



11 May 2015  
EMA/265165/2015  
Product Development Scientific Support Department

## Agenda - EMA-Industry Stakeholders Platform meeting on Paediatric medicines

11 May 2015, 09:30 - 13:00, Room 2D

Chair: Jordi Llinares

Item	Preliminary draft agenda	Initials
1.	Welcome and opening, introduction to the new platform	Jordi Llinares
2.	Expectations for Paediatric medicines platform	Industry Stakeholders
3.	General update on Paediatric medicines	Paolo Tomasi
4.	<b>Class waiver list review:</b> <ul style="list-style-type: none"><li>Motivation, methodology and outcome</li><li>Consequences for regulatory submissions</li><li>Industry stakeholders: Comments</li><li>Discussion</li></ul>	Ralf Herold Ralf Herold Industry Stakeholders All
5.	<b>Early interaction:</b> <ul style="list-style-type: none"><li>Presentation of plans and practicalities for early interactions to foster paediatric medicine development</li><li>Industry stakeholders: Comments</li><li>Discussion</li></ul>	Chrissi Pallidis Industry Stakeholders All
6.	<b>Public summary of the evaluation of a proposed PIP or product-specific waiver:</b> <ul style="list-style-type: none"><li>Industry stakeholders: Questions</li><li>Information on public summaries</li></ul>	Industry Stakeholders Paolo Tomasi
7.	<b>PIP Compliance check during submission validation:</b> <ul style="list-style-type: none"><li>Industry stakeholders: Questions</li><li>Information on compliance check</li></ul>	Industry Stakeholders Paolo Tomasi
8.	Discussion: Next meetings	
9.	A.O.B or Tour de Table	



## List of participants

### Industry Stakeholders:

#### ***EuropaBio:***

Riccardo Mezzasalma

Anthony Compton

Emma Dufour

Angelika Joos

Robert Morgan

Nicole Armbruester

#### ***EFPIA:***

Tiia Metiäinen

Genevieve Le Visage

Kate Beaujeux

Claire Hill-Venning

#### ***EBE***

Regis Le-Lain

Majken Asmussen

#### ***Vaccines Europe:***

Stéphane Callewaer

Beverley Abbott

Susanne Heiland-Kunath

#### ***EGA:***

Andrew Modley

### **Paediatric Committee:**

Dirk Mentzer

Koen Norga

Jacqueline Carleer (by TC)

## **European Medicines Agency:**

Jordi Llinares

Paolo Tomasi

Ralf Herold

Chrissi Pallidis

Gunter Egger

Giovanni Lesa

Thomas Girard

Georgina Gavriilidou

Melanie Carr

Marie-Helene Pinheiro

Agnes Saint-Raymond

Federica Castellani