



Latest development EU cooperation on HTA

Patients' and Consumers' Working Party and Healthcare professionals' Working Party–Joint meeting

**Flora Giorgio, DG SANCO eHealth and HTA Unit
16 September, EMA London**

Definition

Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method.

www.eunethta.eu

EU Objectives in HTA

Article 15 Directive 2011/24:

- *Support cooperation between national HTA Authorities*
- *Support MS in the provision of objective, reliable, timely, transparent , comparable and transferable information [...] to enable effective exchange of information*
- *Avoid duplication of assessments*

EU cooperation in HTA- achievements

- Common HTA methodologies have been produced
→ joint piloting are on-going.
- IT tools and training facilities are in place → for common use and sharing
- EU HTA community built up → more trust between HTA doers, MS authorities and stakeholders.

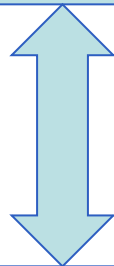
EU Cooperation in HTA – where we are

- **HTA Network** (art 15 Directive 2011/24)– **strategic level** (1st meeting 16 October 2013) → MS representatives (mainly MoH); EMA associated
- **EUnetHTA** (Joint Action HP)– **scientific level** – on-going until October 2015 → HTA doers (mainly HTA Agencies)
- Two levels in synergy and complementary
- Involvement of stakeholders - both @ strategic level and scientific level

STRATEGIC LEVEL: HTA NETWORK

Who: MoH responsible for HTA + Observers

What : Strategic guidance



TECHNICAL SCIENTIFIC LEVEL: Joint Action (EUnetHTA)

Who: HTA agencies, DOING HTA Reports +
Stakeholders

What : capacity building, tools and pilots for
"Joint work"

STAKEHOLDERS



EU cooperation in HTA – HTA Network STRATEGIC VISION

- New phase of cooperation → from "agreeing on " to "doing and learning together" → **PILOTS**
- Up take of EU work in national activities → **MAINSTREAM**
- "Life of HTA Network draft strategy paper" →
More synergies with regulators and payers →
DEFRAGMENTATION
- From "projects" to "permanent" cooperation → **SUSTAINABILITY**

EU cooperation on HTA – key dates

- ***EPSCO informal Council – 22-23 September 2014, Milan***
 - Strategic discussion on cooperation at EU level on HTA
- ***HTA Network meeting, 29 October 2014, Rome***
 - Discussion and adoption (TBC) Strategy paper
 - Discussion on priorities for possible next Joint Action
- ***EUnetHTA Conference " Europe HTA 2.0 teaming up for Value", 30-31 October 2014, Rome***

EU cooperation on HTA – Next steps

- ***Reflection on involvement of Stakeholders in HTA cooperation***
 - @ strategic and technical/scientific level – post JA 2

The input of the Joint WP is welcomed

- ***Implementation of HTA Network strategy***
 - Reflection paper on the conditions to facilitate take up and re-use at national level of joint HTA production including information and joint assessments – planned Spring 2015

SEED (Shaping European Early Dialogues for Health) – EC tender

- **Early Dialogues:**

Dialogues between companies developing health products and HTA agencies to present development plan for the product in question and to ask to HTA agencies specific questions relative to their plan.

To facilitate generation of evidence useful for CT but also for HTA purposes, when appropriate and possible.

SEED (Shaping European Early Dialogues for Health) – EC tender

- *Expected output:*
 - Methodological protocols and codes of conduct
 - Recommendations for a permanent model for conducting early dialogues for HTA bodies
- *Based on 10 Early Dialogues (ED)*

Patients to volunteer to join the "parallel EMA-HTA" advice, as observer, are welcome
Please contact SEED:

earlydialogues@has-sante.fr



www.eunethta2014.it

Under the patronage of the Italian Ministry of Health



Thank you for your attention
flora.giorgio@ec.europa.eu