



STAMP EC expert group 6 May 2015

EU cooperation on HTA – latest developments

Presented by

- Tapani Piha, Head of Unit, HTA and eHealth (DG SANTE, Unit D3)

Followed by a presentation by

- Finn Børlum Kristensen, Professor Finn Børlum Kristensen, Chairman of EUnetHTA Executive Committee,
Secretariat Director, EUnetHTA Secretariat

HTA COOPERATION

- Article 15 of the Cross-border Healthcare Directive
- HTA Network, Strategic arm of EU cooperation on HTA
- EUnetHTA: scientific-technical arm of EU cooperation
 - Joint Action 2 by HTA doers (mainly HTA Agencies) (Until October 2015)
 - Proposed Joint Action 3, implementing arm of the HTA Network

HTA NETWORK

- HTA Network adopted its Strategy
 - October 2014
- Reflection paper "Reuse of Joint Work in national HTA activities"
 - April 2015
- Working paper on "Synergies between HTA and regulatory issues"
 - 1st half 2016
- Future Joint Action 3, 2016-2019 (to be proposed)
- 4th meeting on 23 March 2015
- 5th meeting on 29 October in Paris
 - linked to the HAS 10 year conference



European
Commission

HTA Strategy for the EU

Evidence is global, decision is local

PRODUCTION

From pilots to production of joint work

Well established quality controls

Clear framework for priority setting

MAINSTREAMING

Uptake of joint work in national activities

EU vision to be reflected at regional and national level

SYNERGIES

Answering needs of decision makers

Before and after regulatory requirements

SUSTAINABILITY

Permanent production support

Self-sustainable funding

Act globally

Willingness

Trust

Subsidiarity

Efficiency

Broad scope of EU cooperation in HTA

Mainstreaming- Reflection paper on “Reuse of Joint Work in national HTA activities”

Objective

- Aim to **facilitate take up and reuse** at national/regional level of joint HTA Work and/or HTA work produced by other HTA agencies.

Why

- **Reuse** is essential to **demonstrate the usefulness** of EU cooperation
- To enable **long term sustainability** of "Joint Work"

Working paper on “Synergies between HTA and regulatory issues”- 1st half 2016

- Aim to **facilitate synergies between developers of health technologies, regulators, HTA bodies and decision makers.**
- Synergies for pharmaceuticals may be explored both in the pre- and post-marketing phase, for example by:
 - Conducting parallel early dialogues/scientific advice,
 - Timely exchange of information between regulatory & HTA bodies in pre- and post-marketing phase
 - Cooperation on defining phase IV studies
 - Supporting initiatives on more transparency of scientific data

Summary

- HTA Network – a tangible tool for EU cooperation on HTA
- There is political willingness and financing opportunity to continue the cooperation in the near future
- A need to establish a sustainable mechanism of Joint Work and reuse of HTA by 2019
- EC services look forward to see concrete cooperation output between regulatory and HTA bodies
- Welcome cooperation with STAMP, CAPR and other relevant fora