EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 July 2023
EMA/168978/2023

Agenda – 10th Industry stakeholder platform on research and development support

11 July 2023, 12:30 – 17:30 (room 1D)

Chair: Michael Berntgen

Item	Agenda	Time
1.	**Welcome / Introductions** • Overview of the agenda • Review of status of follow-up actions from the last platform meeting *Michael Berntgen, EMA*	10 min
2.	**Update on latest developments in scientific advice** • Summary of revised guidance • Volume and capacity of the scientific advice offering • Initiatives to progress towards integrated scientific dialogue • Feedback from developers *Iordanis Gravanis (EMA)* *Bertrand Fournier (EUCOPE) and Esteban Herrero-Martinez (EFPIA)*	30 min
3.	**Progress with the implementation of the recommendations to further strengthen the PRIME scheme** • Status of implementation activities and first experiences (expedited scientific advice, development tracker / roadmap, submission readiness meetings) • First experiences from developers' perspective *Kevin Cunningham and Anna Gross (EMA)* *Nadege Le Roux (EFPIA)*	40 min
4.	**Report from the multi-stakeholder workshop on qualification of novel methodologies** • Summary of the workshop outcome • Next steps to strengthen the process for qualification *Thorsten Vetter (EMA)* *Mireille Mueller (EFPIA)*	20 min

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5.	**Cooperation at the HTA/regulatory interface** • Update from the parallel consultations under EUnetHTA 21 • Consultation opportunities during the transition phase • Feedback from developers *Thorsten Olski (EMA) and Stephanie Said (EUnetHTA21)* *Claudine Sapede (EFPIA)*	30 min
Coffee break		20 min
6.	**Progress with the implementation of initiatives to optimise the application of the PIP framework** • Experience with the stepwise PIP (sPIP) concept • Revision of the Key elements and the Summary report template • Feedback from developers *Chrissi Pallidis (EMA) and Sabine Scherer (BfArM, PDCO)* *Marcello Milano (EuropaBio)*	40 min
7.	**Development of complex generics** • Challenges from a developers' perspective • Recent initiatives by EMA *Parminder Kaur (EuropharmSMC) and Susana Almeida (Medicines for Europe)* *Kevin Blake (EMA)*	20 min
8.	**Report from the Focus group on provision of scientific advice for medicinal product developments comprising of drug-device combinations and drug-companion diagnostic combinations** • Analysis of scientific questions on medicinal product development in combination with medical devices or companion diagnostics to be addressed in scientific advice *Alexa Hunter (EuropaBio) and Tim Chesworth (EFPIA)* *Sheila Killalea (HPRA, SAWP) and Ilona Reischl (AGES)* • Limitations for engagement by Notified Bodies *Alex Laan (BSI)* • Medicinal product/Medical device interfaces: NCA challenges *Ilona Reischl (AGES)* • Proposals moving forward to facilitate the scientific dialogue within the current regulatory framework and potentially in the future *Stiina Aarum (EMA)*	80 min
9.	**Summary of follow-up items / Close of the meeting** *Michael Berntgen, EMA*	5 min