9 November 2015
EMA/633298/2015

Agenda – 2nd Industry stakeholder platform - Operation of the centralised procedure for human medicinal products

9 November 2015, 13:00 – 17.00, Meeting room 03-E

Co-Chairs: Michael Berntgen and Evdokia Korakianiti

Item	Agenda	Time
1.	Welcome / Introductions Overview of the agenda *Enrica Alteri, EMA*	10 minutes
2.	**Overview of recent changes in the centralised procedure** • High-level review of key developments since the last platform meeting *Michael Berntgen, EMA* Discussion	20 minutes 10 minutes
3.	**Report on the outcome of the survey on post-authorisation procedures** • Introduction to the survey *Marie-Helene Pinheiro, EMA* • Summary of the feedback from Industry respondents *Judith Creba, EFPIA and Craig Johnson, Vaccines Europe* • Summary of the feedback from EMA respondents *Alberto Ganan, EMA* Plenary discussion *Speakers joined by Melanie Carr, EMA*	5 minutes 20 minutes 20 minutes 15 minutes
	Coffee Break	

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4.	**Selected topic on Variations: operational management of RMP updates during post-authorisation** • Industry's experience and expectations *Kathy Williams, EFPIA* • Recent optimisation initiatives in the procedural management • Future opportunities *Iordanis Gravanis, EMA* Plenary discussion *Speakers joined by Christelle Bouygues, EMA and Susanne Winterscheid, BfArM (by T/C)*	10 minutes 15 minutes 15 minutes
5..	**Optimising early access tools: revision of the guidelines on Accelerated Assessment and Conditional Marketing Authorisation** • Summary of the Industry comments *Geert Preuveneers, EFPIA* • High-level overview of comments received during the public consultation • Direction of travel for the update *Tomas Salmonson, CHMP Chair, and Michael Berntgen, EMA* Plenary discussion *Speakers joined by Zigmars Sebris and Sabrina Spinosa, EMA*	10 minutes 15 minutes 10 minutes
6.	**Labelling review: challenges in the review of mock-ups and specimens** • Industry's experience and expectations *Katariina Gran, EGA* • Overview of experience and opportunities • New elements: QR code, consultation with Health Care Professionals *Monica Prizzi, EMA* Plenary discussion *Speakers joined by Jose Ferrero, EMA*	10 minutes 15 minutes 15 minutes
7.	Summary of follow-up items Close of meeting *Anthony Humphreys, EMA*	5 minutes

Participants List

EMA

Enrica Alteri, Head of Human Medicines Evaluation Division

Peter Arlett, Head of Pharmacovigilance Department

Michael Berntgen, Head of Scientific & Regulatory Management Department

Christelle Bouygues, Regulatory Affairs Officer

Melanie Carr, Head of Corporate Stakeholders Department

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

Iordanis Gravanis, Head of Evaluation Procedures C (Type II Variations)

Birgitta Grundmark, Scientific Officer (Risk Management Specialist)

Sabrina Spinosa Guzman, Scientific Officer (EMA Product Lead)

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

Marie-Helene Pinheiro, Industry Stakeholder Liaison

Monica Prizzi, Scientific Administrator, Labeling Review and Standards Office

Irene Rager, Head of Evaluation Procedures E (PSURs, PSUSAs, PASS)

Zigmars Sebris, Regulatory Affairs Officer

Jose Angel Ferrero Tijera, Scientific Administrator, Labeling Review and Standards Office

Mia Van Petegem, Scientific Officer (EMA Product Lead)

CHMP

Tomas Salmonson, Chair CHMP

PRAC

June Raine, Chair PRAC

CMDh

Susanne Winterscheid, Chair Variation subgroup

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Dagmar Stara

Industry Stakeholder Organisations

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Arlette Duvellory, Sanofi

Chris Walker, Amgen

EFPIA

Judith Creba, Novartis

David Jefferys, Eisai

Geert Preuveneers, MSD

Pär Tellner, EFPIA

Kathy Williams, AstraZeneca

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Susanne Heiland-Kunath, Takeda

Craig Johnson, GSK