



30 October 2018  
EMA/769203/2018

## Agenda – Industry stakeholder platform on research and development support

23 November 2018, 10:30 – 16:30, Meeting room 02-F

Chair: Michael Berntgen

Item	Agenda	Time
1.	<b>Welcome / Introductions</b>  Overview of the agenda  <i>Enrica Alteri, EMA</i>	10 min
2.	<b>Exchange on the practical considerations for the future regulation of integrated drug-device combinations</b>  Discussion on the impact of Article 117 of the Medical Device regulation for integrated drug-device combinations that are regulated as medicines.  Practical implementation steps to enable preparations for implementation of the Medical Device regulation.  <i>Armin Ritzhaupt and Ivana Hayes, EMA</i>  <i>Lars Hyveled-Nielsen, EUCOPE, and Mats Ericson, EBE</i>  Discussion  <i>(with participation of Dario Pirovano and Michael Strubin, MedTech Europe)</i>	40 min



3.	<p><b>Follow-up on experience with digital technology proposals in medicine development programmes</b></p> <p>Presentation of industry experience with qualification of digital technologies.</p> <p><i>Mireille Muller, EBE, and Scott Askin, EFPIA</i></p> <p>Important considerations for successful qualification proposals for digital technologies.</p> <p><i>Francesca Cerreta, EMA</i></p> <p>Discussion</p> <p><i>(with participation of Dario Pirovano and Michael Strubin, MedTech Europe)</i></p>	40 min
4.	<p><b>The evolving framework for innovation: Next Generation Sequencing (NGS)</b></p> <p><i>Claudia Dollins, EBE</i></p> <p><i>Falk Ehmann, EMA</i></p> <p>Discussion</p>	20 min
5.	<p><b>Current challenges in developments with biomarkers</b></p> <p>Review of experience with diversity of cut-off values across developments, from advice and evaluation perspective.</p> <p><i>Francesco Pignatti, Spiros Vamvakas and Frank Petavy, EMA</i></p> <p><i>David Ribeiro, EBE</i></p> <p>Discussion</p>	30 min
<b>Lunch</b>		<b>60 min</b>
6.	<p><b>Reflection on perspectives for scientific advice</b></p> <p>Industry perspective on better using scientific advice as continuum for life-cycle view on evidence generation.</p> <p><i>Emma Du Four, EuropaBio</i></p> <p>Latest experience with parallel consultation.</p> <p><i>Spiros Vamvakas and Jane Moseley, EMA</i></p> <p><i>Chantal Guilhaume, EUnetHTA</i></p> <p>Discussion</p>	30 min

7.	<p><b>Opportunities for “Post-licensing evidence generation” proposals in scientific advice</b></p> <p>Presentation of the paper developed by the focus group.</p> <p><i>Jane Moseley, EMA</i></p> <p><i>Solange Rohou, Vaccines Europe</i></p> <p><i>Chantal Guilhaume, EUnetHTA</i></p> <p>Discussion</p>	40 min
8.	<p><b>Experience with orphan designation reviews</b></p> <p>Update on analysis performed jointly by EMA and EUnetHTA.</p> <p><i>Kristina Larsson, EMA</i></p> <p>Reflection on similarity assessment.</p> <p><i>Laura Liebers, EMA</i></p> <p><i>Anja Langeneckert, EBE</i></p> <p>Discussion</p>	30 min
9.	<p><b>Topics from the paediatric action plan</b></p> <p>Report about recent advances in CHMP/PDCO collaboration.</p> <p><i>Chrissi Pallidis, EMA</i></p> <p>Feedback from the break-out session</p> <p><i>Gunter Egger and Ralph Bax, EMA</i></p> <p>Reflection on the revision of the PIP guideline.</p> <p><i>Angelika Joos, EUCOPE</i></p> <p>Discussion</p>	40 min
10.	<p><b>Summary of follow-up items</b></p> <p>Close of meeting</p> <p><i>Michael Berntgen, EMA</i></p>	10 min

## Parallel break-out sessions

Duration 60 minutes, during the lunch break

Item	Agenda	Room
1.	<p><b>Histology-independent development in oncology</b></p> <p>High-level exchange on the current challenges and discussion on future engagement opportunities.</p> <p><i>Chaired by Pierre Demolis and Francesco Pignatti, EMA</i></p>	2-B
2.	<p><b>Options for a PIP model that adjusts to evidence generation</b></p> <p>Exchange on ideas for a PIP model that allows, in certain cases, to develop along with the evolution of scientific knowledge.</p> <p><i>Chaired by Gunter Egger and Ralph Bax, EMA</i></p> <p><i>(with participation of Koen Norga, Dirk Menzer and Fabio D'Atri)</i></p>	2-J

## Participants List

EMA	Industry Stakeholder Associations
<p>           Enrica Alteri            Michael Berntgen            Armin Ritzhaupt            Ivana Hayes            Francesca Cerreta            Falk Ehmann            Francesco Pignatti            Spiros Vamvakas            Frank Petavy            Jane Moseley            Kristina Larsson            Laura Liebers            Chrissi Pallidis            Gunter Egger            Ralph Bax            Marlena Zarnecka            Zigmars Sebris            Kevin Cunningham            Corinne de Vries            Peter Arlett            Xavier Kurz            Marie Helene Pinheiro            Leonor Enes            Helene Casaert            Andersson Anita         </p>	<p><b>AESGP</b></p> <p>Andrew Thornley</p> <p><b>EBE</b></p> <p>           Mats Ericson            Anja Langeneckert            Mireille Muller            Claudia Dollins            David Ribeiro            Fiona Reekie            Sonja Pumpluen         </p> <p><b>EFPIA</b></p> <p>           Sini Eskola            Scott Askin            Geneviève Le Visage            Isabelle Stoeckert            Sabine Atzor            Susan Longmann            Catherine Weil            David Jefferys         </p> <p><b>EUCOPE</b></p> <p>           Angelika Joos            Joao Duarte            Jill Morrell            Lucia D'Apote            Dot Bruce            Maren von Fritschen            Lars Hyveled-Nielsen         </p> <p><b>EuropaBio</b></p> <p>           Simon Bennett            Alexa Hunter            David King            Emma Du Four            Christiane Abouzeid         </p> <p><b>Medicines for Europe</b></p> <p>           Anabela Godinho            Susana Almeida         </p> <p><b>Vaccines Europe</b></p> <p>           Adam Heathfield            Solange Corriol-Rohou            Muriel Pasté            Virginia Acha         </p>
<p><b>EMA scientific committees and working parties</b></p>	
<p>           Dirk Menzer            Koen Norga            Violeta Stoyanova-Beninska            Pierre Demolis         </p>	
<p><b>European Commission</b></p>	
<p>           Fabio D'Atri            Kaja Kantorska         </p>	

<b>Additional participants</b>	
Agenda items 2 and 3	<b>MedTech Europe</b> Dario Pirovano Michael Strubin
Agenda items 6 and 7	<b>EUnetHTA</b> Chantal Guilhaume Maggie Galbraith
Break-out session 1	<b>Industry Stakeholder Associations</b> Sacha Wissink Nadja Heimonen Debbie Mackenzie Fabrice Marsicano Chitkala Kalidas
Break-out session 2	<b>Industry Stakeholder Associations</b> Heidi Kern Silvia Garcia Anthony Compton Claudia Hey Martina Hoeth