



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 April 2016
EMA/186832/2016

Agenda – 3rd Industry stakeholder platform - Operation of the centralised procedure for human medicinal products

21 April 2016, 13:00 – 17.00, Meeting room 03-F

Co-Chairs: Michael Berntgen and Evdokia Korakianiti

Item	Agenda	Time
1.	Welcome / Introductions Overview of the agenda <i>Anthony Humphreys, EMA</i>	10 minutes
2.	MAA evaluation under accelerated assessment Preparing for accelerated assessment: <ul style="list-style-type: none">Better processes to facilitate earlier authorisation <i>Victoria Palmi Reig, EMA</i>Specific aspects concerning GxP inspection <i>Andrei Catalin Spinei / Sophia Mylona, EMA</i> Industry experience with the preparation for an accelerated assessment – good practices to share <i>Anne de Bock, EFPIA</i> Plenary discussion	15 minutes 15 minutes 20 minutes 20 minutes
3.	Initial practical experience with PRIME eligibility requests Hands-on feedback from preparing request packages <i>Fiona Reekie, EFPIA</i> Observations post-launch <i>Jordi Llinares/Zahra Hanaizi, EMA</i> Plenary discussion	10 minutes 10 minutes 10 minutes
Coffee Break		



4.	Pre-submission interactions for MAA submission	
	Review of recent pre-submission interactions in the centralised procedure and best practices <i>Michael Berntgen / Hector Boix Perales, EMA</i>	15 minutes
	Learnings from applicant's perspectives and potential opportunities for improvement <i>Nadege LeRoux, EFPIA</i>	15 minutes
	Plenary discussion	15 minutes
5.	Updates on operations in the centralised procedure	
	Update on patient involvement in evaluation activities <i>Isabelle Moulon, EMA</i>	10 minutes
	Progress update on improvement actions following the survey on post authorisation procedures <ul style="list-style-type: none"> • Variation management • PSUR process / post-authorisation guidance • Procedural support in the post authorisation phase <i>Evdokia Korakianiti / Alberto Ganan / Ana Zanoletty, EMA</i>	30 minutes
	Plenary discussion	
6.	Introduction to the upcoming survey on initial Marketing Authorisation procedures <i>Marie-Helene Pinheiro, EMA</i>	10 minutes
7.	Summary of follow-up items	5 minutes
	Close of meeting <i>Enrica Alteri, EMA</i>	

Participants List

EMA

Enrica Alteri, Head of Human Medicines Evaluation Division

Michael Berntgen, Head of Scientific & Regulatory Management Department

Hector Boix Perales, Scientific Officer (Procedure Manager)

Melanie Carr, Head of Stakeholders and Communication Division

Thomas Castelnovo, Head of Evaluation Procedures A (Initial MAA, Extension application, PAM)

Andrei Catalin Spinei, Scientific Administrator (Manufacturing and Quality Compliance)

Zahra Hanaizi, Scientific Officer, Product Development Scientific Support Department

Anthony Humphreys, Head of Procedure Management and Committees Support Division

Alberto Ganan Jimenez, Head of Service for Evaluation Procedures D (type IB variations)

Evdokia Korakianiti, Head of Procedure Management Department

Jordi Llinares, Head of Product Development Scientific Support

Isabelle Moulon, Head of Patients and Healthcare Professionals' Department

Sophia Mylona, Scientific Administrator (Clinical and Non Clinical Compliance)

Victoria Palmi Reig, Scientific Officer (Procedure Manager)

Marie-Helene Pinheiro, Industry Stakeholder Liaison

Agnieszka Szmigiel, Scientific Administrator (Signal Management, Pharmacovigilance Department)

Ana Zanoletty, Scientific Officer (Procedure Manager)

CHMP

Robert Hemmings

European Commission

Dagmar Stara

Industry Stakeholder Organisations

AESGP

Christelle Anquez-Traxler

Mark Griffiths

EBE

Christine Mayer-Nicolai

Chris Walker

EFPIA

Anne de Bock

Nadège Le Roux

Marcello Milano

Eamon O'Loinsigh

Fiona Reekie

Pär Tellner

EUCOPE

Annelise Brossel

Tara Hutton

EuropaBio

Christiane Abouzeid

Emma Du Four

Lise Camilla Hoffmann

Riccardo Mezzasalma

Mireille Muller

Aimad Torqui

Medicines for Europe

Johannes Braun

Tomaž Kralj

Eva Pantau

Beata Stepniewska

Hedley Young

Vaccines Europe

Anna Czwarno

Susanne Heiland-Kunath