EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Exchange between EMA and HTA bodies to facilitate joint production of relative effectiveness assessments

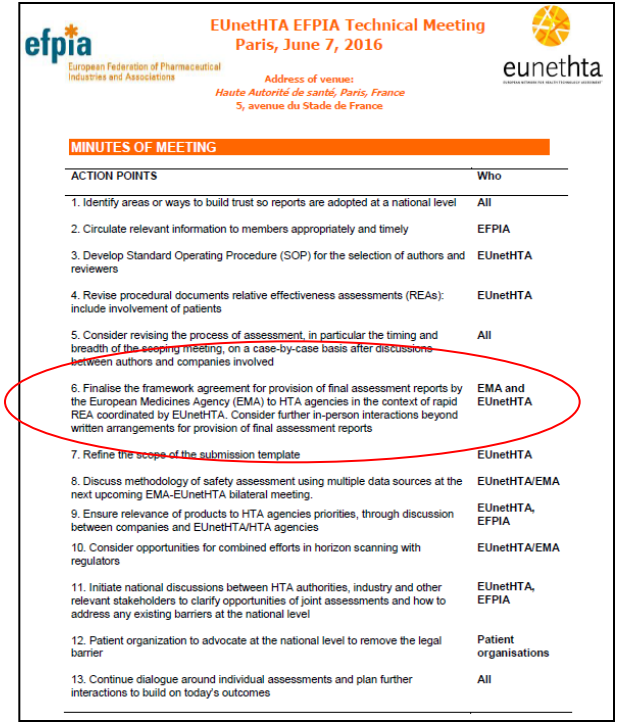
Industry stakeholder platform - operation of the centralised procedure for human medicinal products

3 July 2017

Presented by Michael Berntgen (EMA) and Michelle Mujoomdar (EUnetHTA)

Background: EMA/EUnetHTA collaboration under Joint Action 3, work package 4

- Joint production of relative effectiveness assessment (REA) of pharmaceuticals is one of the deliverables of EUnetHTA Joint Action 3 (work package 4).
- Knowledge of the regulatory assessment is relevant for the REA preparation:
  - Availability early during REA production
  - Focus on clinical aspects, labelling and benefit/risk
- Technical meeting in June 2016 to discuss operational aspects with EUnetHTA, HTA agencies, pharmaceutical industry, EFPIA, EMA and the European Commission.



efpia
European Federation of Pharmaceutical Industries and Associations

EUnetHTA EFPIA Technical Meeting
Paris, June 7, 2016

eunethta

Address of venue:
Haute Autorité de santé, Paris, France
5, avenue du Stade de France

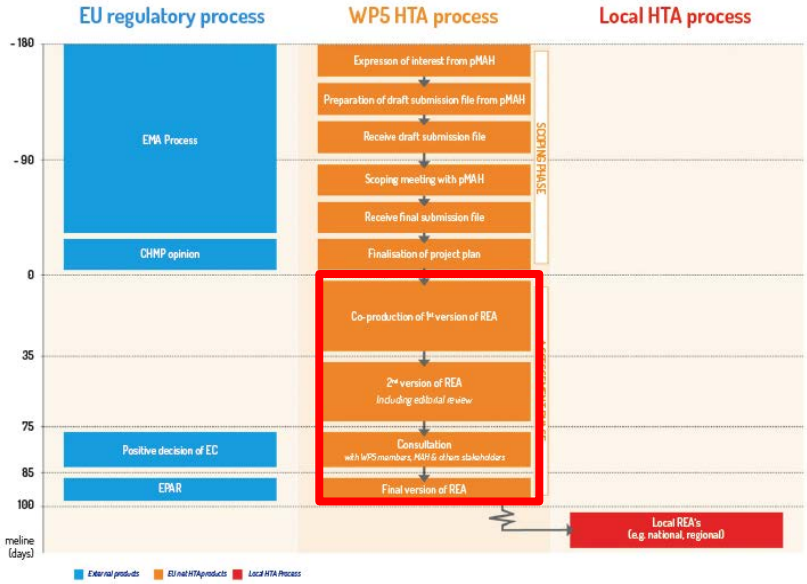
MINUTES OF MEETING

ACTION POINTS	Who
1. Identify areas or ways to build trust so reports are adopted at a national level	All
2. Circulate relevant information to members appropriately and timely	EFPIA
3. Develop Standard Operating Procedure (SOP) for the selection of authors and reviewers	EUnetHTA
4. Revise procedural documents relative effectiveness assessments (REAs): include involvement of patients	EUnetHTA
5. Consider revising the process of assessment, in particular the timing and breadth of the scoping meeting, on a case-by-case basis after discussions between authors and companies involved	All
6. Finalise the framework agreement for provision of final assessment reports by the European Medicines Agency (EMA) to HTA agencies in the context of rapid REA coordinated by EUnetHTA. Consider further in-person interactions beyond written arrangements for provision of final assessment reports	EMA and EUnetHTA
7. Refine the scope of the submission template	EUnetHTA
8. Discuss methodology of safety assessment using multiple data sources at the next upcoming EMA-EUnetHTA bilateral meeting.	EUnetHTA/EMA
9. Ensure relevance of products to HTA agencies priorities, through discussion between companies and EUnetHTA/HTA agencies	EUnetHTA, EFPIA
10. Consider opportunities for combined efforts in horizon scanning with regulators	EUnetHTA/EMA
11. Initiate national discussions between HTA authorities, industry and other relevant stakeholders to clarify opportunities of joint assessments and how to address any existing barriers at the national level	EUnetHTA, EFPIA
12. Patient organization to advocate at the national level to remove the legal barrier	Patient organisations
13. Continue dialogue around individual assessments and plan further interactions to build on today's outcomes	All

The concept: bridge from regulatory opinion to relative effectiveness assessment

Collaboration between regulatory and HTA assessors in the context of joint production of relative effectiveness assessment:

- make available to HTA reviewers the outcome of the regulatory assessment based on the **final** CHMP opinion
- facilitate mutual understanding of the outcomes of each decision making
- respecting the respective **remits** and under **confidentiality** arrangements



In practice: touchpoints from an applicant's perspective

Once a product has been selected for joint REA production under work package 4:

Joint communication from EMA and EUnetHTA on the interaction that will take place to support this joint production

Once the final CHMP opinion has been adopted by the CHMP:

Information to the applicant that the specified parts of the final CHMP assessment report will be provided to the concerned HTA bodies (HTA bodies acting as author and co-author, and WP4 co-lead partner), under Confidentiality arrangements

Note: for initial MAA this concerns the sections Problem statement; Clinical aspects; Clinical efficacy; Clinical safety; Benefit-risk balance; Recommendations

Engagement and take home messages

Key engagements with stakeholders:

- June 16 – EUnetHTA/EFPIA technical meeting
- Dec 16 - EMA/EUnetHTA bilateral on operational details
- 1Q17 - Discussion with the CHMP and within EUnetHTA
- June 17 – EUnetHTA/EFPIA high-level meeting
- July 17 – Industry stakeholder platform

<u>This new type of interaction is deemed essential to support timely and robust joint REA production:</u>

- Important to cascade this process to both functions within industry (market access and regulatory affairs)
- Need to ensure alignment / information flow on project level
- With the first two pilots there will be experience gain on all sides