

19 April 2016
EMA/40570/2016
Stakeholders and Communication Division

Agenda - EMA Workshop on the collaboration with General Practitioners/Family Physicians

19 April 2016, 09:00hrs to 16:45hrs – meeting room: 2D

Chair: I. Moulon (EMA)

Background

At the moment, the feedback EMA gets from primary care is very limited despite the wealth of knowledge and data available in this environment. Recognising the importance of further improving the state of play, the EMA would like to facilitate, in collaboration with the key representative organisations, an open discussion with GPs, which could point towards more concrete areas of engagement.

The aim is to open up bi-directional avenues that can:

- on one hand, help EMA to gain a better understanding of how medicines are being used in real clinical practice and the potential impact of specific regulatory actions on patient care
- on the other hand, support the creation of more awareness amongst GPs on how they can better inform regulatory discussions on benefit-risk evaluation of medicines and promote the alignment of regulatory decisions with the reality of clinical practice.

Objectives

1. Discuss, on the basis of examples covering input into safety reviews, involvement in the review of product information and additional risk minimisation measures, how general practice has or could be impacted by regulatory actions
2. Identify what type of input collected at primary care level, would add value into the benefit-risk assessment once a medicinal product is introduced in the market and how this could be included into the regulatory decision-making process
3. Identify areas where collaboration would mutually benefit GPs and EMA
4. Investigate if a specific area and format of collaboration could be piloted with a group of GPs and how such group could be established as a pool of EMA experts

19 April 2016			
08:30	Registration and reimbursement arrangements		
09:00	Welcome	I. Moulon (EMA)	
	Health and safety information		
	Interests disclosure		
09:05	Introduction and objectives	I. Moulon (EMA)	
09:15	Opening remarks	G. Rasi (EMA)	
1. Involvement of GPs in EMA activities			
09:30	1.1	What is already in place: examples covering input into safety reviews, involvement in the review of product information and additional risk minimisation measures	I. Silva (EMA)
	1.2	What would be the impact in general practice?	W. Marrocco (EFPC)
	1.3	What would be the impact in the regulatory decision-making process?	H. Janssen / G. Genov (EMA)
10:45	Coffee		
2. Areas of collaboration			
11:00	2.1	Where are the gaps/ opportunities? Discussion on potential areas of collaboration that would be mutually beneficial for GPs and EMA: reflection and remarks by UEMO, WONCA and EFPC	T. Christiaens (EFPC)
12:30	Lunch		
3. Way forward			
13:30	Introduction to breakout session		I. Silva (EMA)
13:45	Participants will be asked to reflect on the following points: <ul style="list-style-type: none">Priorities and format of collaboration that could be pilotedHow can we establish a pool of GPs to act as EMA experts?		Facilitators: A. Stavdal (WONCA)/ I. Moulon (EMA) N. Kopcavar Gucek (UEMO) / I. Silva (EMA)
14:45	Coffee		
15:00	Feedback from breakout session		
15:45	Next steps		I. Moulon (EMA)
16:00	Take home messages from WONCA, UEMO and EFPC		
16:30	Conclusions		G. Rasi (EMA)
16:45	End of meeting		