



Topic 5 bis

Synergies between regulatory and HTA issues- next steps

European Commission
DG SANTE - Health Systems,
Medical Products and Innovation

Synergy between regulatory and HTA issues

Rationale: [...] While specificity must be maintained to meet the objectives of each phase, **more synergy and de-fragmentation should be achieved.** This would not only speed patient access to potentially innovative technologies, but also contribute to increase the business predictability and the reduction of administrative hurdles, both for public regulators and technology developers*

**HTA Network MWP 2013-2015*

Synergy between regulatory and HTA issues

*- An implementation plan need will need to be developed to identify who takes lead on proposed actions. **

** Minutes HTA Network meeting 20/5/2016*

Why a coordination/synergy group?

- *To take stock of which Fora/Bodies are addressing specific topics*
- *To avoid that some of these bodies develop same topics in parallel → **avoid duplication create synergies (i.e. EMA-EUnetHTA Joint work plan)***
- *To **facilitate contacts/interactions between the different key players** represented in different Fora/ Bodies to contribute to the common objective of facilitating access to medicines*

Proposed guiding principles

- *Keep it small /manageable size*
- *Focus its activities: not to address the actions but to identify where the actions are addressed*
- *Involve key players*
- *Proposal for composition: 2 HTA Network, 2 EUnetHTA, 2 STAMP, 1 HMA, 1 EMA*
- *Possibility to enlarge it if needed on ad hoc basis*

Questions to the HTA Network:

- 1) To agree or not on the possibility **to set up such coordination group** as an instrument to avoid that the actions identified are independently developed by different fora leading to duplication and uncertainty.*
- 2) **To enable the EC to approach the other identified players** to check their interest in such coordination group/task force.*
- 3) **To provide two volunteers** to help the Commission in this task and be the HTA Network representatives to such potential group.*