17 September 2015
EMA/292901/2015
Stakeholders and Communication Division

Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting
Workshop on risk minimisation measures

16 Sep 2015, 09:00hrs to 16:45hrs – meeting room: 3E

Chairs: I. Moulon (EMA), T. Salmonson (CHMP), J. Raine (PRAC) and M. Berntgen (EMA)

Background

Planning and implementing risk minimisation measures and assessing their effectiveness are key elements of risk management. A variety of tools, including those specifically targeting communication with healthcare professionals, patients and/or carers, are currently available for additional risk minimisation. This field is continuously developing, with new tools likely to be developed in the future building upon technology advances. In addition, the evaluation of effectiveness of risk minimisation measures is an evolving area of medical sciences with a need for universally agreed standards and approaches.

Whilst taking advantage of relevant elements of methodology from pharmacoepidemiology and other disciplines, such as social/behavioural sciences and qualitative research methods, it is important to bring on board healthcare professionals (HCPs) and patients in the shaping of adequate and proportional risk minimisation measures, which are balanced with the benefit for patients and produce the desired public health outcome in the context of the healthcare delivery system.

Objectives

1. Provide an overview to PCWP and HCPWP members of the regulatory environment supporting the development of risk minimisation measures;
2. Share current practices, experience and lessons learnt in the implementation and evaluation of the effectiveness of additional risk minimisation measures, using concrete examples;
3. Gain a better understanding of the challenges and opportunities posed by the implementation and evaluation of risk minimisation measures in real life clinical practice;
4. Reflect on best practices and key principles that can lead the way forward.

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16 September 2015			
08:30	Registration and reimbursement arrangements		
09:00	Welcome Health and safety information Interests disclosure		I. Moulon (EMA)
09:05	Introduction and objectives		G. Rasi (EMA)
09:15	Opening remarks		D. Haerry (PCWP)/ G. Calvo (HCPWP)
1. Development of risk minimisation measures Session chair: Tomas Salmonson, Chair of CHMP			
09:30	1.1	What are risk minimisation measures and why are they imposed?	S. Straus (CBG-MEB/ PRAC)
	1.2	Practical experience on risk minimisation: Patients' and Healthcare professionals' views	M. Greco (EPF) / C. Kirke (HSE)
	1.3	How does the Regulatory network communicate about risk minimisation?	J. Garcia Burgos (EMA)/ V. Macolić Šarinić (HALMED/PRAC)
11:15	*Coffee*		
2. Implementation and evaluation of risk minimisations measures Session chair: Michael Berntgen, EMA			
11:30	2.1	Overview of methodologies and studies evaluating risk minimisation measures	G. Mazzaglia (EMA)
	2.2	Feasibility and effectiveness of interventions: the valproate case study – a clinician's viewpoint	M. de Visser (EAN)
	2.3	Patient perspectives on monitoring effectiveness of risk minimisation measures in the field of multiple sclerosis	C. Thalheim (EMSP)
	2.4	Case studies looking at regulatory action and/or communication – a national experience	R. Suvarna (MHRA/PRAC)
13:15	*Lunch*		

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3. Challenges and opportunities Session chair: June Raine, Chair of PRAC		
14:15	3.1 When science and regulatory action meet reality: barriers and critical success factors to managing risk 3.2 Strengthening the planning and implementation of risk minimisation	P. Brown (University of Amsterdam) P. Arlett (EMA)
15:00	Panel invited to comment on the role and responsibilities of the different actors in risk minimisations, focussing on: • How to promote feasibility • How to promote effectiveness • How to engage better Followed by an open discussion	D. Singer (EACPT)/ P. Mol (University of Groningen)/ M. Greco (EFCCA/PRAC)
16:30	Take home messages by J. Raine, Chair of PRAC	
16:45	*End of meeting*	