



Topic 4:

Follow-up of the Reflection Paper on synergies between regulatory and HTA issues - Synergy Group -

HTA Network meeting, 29 March 2017

DG SANTE

**Unit B4 – Medical products:
safety, quality, innovation**

Health



Reflection Paper on synergies between regulatory and HTA issues

- **Aim:** To identify activities along the life-cycle of health technologies in which cooperation between regulatory and HTA bodies can contribute to facilitating efficient access to effective, safe, innovative, and added value technologies.
 - On-going and new activities
 - To be addressed in both short and medium/long term
 - Focused on pharmaceuticals
- Drafting WG: 9 MS + EMA
- STAMP and HMA provided input
- **Unanimously adopted by the HTA Network in November 2016**

Reflection Paper – Follow-up

Ad-hoc Synergy Group

- Suggested and agreed by HTA Network as follow-up mechanism
- "Ad hoc" coordination mechanism
- Equal numbers of HTA representatives (i.e. HTA Network and EUnetHTA JA3) and regulators (i.e. STAMP, HMA, EMA).
- **Objectives:**
 - to map the actions identified in the Reflection Paper (on-going or planned by different fora), in order to create synergies and avoid duplication and uncertainty;
 - to facilitate contacts/interactions between different fora to contribute to the common objective of facilitating access to medicines;
 - to suggest the best way forward in specific areas identified in the Reflection Paper.



Ad-hoc Synergy Group

Composition

- Approx.10 experts
 - 5 HTA representatives: HTA Network (DE, FR, IT, PT, UK) and EUnetHTA
 - 5 regulators' representatives: STAMP and HMA (CZ,DK,ES,GR), EMA (1)
- Facilitated by the European Commission

Output

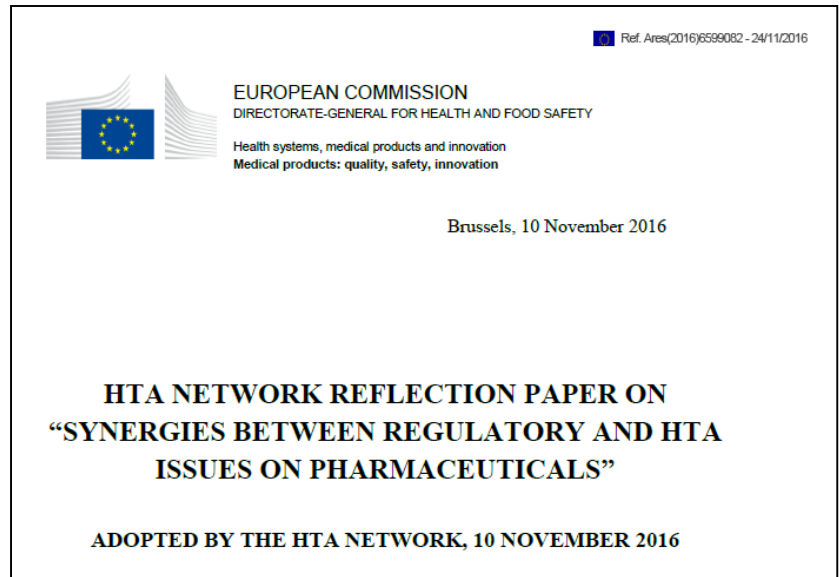
- A document outlining the mapping of actions relevant to the topics identifies in the Reflection Paper, indicating who does what by when.
- A final report including proposals for the next steps to further improve synergies between regulatory and HTA issues



European
Commission

Next steps

- Confirmation of representatives from HTA Network
- Convene e-meeting to organise the Group and work



Thank you!



http://ec.europa.eu/health/technology_assessment/policy/network/index_en.htm