Reflection Paper on synergies between regulatory and HTA issues

DG SANTE

Unit B4 – Medical products: safety, quality, innovation

STAMP meeting, 28 June 2016

Health

European Commission

Outline

- Aim of the Reflection Paper
- Drafting process
- Areas for possible collaboration
- Input from STAMP and HMA
- Next steps

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EU Cooperation on HTA

HTA Network

- **Policy and strategic cooperation**
- Set up October 2013
- Art 15 Directive 2011/24/EU
- MS representatives (mainly MoH)

EUnetHTA Joint Action

- **Scientific and technical cooperation**
- JA 3 launched in June 2016
- Co-funded by the Public Health Programme and MS
- HTA doers (mainly HTA Agencies)

- These two levels work in synergy and complementary
- Involvement of stakeholders - both at strategic level and scientific level

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1. Aim of the Reflection Paper

- **To identify 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.
  - On-going and new activities
  - To be addressed in both short and medium/long term
- Focused on pharmaceuticals
- Implementation of the activities identified - not in the scope of the Reflection Paper yet…

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2. Drafting process so far

- Drafting WG – 1 meeting (February 2016)
  - 9 MS: AT, DE, HU, IT, NL, NO, PL, SE, UK + EUnetHTA and EMA
  - Rapporteur: IT (AIFA). Co-Rapporteurs: NO and UK
- Consultation of stakeholders (April 2016)
- Presentation of draft Reflection Paper to HTA Network (May 2016)
- Collecting input from all MS
- Revision of Reflection Paper by including comments from all MS – recirculation to HTA Network

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3. Areas for possible collaboration

a) Pre-marketing phase

- Early dialogues/scientific advice with developers of pharmaceuticals involving regulators and HTAs
- Alignment in the definition and application of concepts such as unmet medical need and therapeutic innovation
- Horizon scanning programmes for the identification of emerging therapies with potential added value, but uncertainty on clinical outcomes needs.
- Foster research and dialogue with main stakeholders mainly in therapeutic areas with unmet medical needs
- Foster cooperation on research needs which address regulatory and HTA issues (e.g. methodologies, such as novel study design, selection of comparators, validation of endpoints and scientific guidelines).

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3. Areas for possible collaboration

b) Market entry

- Sharing information on approaches for the identification of the eligible population to the treatment
- Early sharing of information between regulators and HTAs in order to facilitate efficient mechanisms for patient access to novel pharmaceuticals
- Optimisation of the regulatory assessment reports (for example, structure and content) to better serve as reference for subsequent HTA.

c)Post-marketing launch phase

- Initiatives to jointly provide guidance on the design of post-marketing authorisation studies that can fulfil both regulatory and HTA information needs
- Collaboration around RWD generation, including mechanisms to facilitate greater engagement of pharmaceutical companies in data collection and sharing of periodic benefit-risk assessment reports and therapeutic value re-assessments.

4. Input from STAMP and HMA

- **Presentation of Reflection Paper to HMA** – 2 June
  - Circulation of Reflection Paper – written comments by September 2016

- **Presentation of Reflection Paper to STAMP** – 28 June
  - Written comments by 1 September 2016
  - Comments to be sent to:
    - Rapporteur A.Cangini@aifa.gov.it
    - Co-rapporteurs: Zoe.Garrett@nice.org.uk; Oyvind.Melien@helsedir.no; Kristin.svanqvist@noma.no
    - SANTE-HTA-NETWORK@ec.europa.eu

5. Next steps

- Finalisation of the Reflection paper by the HTA Network
  - incorporating input from HMA and STAMP
  - Consultation of drafting WG – 2nd meeting (September 2016 – to be confirmed)
- Planned adoption date 10 November 2016 (2nd annual meeting of HTA Network)
- Implementation of the identified areas for collaboration

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Thank you!

http://ec.europa.eu/health/technology_assessment/policy/network/index_en.htm