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

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20th May 2016

HTA NETWORK REFLECTION PAPER on The interaction between regulatory and HTA issues on pharmaceuticals - Draft 1

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

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

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)
- **Post-marketing phase** (Guidance on the design of post-marketing authorisation studies; Collaboration around real world data (RWD) generation)

Stakeholders: main comments

- ✓ Fostering cooperation on research needs which could address regulatory and HTA issues
- ✓ Handling conflict of interests in early dialoge/scientific advice
- ✓ Patients and healthcare professionals involvement in the interaction between Regulatory and HTA bodies (for istance in early dialogues/scientific advices process), building on existing experiences and practices.

Next steps : content

- ✓ Further discussion by HTA Network on possible areas for collaboration

- ✓ HTA Network discussion and identification of actions to be addressed in both the short and medium-long term

Next steps : process

- ✓ Revised version following the HTA Network comments
- ✓ Further consultation of the Regulatory side

  (e.g.: Heads of Medicine Agency, STAMP)
- ✓ WG meeting (to be confirmed)
- ✓ Plan for adoption by the HTA Network at the meeting in November 2016
- ✓ Implementation plan (who takes lead on proposed actions)