare professionals and the patient/healthcare professional communication. The reflection should also cover whether there is existing evidence confirming a need to change/improve and/or point out to what specifically needs to be supported by evidence.		
11:30	Introduction to the breakout sessions	I. Silva (EMA)
11:45	2.1 Issues around 'Producing information': as a producer of authoritative medicines information, what are the challenges and opportunities EMA should be looking at? 2.2 Issues around 'Disseminating information': bearing in mind how information is channelled from EMA to patients and healthcare professionals, are we reaching our target groups? What's the role of the different actors in channelling information? 2.3 Issues around 'Using information': what are the key issues that still remain as obstacles to using information on medicines to support communication at the point of care?	
13:15	*Lunch*	
14:15	Feedback from the breakout sessions	
3. Where would we benefit from further research?		
14:45	3.1 Do information tools need adapting for an effective communication in healthcare?	S. Rubinelli (EACH)
15:30	3.2 Open discussion to identify areas that would benefit from future research, focussing on: • What needs to be researched? The 'knowns' and 'unknowns' about medicines information and benefit/risk communication. • Emerging trends: how is medicines information incorporating advances in science (e.g. genomics) and clinical care (e.g. patient reported outcomes); how to make the best use of digital tools, including internet and social media? • Who needs to be involved?	EMA moderators: I. Moulon/ M.A. Heine
16:30	Take home messages	I. Moulon (EMA)
16:45	*End of meeting*	