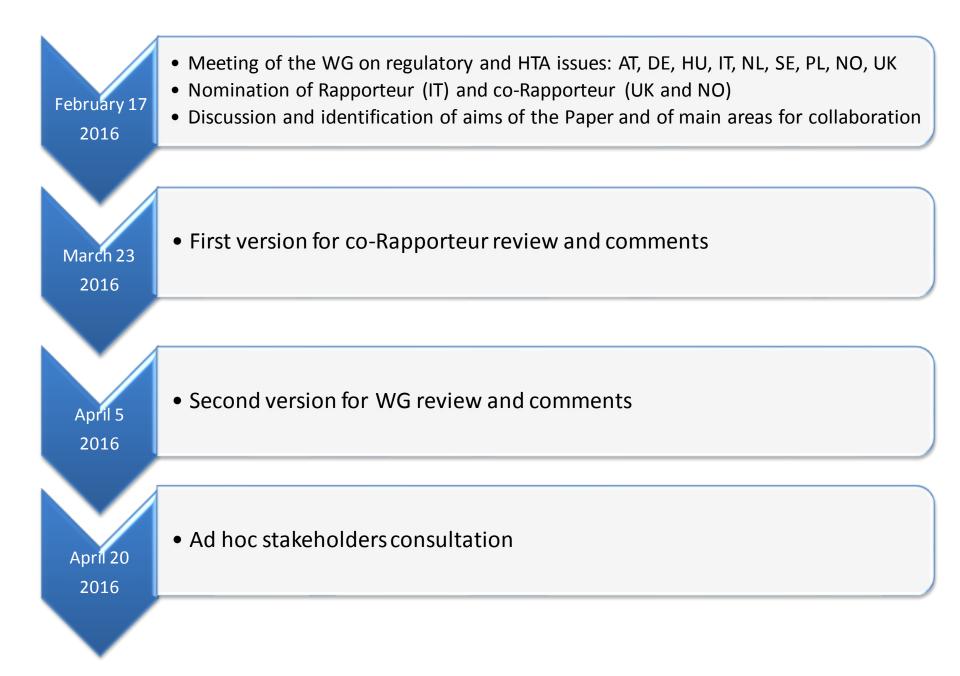
HTA NETWORK REFLECTION PAPER on The interaction between regulatory and HTA issues on pharmaceuticals

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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</u> <u>medium-long term</u> in which cooperation can bring benefits"
- ✓ It was decided to focus first on pharmaceuticals





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)