30 November 2022
EMA/832164/2022

# Agenda – 9th Industry stakeholder platform on research and development support

5 December 2022, 09:30 – 15:00 (WebEx)

Chair: Michael Berntgen

| Item | Agenda | Time |
|---|---|---|
| 1. | **Welcome / Introductions**<br>• Overview of the agenda<br>• Review of status of follow-up actions from the last platform meeting<br><br>*Michael Berntgen, EMA* | 10 min |
| 2. | **Recent developments to address scientific advice capacity and scope**<br>• Update on Scientific Advice guidelines<br>• Proposed changes to the Science Advice offering<br><br>*Iordanis Gravanis, EMA*<br>*Esteban Herrero Martinez, Industry* | 30 min |
| 3. | **Closing report from the Focus group on review and strengthening the framework for qualification of novel methodologies**<br>• Overview of types of methodologies for qualification in the future<br>• Identification of procedural and expertise needs for future qualification of different types of methodologies<br>• Recommendations to strengthen the process for qualification<br><br>*Thorsten Vetter, EMA*<br>*Mireille Mueller, Industry* | 45 min |
| 4. | **Progressing parallel Joint Scientific Consultations**<br>• Status update from the second call of expression of interest<br>• Future dialogue opportunities<br><br>*Thorsten Olski, EMA, and Antje Behring, EUnetHTA 21* | 15 min |
| ***Coffee break*** | | 10 min |

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| 5. | **Implementation of the recommendations from the PRIME 5-year review**<br>• Progress update on implementation activities<br><br>*Kevin Cunningham, Francesca Cerreta, EMA*<br>*Joao Duarte, Nadege Le Roux, Pedro Franco, Industry* | 20 min |
| 6. | **Delivery of the EMA/EC Paediatric Action Plan**<br>• Overview of achievements under the action plan<br><br>*Gunter Egger, EMA* | 10 min |
| 7. | **Closing report from the Focus group on the practical application of principles relevant for the PIP framework**<br>• Description of the 'step-wise' PIP model including elements to guide a scientific justification to support a case-by-case discussion<br>• Practical arrangements that support dialogue on an 'step-wise' PIP<br>• Review and identification of suitable key elements for a PIP<br>• Proposals for milestone terminology for PIPs<br><br>*Chrissi Pallidis, EMA together with Sabine Scherer (PDCO member)*<br>*Gesine Bejeuhr, Marcello Milano, Industry* | 45 min |
| 8. | **Changes to the Paediatric Annual Report preparation**<br>• Optimisation of the process<br><br>*Isabel Sanchez Vigil de la Villa, EMA* | 15 min |
| ***Lunch break*** | | 45 min |
| 9. | **Expert panels scientific advice to medical device manufacturers**<br>• Overview of the pilot for scientific advice on certain medical devices<br><br>*Silvy Da Rocha Dias, Miguel Antunes, EMA* | 15 min |
| 10. | **Progress with the development of a pilot for scientific advice on drug-device combinations**<br>• Presentation of challenges and opportunities<br>• Identification of use cases<br><br>*Tim Chesworth, Shayesteh Fürst-Ladani, Claudia Popp, Lars Hyveled Nielsen, Industry* | 30 min |
| 11. | **Follow-up on strengthening patient-centric development**<br>• Feedback from the multi-stakeholder workshop<br>• Update on the pilot seeking early patient input in MAA reviews<br><br>*Juan Garcia, EMA*<br>*Susan Bhatti, Industry* | 30 min |
| 12. | **Summary of follow-up items / Close of the meeting**<br>*Michael Berntgen, EMA* | 5 min |