

# HTA Network Synergy Group

## Update on progress and next steps

9 February 2018  
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# Background

- ✓ 10 November 2016: adoption of Reflection Paper on “Synergies between Regulatory and HTA issues on Pharmaceuticals” by the HTA Network
- ✓ Establishment of the Synergy Group, composed of similar numbers of HTA representatives (HTA Network and EUnetHTA JA3) and regulators (STAMP, HMA, EMA), chaired by AIFA.
- ✓ 26 June 2017: Kick-off meeting of the Synergy Group



# Objectives of the Synergy Group

- ✓ To map the activities - planned or ongoing - relevant to the collaboration areas identified in the Reflection Paper
- ✓ To provide an overview of the work carried out by various *fora*, avoiding duplication of efforts and facilitating synergies
- ✓ To stimulate discussion on further collaborations/interactions amongst different bodies



# Data collection and analysis

- July-September 2017: agreement on a table template for the mapping exercise
- November 2017-January 2018: data collection
- All Group members provided their contribution to the mapping exercise
- AIFA collected all inputs and discussed the contents with Group's Representatives to ensure consistency of the information



# Template for data collection as agreed by all participants of the Synergy Group

Collaboration area identified in the Reflection Paper	Participating organisations	Activities related to the collaboration area	Ongoing /Planned Please specify: O/P	Start date and expected end date (MM/YYYY)	Expected deliverables	Potential challenges to the implementation of joint synergistic activities	Supportive/reference documents available (e.g. website, links to the documents)
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## **The table aims to collect data on the activities related to collaboration areas identified in the Reflection Paper:**

### ***Pre-marketing:***

- ✓ Early dialogues/scientific advice
- ✓ Definition of unmet medical need
- ✓ Definition of therapeutic innovation
- ✓ Horizon scanning
- ✓ Promotion of research and dialogue in therapeutic areas with unmet medical need
- ✓ Cooperation on research needs (such as novel study designs, validation of endpoints etc.)



## **The table aims to collect data on the activities related to collaboration areas identified in the Reflection Paper (cont'd):**

### ***Market entry:***

- ✓ Information exchange on eligible patient populations
- ✓ Early information exchange on novel pharmaceuticals
- ✓ Cooperation on regulatory assessment reports





## **The table aims to collect data on the activities related to collaboration areas identified in the Reflection Paper (cont'd):**

### ***Post-marketing – RWE and safety:***

- ✓ Initiatives on post-marketing studies (e.g. PASS, PAES)
- ✓ Development of late dialogues with manufacturers
- ✓ Collaboration on RWD (e.g. disease/product specific registries)





# The table aims to collect data on the activities related to collaboration areas identified in the Reflection Paper (cont'd):

## *Other areas*

- ✓ Initiatives on patients involvement
- ✓ Other initiatives (ATMPs/personalised medicine/orphan drugs)



## Preliminary results

- Most collaboration areas identified in the Reflection paper seem to be covered (planned or ongoing) with the exception of *"Promotion of research and dialogue in therapeutic areas with unmet medical need"*.
- Overall, different Groups deal with similar activities, although they have different aims and remits
- In general, little duplication or replication of the activities related to regulatory and HTA synergies



## Areas for possible collaboration

- General interest in the definition of unmet need/therapeutic innovation expressed by different participants
- Real World Data is of interest to different *fora*
- HTA Network Multiannual Work Programme 2016-2020, EMA/EUnetHTA work plan and HMA reported initiatives on patients involvement



## Conclusions and next steps

- Information exchange on activities of common interest to different Groups is envisaged
- The table will be further discussed among the Synergy Group participants. Updates may be necessary.
- The final outcome of the mapping exercise will be presented during the next meeting of the HTA Network.



Thank you for your attention

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