



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 April 2017
EMA/762357/2016
Stakeholders and Communication Division

Agenda – Workshop on personalised medicines: role of patients, consumers and healthcare professionals

EMA Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting

14 March 2017, 08:30hrs to 17:15hrs – meeting room: 3E

Chair: I. Moulon (EMA)

Background

Rapid advances in science are leading to medicines that are developed, manufactured, assessed and used in completely new ways. This reflects and springs from our evolving understanding of the scientific basis of disease, and the determiners of individual response to medicines. The EU Medicines Agencies Network Strategy to 2020, published in December 2015, recognises the potential impact of these changes in a healthcare environment that must cope with trends such as an aging population, population migration, and the burdens of polypharmacy and chronic diseases.

Medicines targeted at the individual patient will represent an increasing part of the armamentarium. As new technologies emerge we are seeing new advanced therapies and more combination and borderline products. The regulatory network is working hard to ensure it has the capability to regulate the novel products of the future. This means strengthening its capability to adequately assess and monitor these new medicines, so that we can make them promptly available to relevant patients and assure their safety, efficacy and quality throughout the product lifespan.

Patients and their healthcare professionals are at the very heart of personalised medicine. It is therefore crucial that their needs and expectations are clearly defined, understood and responded to in the best possible way. The PCWP and HCPWP would like to provide an opportunity to create awareness amongst their members of how the work of EMA relates to personalised medicine. The working parties would also like to reflect on priority areas that may support future contributions in wider multi-stakeholder discussions.



Objectives

1. Understand how the European and global landscapes are shaping policy developments;
2. Illustrate how the activities of the European Regulatory Medicines Network contribute to personalised medicine, within the existing legislation and regulatory tools;
3. Discuss how clinical practice and public participation can support personalised medicine in the context of EU regulatory activities;
4. Identify areas requiring attention from EU regulators, patients, healthcare professionals and civil society at large.

The morning sessions will be broadcast live on EMA's website, from 8:50 to 13:15.

You can follow the broadcast by clicking on the 'multimedia' tab on the [event page](#) on the day of the event.

14 March 2017		
08:30	Registration and reimbursement arrangements	
08:50	Welcome Health and safety information Interests disclosure	Isabelle Moulon (EMA)
09:00	Introduction and objectives	Guido Rasi (EMA)
09:10	Opening remarks	Kaisa Immonen (PCWP) Gonzalo Calvo (HCPWP)
Session 1: Setting the scene: the rise of personalised medicine		
Chairs: Marisa Papaluca (EMA) and Gonzalo Calvo (HCPWP)		
09:20	<ul style="list-style-type: none"> European Commission's policy development in the field of personalised medicine 	Irene Norstedt (EC)
09:35	<ul style="list-style-type: none"> US' precision medicine initiative 	Sandra Kweder (US FDA)
09:50	<ul style="list-style-type: none"> International Consortium for Personalised Medicine (IC PerMed) 	Mária Judit Molnár (IC PerMed)
10:05	<ul style="list-style-type: none"> Societal implications of personalised medicine 	Luca Pani (CHMP/SAWP)
10:20	<ul style="list-style-type: none"> Open discussion Key take-home messages from the session 	
10:45	<i>Coffee</i>	
Session 2: Regulatory challenges and opportunities		
Chairs: Tomas Salmonson (CHMP) and Kaisa Immonen (PCWP)		
11:00	<ul style="list-style-type: none"> Personalised, precision, targeted, stratified: what does experience with medicines' evaluation tell us so far? 	Robert Hemmings (CHMP/SAWP)

11:30	<ul style="list-style-type: none"> Perspectives from EMA Scientific Committees 	Bruno Sepodes (COMP) Margarida Menezes Ferreira (CAT) Dirk Mentzer (PDCO) June Raine (PRAC)
12:10	<ul style="list-style-type: none"> Challenges experienced or anticipated by other regulators and payers 	Anna Bucsecs (MoCA)
12:25	<ul style="list-style-type: none"> Opportunities for clinical research transformation: EORTC's lessons learned for precision medicine in Europe 	Denis Lacombe (EORTC)
12:40	<ul style="list-style-type: none"> Open discussion Key take-home messages from the session 	
13:15	<i>Lunch</i>	
Session 3: What are the priorities for patients and healthcare professionals?		
Chairs: Isabelle Moulon (EMA) and June Raine (PRAC)		
14:15	<ul style="list-style-type: none"> What does 'personalised' mean to patients and healthcare professionals 	Julian Isla (DFS) Ulrich Jäger (EHA)
14:45	<ul style="list-style-type: none"> Capturing input and adopting innovation in practice <p>Discussion on existing tools and challenges to capture the input of patients and healthcare professionals to inform benefit-risk assessment, clinical trial design, patient registries and new data sources</p> <p>Discussion on whether novel technologies or methods provide 'actionable' data to face real-life issues in clinical practice; how they can be best reflected in scientific opinions and product information</p>	Kaisa Immonen (PCWP) Gonzalo Calvo (HCPWP) All (facilitated discussion)
15:30	<i>Coffee</i>	
15:45	<ul style="list-style-type: none"> Developing Awareness and Empowerment <p>Discussion around areas for which training and communication are needed to promote awareness and understanding around novel approaches in medicines development, evaluation and monitoring and how they are being used by EMA scientific committees</p>	Kaisa Immonen (PCWP) Gonzalo Calvo (HCPWP) All (facilitated discussion)
16:30	<ul style="list-style-type: none"> Discussion on priorities and objectives for follow-up 	
17:00	Final remarks	
17:15	<i>End of meeting</i>	