

22 November 2016
EMA/421229/2016

Agenda EMA - EUnetHTA meeting

7 December 2016, 10.00-16.00 BST
European Medicines Agency, London, Room 2E

Co-chairs: Hans-Georg Eichler (EMA) and Wim Goettsch (EUnetHTA)

Item	Preliminary draft agenda	Name
1	Welcome by the EMA's Executive Director	Guido Rasi
2.	Introduction to the day and adoption of draft agenda	Hans-Georg Eichler and Wim Goettsch
3.	Update from DG SANTE on activities related to the EMA/EUnetHTA dialogue (e.g. Joint Action 3, HTA Network, upcoming events)	Ioana-Raluca Siska
4.	Overview of the establishment of Joint Action 3: introduction to structure and partners, status of work packages relevant for the collaboration with regulators	Wim Goettsch
5.	Topics and priorities for the development of an EMA/EUnetHTA work plan	Michael Berntgen and Wim Goettsch
6.	Experiences and perspectives for multi-stakeholder scientific advice to developers: plans for the activities under work package 5a and reflection on future models	Topic leads: <ul style="list-style-type: none"> EMA: Jane Moseley, Spiros Vamvakas EUnetHTA: François Meyer (HAS) and Antje Behring (G-BA)
7.	Opportunities for advice on post-licensing data generation plans (including registries and real world evidence) and related developments under work package 5b	Topic leads: <ul style="list-style-type: none"> EMA: Xavier Kurz, Alison Cave, Jane Moseley EUnetHTA: François Meyer (HAS) and Antje Behring (G-BA)

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8.	Bridge from regulatory approval to market entry: facilitating sharing the regulatory review and related information in view of joint relative effectiveness assessments under work package 4	Topic leads: <ul style="list-style-type: none"> • EMA: Michael Berntgen • EUnetHTA: Marianne Klemp (NIPHNO) and Michelle Mujoomdar (EUnetHTA Directorate / ZIN)
9.	Approaches for collaboration on horizon scanning to assist in joint priority setting – review of methodologies (business pipeline reviews, PRIME scheme)	Topic leads: <ul style="list-style-type: none"> • EMA: Corinne de Vries, Enrico Tognana, Jordi Llinares • EUnetHTA: Wim Goettsch
10.	Experience with Patient engagement in the context of regulatory and HTA activities	Topic leads: <ul style="list-style-type: none"> • EMA: Isabelle Moulon • EUnetHTA: Antje Behring (G-BA)
11.	Action points from previous meetings	All
12.	Closing remarks	Hans-Georg Eichler and Wim Goettsch