AGENZIA ITALIANA DEL FARMACO

Tutela Ricerca e Sviluppo per la Salute

Update on the Synergy Group

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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

- January 2018: data collection on the basis of an agreed table
- All Group members provided their contribution to the mapping exercise
- March 2018 Synergy group meeting to finalise the table merging all contributions

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*)

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

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 activities seem to be covered (planned or ongoing)

•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*
- Patients involvement initiatives

Conclusions and next steps

- Information exchange on activities of common interest to different Groups is envisaged

- Further efforts are needed to keep pace with the future activities for which regulatory/HTA synergy may be worthwhile

- AIFA will draft a report summarizing key results by July 2018

- The final outcome of the mapping exercise will be presented during the next meeting of the HTA Network.

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