3 July 2017
EMA/141280/2017
Human Medicines Evaluation Division

Final Agenda – 4th Industry Stakeholder Platform meeting - operation of the centralised procedure for human medicinal products

3rd July 2017, Time: 10:00-17:00, Meeting room 2F

Chair: Evdokia Korakianiti and Jordi Garcia Llinares

Item	Preliminary draft agenda	Time
1.	**Welcome and introductions** – *, EMA speaker* – *Tomas Salmonson, CHMP chair*	5 min
2.	**Initial MAA : EMA-Industry Initial MAA survey outcome** • Results presentations – EMA feedback, *Marie-Helen Pinheiro (EMA)*, EMA results: *Thomas Castelnovo, Gaelle Andriantafika, (EMA),* CHMP results: *Mia Van Petegem (EMA)* – Industry feedback, *Fiona Reekie (EFPIA WG Member)* • Discussion and next steps	120 min
3.	**Strengthening the EMA support to Committees and the Network** - *Zaide Frias, (EMA)*	15 min
	Lunch break	60 min
4.	**Initial MAA: New accelerated assessment process exchange and CMA report feedback**: • Optimising Applicants' MAA submissions to foster regulatory outcomes – Industry experience and recommendations on new AA process; comments on CMA report, *Mireille Muller (Novartis)* – Experience with new AA process, *Victoria Palmi (EMA)* • Discussion and next steps	45 min

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Item	Preliminary draft agenda	Time
5.	**Initial MAA : From benefit / risk to effect table: core tool to facilitate decision making** - EMA experience on the use of the B/R to the effect table: from Rapporteurship to CHMP discussion, to EPAR , *Francesco Pignatti, Andreas Kouroumalis (EMA)* - Industry experience: Feedback from Industry on the use of the B/R in the clinical overview, *Nadege Le Roux (Celgene)* - Discussion and next steps	45 min
6.	**English version labelling review** - Overview of the new process for initial MAA and data from two years experience, *Alexios Skarlatos (EMA)* - Feedback from Industry including challenges in procedures other than initials, *Anne de Bock (AstraZeneca)*	20 min
	Coffee break	15 min
7.	**Post authorisation**: building quality in submissions to reach outcomes faster and a more sustainable medicinal lifecycle management : a. Clinical Type IIs - Feedback from Industry on new rolling PRAC variations and recent PAG updates, *Simon Bennett (Biogen)* - Updates on Clinical variations, *Iordanis Gravanis (EMA)* b. Quality variations - Industry experience with lifecycle management for quality changes- areas to focus, *Meike Vanhooren (Pfizer)* - Simplification opportunities and Experience with commonly seen issues, *Alberto Ganan (EMA)* c. PAMs- Addressing issues in identifying the correct evaluation path, *Hector Perales Boix (EMA)* d. PSUR roadmap next steps, *Irene Rager (EMA)*	60 min
8.	**Update following the consultation with Industry associations on the "Best Practice Guide Best practice guide on measures improving predictability of submissions / responses and adherence to communicated submission / responses deadlines"** - *Christer Backman, Chair of HMA/EMA TaskForce*	15 min
9.	**Update on the collaboration with EUnetHTA after Opinion (Joint Action 3, work package 4)** - *EMA, Michael Berntgen* - *EUnetHTA, Michelle Mujoomdar*	10 min

Item	Preliminary draft agenda	Time
10.	**General discussion and agreement on next steps** - *Evdokia Korakianiti, Jordi Garcia Llinares (EMA)* - *Tomas Salmonson (Chair of CHMP)*	15 Min
11.	**Close of meeting**	

Proposed dates for next meetings: TBC

List of topics for future Centralised Platform meetings:

1. Patient involvement in evaluation activities update from public hearings, EMA speaker
2. Lessons learned from Clusters

Network

- Tomas Salmonson Chair of CHMP
- Christer Beckman Chair of HMA/EMA TaskForce
- Peter Bachmann Chair of CMDh
- Michelle Mujoomdar *EUnetHTA* via TC
- Andrea Laslop CHMP member

EMA

- Zaide Frias Head of Human Medicines Evaluation Division (E)
- Evdokia Korakianiti Head of Procedure Management Department (E-PM)
- Jordi Garcia Llinares Head of Scientific and Regulatory Management Department (E-SR)
- Melanie Carr Head of Corporate Stakeholders Department (S-CS)
- Marie-Helene Pinheiro Head of Industry Liaison Office (S-CS-IND)
- Thomas Castelnovo Head of Evaluation Procedures A Service (E-PM-EPA)
- Iordanis Gravanis Head of Evaluation Procedures C Service (E-PM-EPC)
- Alberto Jimenez Ganan Head of Evaluation Procedures D Service (E-PM-EPD)
- Michael Berntgen Head of Product Development Scientific Support Department
- Gaelle Andriantafika Procedure Manager in E-PM-EPA Service
- Mia Van Petegem EMA Product Lead in E-SR-ECV Office
- Victoria Palmi Procedure Manager in E-PM-EPA Service
- Francesco Pignatti Head of Oncology, Haematology & Diagnostics Office E-SR-ONC)
- Alexios Skarlatos Head of Labelling Review & Standards Office (E-SR-LRS)
- Hector Perales Boix Procedure Manager in E-PM-EPA Service

- Irene Rager Head of Evaluation Procedures E Service (E-PM-EPE)
- Andreas Kouroumalis EMA Product Lead in E-SR-ECV office
- Sonia Ribeiro Head of Regulatory Affairs Office (E-SR-REA)
- Constantinos Ziogas Head of SME Office (S-CS-SME)
- Leonor Enes Scientific Officer in SME Office (S-CS-SME)
- Enrico Tognana Business Analysis & Forecasting Specialist in D-DS-SIS Office

Industry

- **AESGP**
    - Pilar Garcia (GSK)
    - Christelle Anquez (AESGP) via TC
- **EBE**
    - Sally Bruce (GSK)
    - Mireille Collombat (Actelion)
    - Kevin Sinnett (Amgen)
    - Maria Pascual (Tigenix)
    - Susan Bhatti (Merck)
- **EFPIA**
    - Par Tellner (EFPIA)
    - Mireille Muller (Novartis)
    - Fiona Reekie (UCB)
    - Nadege Le Roux (Celgene)
    - Seema Shah (Roche)
    - Meike Vanhooren (Pfizer)
    - Eszter Teleki (BMS)
- **EuropaBio**
    - Véronique Sabot (Sanofi)
    - Katarina Jelic Maiboe (Novo Nordisk)
    - Nadia Assenova (Alexion)
    - Emmanuelle Voisin (Voisin Consulting)
    - Simon Bennet (Biogen)
    - Esteban Herrero-Martinez (AbbVie)
- **Medicines for Europe**
    - Rashi Sharma (**Mylan)**
    - Katariina Gran Mujoomdar (Teva)
    - Vesna Schauer-Vukasinovic (Sandoz)
- **Vaccines Europa**
    - Anne De Bock **(AstraZeneca)**
    - Stéphane Callewaert **(GSK)**
    - Heiland-Kunath **(Takeda)**
    - Jeroen De Wilt (**MSD)**