21 April 2015
EMA/207894/2015

Agenda – Industry stakeholder platform - Operation of the centralised procedure

24 April 2015, 09:30-13:30, Meeting room 03-F

Co-Chairs: Evdokia Korakianiti and Michael Berntgen

Item	Agenda	Time
1.	Welcome / Introductions Objective of the platform meetings *Anthony Humphreys, EMA*	10 minutes
2.	**Status update of changes to the operations in the centralised procedure** • Background of the operational changes • Progress with the implementation programme and upcoming changes *Evdokia Korakianiti, EMA* Discussion	 15 minutes 10 minutes
3.	**EMA product team and applicant/MAH interaction** • Industry's perspective: Expectations for support from the EMA product team and first experiences *Clare Lavery, EFPIA* • Composition and roles within the EMA product team • Practical aspects of applicant contacts with the product team *Michael Berntgen, EMA* • Experience from the perspective of EPLs and PMs *Pavel Balabanov, Leonor Enes and Viktor Vlcek, EMA* Plenary discussion *Speakers joined by Enrica Alteri, Anthony Humphreys and Jose Ramon Cozar*	 15 minutes 15 minutes 15 minutes 30 minutes

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	Coffee Break	
4.	**Variations process management from validation to EC decision, including classification / validation** • Industry's experience and expectations *Craig Johnson, EFPIA; Beata Stepniewska, EGA* • Planning and interactions before variation submission • Procedural management of Type IB and Type II variations • Specific aspects about the classification *Alberto Ganan and Iordanis Gravanis, EMA* Plenary discussion *Speakers joined by Enrica Alteri, Anthony Humphreys, Thomas Castelnovo, Sonia Ribeiro and Jose Ramon Cozar*	20 minutes 25 minutes 30 minutes
5.	**New practice for the management of clarification meetings** • Introduction of the new guidance for applicants • Expectations and practical experience so far *Pavel Balabanov, EMA* Discussion	15 minutes 5 minutes
6.	**EMA survey on experience with post-authorisation procedures** • Outline of the survey objective and its structure • Information about the expected timeframe and reporting *Marie-Helene Pinheiro, EMA*	10 minutes
7.	Summary of follow-up items Close of meeting *Enrica Alteri and Michael Berntgen, EMA*	10 minutes

Participants' list

European Medicines Agency

Name
Enrica Alteri, Head of Human Medicines Evaluation Division
Pavel Balabanov, Scientific & Regulatory Management Department
Michael Berntgen, Head of Scientific & Regulatory Management Department
Melanie Carr, Head of Corporate Stakeholders Department
Thomas Castelnovo, Head of Evaluation Procedures A (Initial MAA, Extension application, PAM), Procedure Management Department
Jose Ramon Cozar, Quality of Medicines office
Leonor Enes, Procedure Management Department
Ana Hidalgo-Simon, Head of Specialised Scientific Disciplines Department
Alberto Ganan Jimenez, Head of Evaluation Procedures D (Type IB Variations), Procedure Management Department
Iordanis Gravanis, Head of Evaluation Procedures C (Type II Variations), Procedure Management Department
Anthony Humphreys, Head of Procedure Management and Committees Support Division
Evdokia Korakianiti, Head of Procedure Management Department
Marie-Helene Pinheiro, Industry Stakeholder Liaison
Sonia Ribeiro, Head of Regulatory Affairs Office
Viktor Vlcek, Procedure Management Department

Industry associations

Association	Representative
AESGP	Anne-Laure Astecker, HRA Pharma
	Mark Griffiths, Pfizer Consumer Healthcare
	Miranda Moussa, AESGP
EBE	Piers Allin, EBE
	Albane de Sanit-Denis, Sanofi-Aventis
	Mark Rutter, Abbvie
	Chris Walker, Amgen

EFPIA	Isabelle Clamou, Amgen
	Anne De Bock, AstraZeneca
	David Jefferys, Eisai
	Craig Johnson, GSK
	Clare Lavery, Janssen
	Pär Tellner, EFPIA
EGA	Dora Halmai, Mylan
	Katariina Gran, Teva
	Paul Harwood, Hospira
	Tomaz Kralj, Krka
	Vesna Schauer-Vukasinovicm, Sandoz
	Beata Stepniewska, EGA
EUCOPE	Susan Cameron-Laxton, Vertex Pharmaceuticals
	Nadège Le Roux, Celgene International Sarl
	Frederic Pailloux, Voisin Consulting Life Sciences
	Maren von Fritschen, EUCOPE
	Daniel Warren, Norgine
EuropaBio	Geneviève Le Visage, Novartis
	Christine Mayer-Nicolai, Merck Serono
	Riccardo Mezzasalma, EuropaBio
	Fiona Reekie, Biogen
	Aimad Torqui, MSD
	Martine Zimmermann, Alexion
Vaccines Europe	Mary Allin, Pfizer
	Carole Ifi, GSK
	Aleksandra Opalska, Vaccines Europe
	Emmanuelle Pirat, SP