



13 April 2016
EMA/43044/2016
Product Development Scientific Support

Agenda of the 2nd EMA-Industry Stakeholders Platform meeting on Paediatric medicines

15 April 2016, 10:00 – 13:30, room 2D

Chair: Jordi Llinares Garcia
Head EMA Product Development Scientific Support Department

Health and safety information

In accordance with Agency policy, delegates are to be shown a slide show with health and safety and emergency information and procedures. This is to be displayed at the start of this meeting using the Crestron system as delegates are entering the meeting room. In addition, the chairperson or meeting secretariat is to draw the delegates' attention to the slideshow and indicate where the nearest fire exit(s) to the meeting room are. Should there be an evacuation during the meeting, staff will guide delegates out of the building via the nearest fire exit, and assist anyone with a mobility impairment.

Item	Preliminary draft agenda	Initials	Mins
1.	Introduction to the 2nd EMA-Industry Stakeholders Platform meeting on Paediatric medicines	Marie Helene Pinheiro	
2.	Electronic submission: <ul style="list-style-type: none">• of PDCO opinions and EMA decisions <i>EMA will provide an update on the implementation status for electronic submissions and plans for revised handling of applications.</i>	Paolo Tomasi	10
3.	Early interaction on paediatric development and PRIME <i>EMA will provide a reminder on the early paediatric interaction meeting with medicines developers to stimulate early dialogue on the development of their medicines for use in children and how it could integrate with PRIME.</i>	Giovanni Lesa / Jordi Llinares Garcia	15
4.	Revised templates (scientific part of application, summary report, Opinion Annex I)	Ralf Herold	15



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	<i>The EMA has revised the template for the EMA/PDCO Summary report and for the scientific part of the application for agreement of a PIP/waiver with the objective to increase the focus of the submission and of the assessment.</i>		
5.	EFPIA feedback on EMA standard PIPs <i>Standard paediatric investigation plans (PIPs) are for use by applicants to help the agreement of PIPs on specific types or classes of medicines. EFPIA will present their feed-back on the uptake of the initiative.</i>	Kate Bejeaux	20
	Questions and discussion	Participants	10
Break			15
6.	Recruitment of paediatric subjects in clinical trials and the proposal to create a pan-European Paediatric Clinical Trials network (EUPCTN) <i>Recruitment of paediatric patients is often considered challenging from industry stakeholders. Resourceful thinking to overcome obstacles has produced a proposal that is being discussed by IMI.</i>	Heidrun Hildebrand / Genevieve Le Visage	20
Other updates			
7.	Interactions Scientific Advice Working Party (SAWP) and PDCO <i>Some quantitative data of procedures discussed by both the SWP and the PDCO will be presented. Participant will be invited to share their views on the experience with the aim to progress in defining best practice.</i>	Cecile Ollivier/Myriam Chapelin	15
8.	Expert meeting on paediatric development of fixed-dose combinations for the treatment of the human immunodeficiency virus (HIV) <i>The report of the meeting was recently published on the EMA website. EMA will summarise the implication and expected requirements of future applications. Views from participants on points in need of clarification will be sought.</i>	Thorsten Olski	5
9.	Update on recent activities by Enpr-EMA <i>The activities of Enpr-EMA and its working groups span over several paediatric fields. Highlights from the most important ones will be presented to increase awareness and promote fruitful interaction with the stakeholders.</i>	Irmgard Eichler	10
10.	A.O.B or Tour de Table	Participants	

List of participants

Name	Represents
John Watson	Eucope
Mireille Collombat	Eucope
Jens Peters	Eucope
Julien Rongere	Eucope
Stephane Callewaert	Vaccines Europe
Genevieve Le Visage	EFPIA
Gloria Garcia Palacio	EFPIA
Esteban Herrero-Martinez	EFPIA
Par Tellner	EFPIA
Kate Beaujeux	EBE
Claire Hill-Venning	EBE
Laila Narouz-Ott	EBE
Heidi Kern	EBE
Mia Bengtstrom	AESGP
Andreas Franken	AESGP
Martine Zimmermann	EuropaBio
Angelika Joos	EuropaBio
Claudia Hey	EuropaBio
Margalena de Azero (remote participant)	Vaccines Europe
Richard Pilsudski (remote participant)	Vaccines Europe
Susanne Heiland-Kunath (remote participant)	Vaccines Europe
Mary Allin (remote participant)	Vaccines Europe
Anna Czwaro (remote participant)	Vaccines Europe
Heidrun Hildebrand (remote participant)	EFPIA
Jordi Llinares	EMA
Paolo Tomasi	EMA
Roberto De Lisa	EMA
Cecile Ollivier	EMA
Emilie Desfontaine	EMA
Evyenia Shaili	EMA
Giovanni Lesa	EMA
Irmgard Eichler	EMA
Janina Karres	EMA
Marie-Helene Pinheiro	EMA
Marketa Lisakova	EMA
Myriam Chapelin	EMA
Ralf Herold	EMA
Thorsten Olski	EMA
Zahra Hanaizi	EMA
Andrea Ecker (remote participant)	EMA