HTA NETWORK REFLECTION PAPER on The interaction between regulatory and HTA issues on pharmaceuticals

Simona Montilla, AIFA

10th November 2016

HTA NETWORK REFLECTION PAPER on The interaction between regulatory and HTA issues on pharmaceuticals

Objectives

- ✓ *"identifying 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 while guaranteeing the sustainability of healthcare systems"*

- ✓ *"identifying areas that can be addressed in <u>both the short and medium-long term</u> in which cooperation can bring benefits"*

- ✓ It was decided to focus first on pharmaceuticals

Approach

Pre-marketing phase	Market Entry phase	Post-marketing phase
• Possible areas for collaboration • Action points to be addressed	• Possible areas for collaboration • Action points to be addressed	• Possible areas for collaboration • Action points to be addressed

However, in several activities, while the distinction is useful (between life cycles phases), a continuous link between the different phases will need to be implemented, for example generation of Real World Evidence Data may need to be considered both at pre and post- marketing phase.

Possible areas for collaboration

- **Pre-marketing phase** (Early dialogues/scientific advice; Concepts such as unmet clinical need and therapeutic innovation, Horizon scanning programmes; Disease-specific guidelines, Fostering cooperation on research needs)
- **Market entry phase** (Sharing information on approaches for the identification of the eligible population; Early sharing of information between regulators and HTAs; Optimisation of the regulatory assessment reports)
- **Post-marketing phase** (Guidance on the design of post-marketing authorisation studies; "Late dialogues" concept; Collaboration around real world data (RWD) generation)

Process 1

February 17 2016

- Meeting of the WG on regulatory and HTA issues: AT, DE, HU, IT, NL, SE, PL, NO, UK
- Nomination of Rapporteur (IT) and co-Rapporteur (UK and NO)
- Discussion and identification of aims of the Paper and of main areas for collaboration

March 23 2016

- First version for co-Rapporteur review and comments

April 5 2016

- Second version for WG review and comments

April 20 2016

- Ad hoc stakeholders consultation

Process 2

June 2016

- Presentation of the draft Reflection Paper to STAMP
- Comments by 1 September 2016

June 2016

- Presentation of the draft Reflection Paper to HMA
- Comments by October 2016

September 2016

- Fine-tuning of the Reflection paper by the Rapporteur and Co-rapporteurs taking into account comments from stakeholders

October 2016

- Circulation of the revised Reflection Paper to the WG => FINAL

Main comments

- ✓ **STAMP and HMA**
  - ✓ Recognised the importance of building synergies between regulatory and HTA bodies
  - ✓ Positive, constructive comments
  - ✓ Need to respect the remits of all involved parties
  - ✓ Need to coordinate with similar planned/on-going activities/initiatives from regulators (e.g. HMA Multi Annual Work Plan)
  - ✓ Requests for clarifications and fine-tuning of the text (e.g. declaring vs handling conflict of interests in early dialogues/scientific advice, RWD vs RWE)
  - ✓ Need to clarify the implementation mechanism for the activities identified in the Reflection paper

Next steps

- ✓ ADOPTION by the HTA Network
- ✓ REFLECT on the implementation mechanism

  →Synergy group ?

  - For mapping and prioritisation of activities identified in the Reflection Paper
  - Representation from all interested parties (HTA Network, EUnetHTA, STAMP, HMA, EMA, …)