5 March 2015
EMA/59760/2015
Stakeholders and Communication Division

Agenda - EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting
Information session on Biosimilars

5 March 2015, 09:00hrs to 16:30hrs – meeting room: 3E

Chair: I. Moulon (EMA)

Background

The European Commission's consensus information paper 2013 on 'What you need to know about biosimilar medicinal products'[1] identifies the need for healthcare professionals and patients to share a thorough understanding of biological medicines, including biosimilar medicines as a means to build confidence in using either type of therapy.

This information session is EMA's contribution to promote PCWP and HCPWP further understanding of biosimilar medicines in the context of the EU regulatory system. The intention is to raise awareness about how they are evaluated as well as on the current and foreseen challenges and opportunities brought forward by this type of medicines. The global and national contexts of approval and use of biosimilars may be touched upon in some of the presentations in order to illustrate a specific point however the focus will remain on the European dimension.

Presentations will be made publicly available after the meeting.

Objectives

1. Provide an overview to PCWP and HCPWP members of the science behind biosimilars and how they are evaluated by regulators;
2. Explore how to bridge the scientific evaluation with clinical reality and public acceptability of biosimilars;
3. Discuss the role of communication in promoting better understanding of biosimilars.

[1] http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/biosimilars_report_en.pdf

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

5 March 2015		
08:30	Registration and reimbursement arrangements	
09:00	Welcome Health and safety information Interests disclosure Introduction and objectives	I. Moulon
09:15	Address by Sir Kent Woods, Chair of EMA Management Board	
1. What do we know about biosimilars?		
09:30	1.1 What are the particular concerns? Perspectives from: • Healthcare professionals • Patients	 M. Delvaux D. Haerry
10:00	1.2 What is a biosimilar?	P. Kurki
10:40	*Coffee*	
11:00	1.3 Key scientific and regulatory concepts • Assessing comparability • Extrapolation • Immunogenicity • Interchangeability • Post-authorisation activities	 C. Schneider M. Weise R. Thorpe P. Kurki T. Giezen
12:30	Q&As	
13:15	*Lunch*	
2. What is needed to better understand biosimilars?		
14:15	2.1 How to address challenges?	G. Calvo
14:35	2.2 How can communication help?	A. Lightbourne C. Jacklin
15:15	2.3 The consensus information paper on biosimilars and its follow up at European level	H. Juhász
15:45	Q&As	
16:15	Conclusions	I. Moulon
16:30	*End of meeting*	