



EU cooperation on HTA

DG SANTE
B4 – Medical products:
safety, quality, innovation

27 March 2017

Outline

- 1. EU cooperation on HTA**
- 2. Follow-up of the Reflection Paper on Synergies between Regulatory and HTA issues
- Synergy group**
- 3. New initiative on strengthening EU cooperation on HTA – results of the public consultation**
- 4. Next steps**



HTA Network

- **Policy and strategic cooperation**
- Art 15 Directive 2011/24
- Set up October 2013
- Multiannual work programme
- **Permanent**



**Synergy and
complementarity**

EUnetHTA Joint Action

- **Scientific and technical cooperation**
- Started in the 1990's – EUnetHTA 1 & 2
- Joint Action 3 – **2016 – 2020**

Reflection Paper on synergies between regulatory and HTA issues (1)

Aim: *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**
- **Drafting WG: 9 MS + EMA**
- **STAMP and HMA provided input**
- **Unanimously adopted by the HTA Network in November 2016**

Reflection Paper – Follow-up (2)

Ad-hoc Synergy Group

Suggested and agreed by HTA Network as follow-up mechanism

"Ad hoc" coordination mechanism

Equal numbers of HTA representatives (i.e. HTA Network and EUnetHTA JA3) and regulators (i.e. STAMP, HMA, EMA).

Objectives:

- To map the actions identified in the Reflection paper (on-going or planned by different fora), in order to create synergies and avoid duplication and uncertainty;
- To facilitate contacts/interactions between different fora to contribute to the common objective of facilitating access to medicines;
- To suggest the best way forward in specific areas identified in the Reflection Paper.

Reflection Paper – Follow-up (3)

Ad-hoc Synergy Group

Composition

- Approx.10 experts
 - **5 HTA representatives: HTA Network (DE, FR, IT, PT, UK) and EUnetHTA**
 - **5 regulators' representatives: STAMP (2), HMA (2), EMA (1)**
- Chaired by the Commission.

Output

- A document outlining the mapping of actions relevant to the topics identifies in the Reflection Paper.
- A final report to the Commission - proposals for next steps to further improve synergies between regulatory and HTA issues

! STAMP and HMA - to send nominations by 28 March

Reflection Paper – Follow-up (4)

Ad-hoc Synergy Group

Proposed organisation of work

Election of Rapporteur

E-meetings + maximum two face to face meetings in Brussels

Additional work via e-mail.

Members of the Group will have to report back to their respective organisations ensuring that discussions and conclusions of the Synergy Group are reflected in the on-going activities of each organisation.

Policy options

Inception impact assessment

Option 1	Option 2	Option 3	Option 4	Option 5
Status quo – voluntary cooperation	Long-term voluntary cooperation (beyond 2020)	Cooperation through the collection, sharing and use of common tools and data	Cooperation on production of joint REA (relative effectiveness assessments) reports	Cooperation on production of joint Full HTA reports (REA+ Non-clinical: economic, ethical, legal, etc.)
Non-legislative / <i>voluntary</i>		Legislative / <i>voluntary + mandatory</i>		

+ Issues
to be addressed



Public consultation

- Launched: 21/10/2016
- Deadline: 13/01/2017

Total number of replies = 249

- **Questionnaire for citizens:** 63 (from 21 MS)

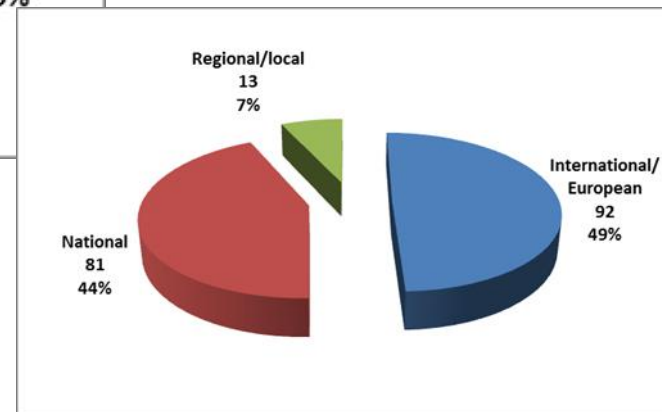
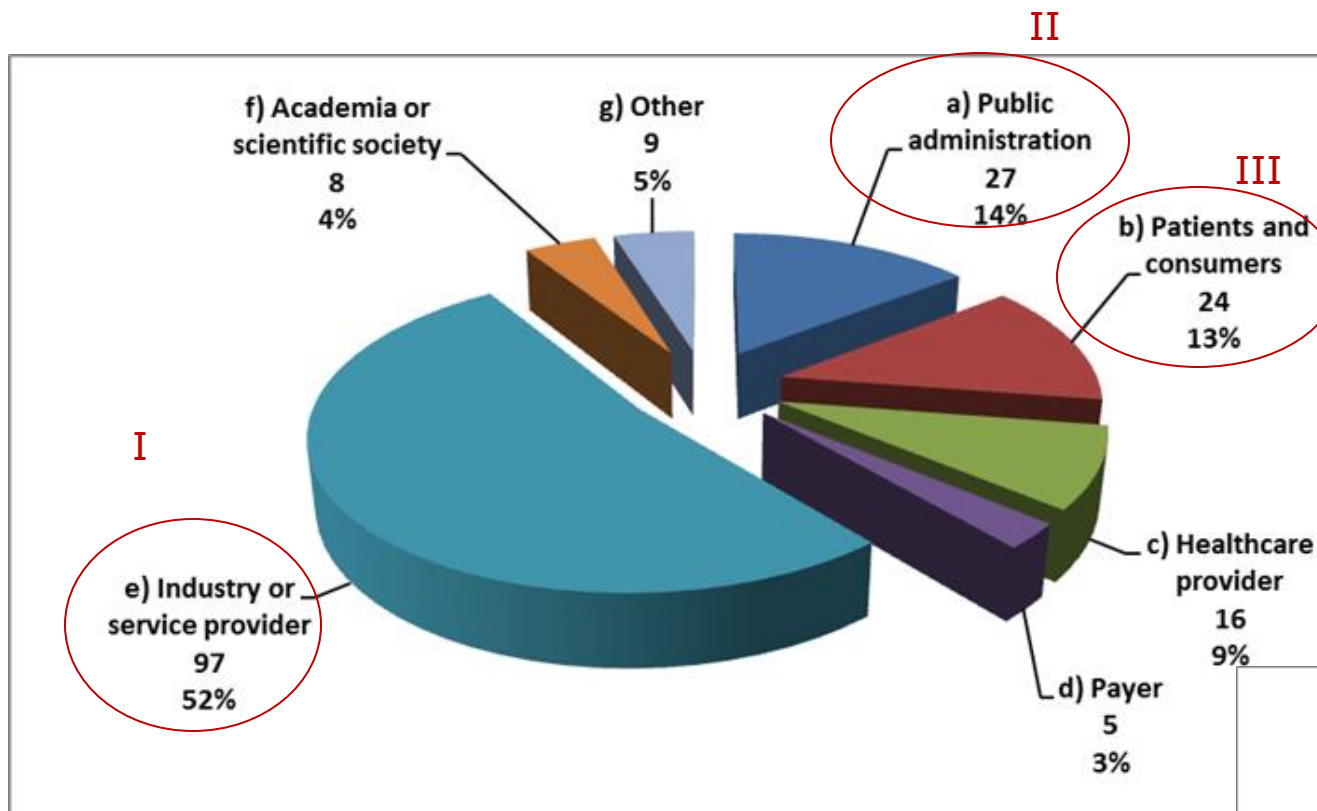
Profile: Tertiary education; with background/working in HTA sector, healthcare sector or industry

- **Questionnaire for administrations, organisations, associations:** 150
- **Questionnaire for SMEs** (DG GROW – SME Network): 36 replies



- **98% consider HTA useful**
- **83% consider very important or important** to assess whether a new health technology works better, equally well or worse than health technologies already available
- **Most important factors to be considered when carrying out HTA** (very high or high importance):
 - Transparency of the HTA process (98 %) -> involving stakeholders
 - Expertise of the assessor (96%) -> high-quality reports
 - Independence of the assessor (94%) -> no conflict of interest
 - Timely delivery of the assessment report (92%) -> useful for decision making
- **HTA information should be accessible to doctors and patients/patients' representatives**
- **57% consider that clinical assessment should not be performed in parallel by HTA bodies in the MS**

186 contributions



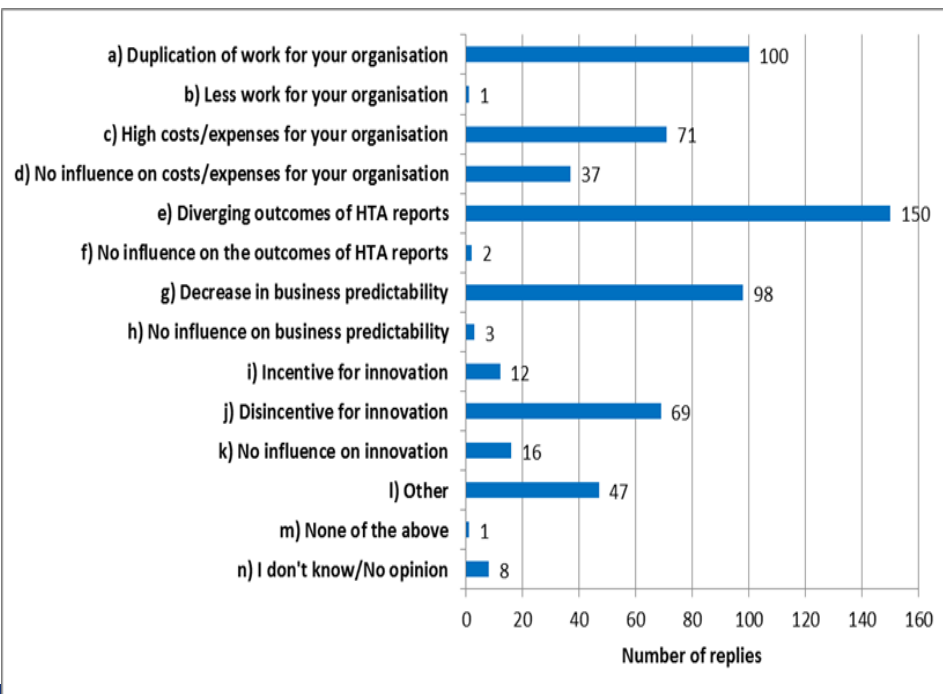
Differences between MS acknowledged by most respondents, including

(agreement + strong agreement)

- HTA processes 91 %
- HTA clinical methodology 80 %
- HTA economic methodology 85 %

Most important consequences of the different HTA procedures and/or methodologies across EU

- Diverging outcomes of HTA reports
- Duplication of work
- Decrease in business predictability
- High costs for the organisations
- Disincentive for innovation



Current EU cooperation

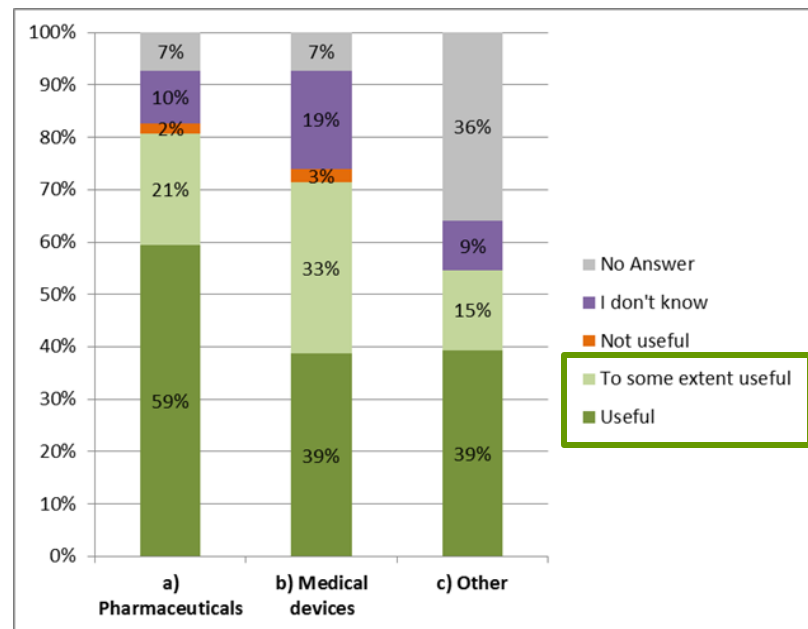
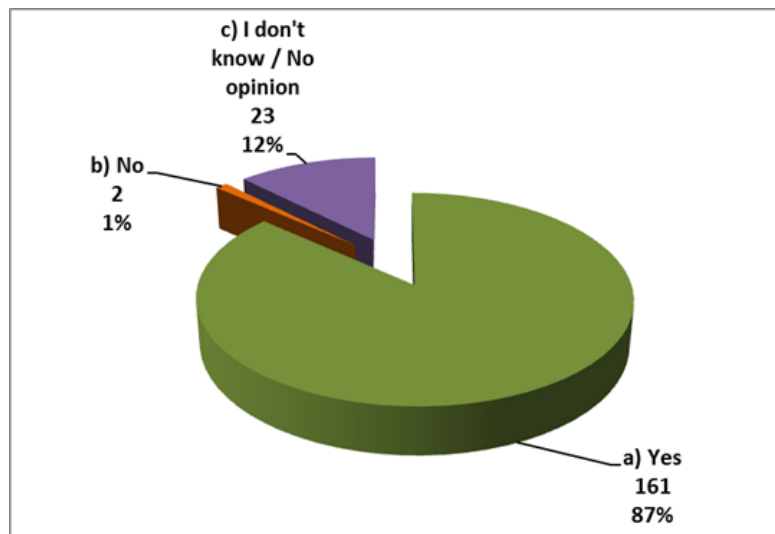
- **Participation** to EU-funded actions: 32%
- **Awareness** of EU funding actions: 47%
- EU cooperation **useful/to some extent useful**: 69%

Uptake of joint work remained low:

E.g. Used to a **great/limited extent**:

- Joint tools – 9/33%
- Guidelines – 9/32%
- Early dialogues – 11/23%
- Joint clinical assessments (REA) – 3/51%
- Joint full HTA (clinical + non-clinical/economic) – 1/21%

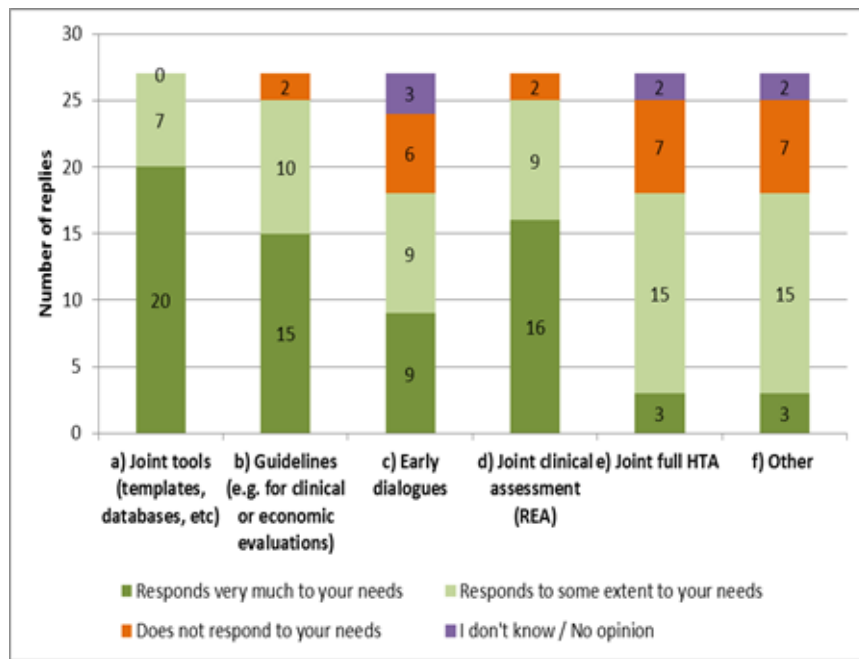
- **EU cooperation beyond 2020: supported by:**
 - **87% of all respondents**
- **Scope of EU cooperation** (useful and to some extent useful)
 - Pharmaceuticals 80%
 - Medical technologies 72%
 - Other technologies 54%



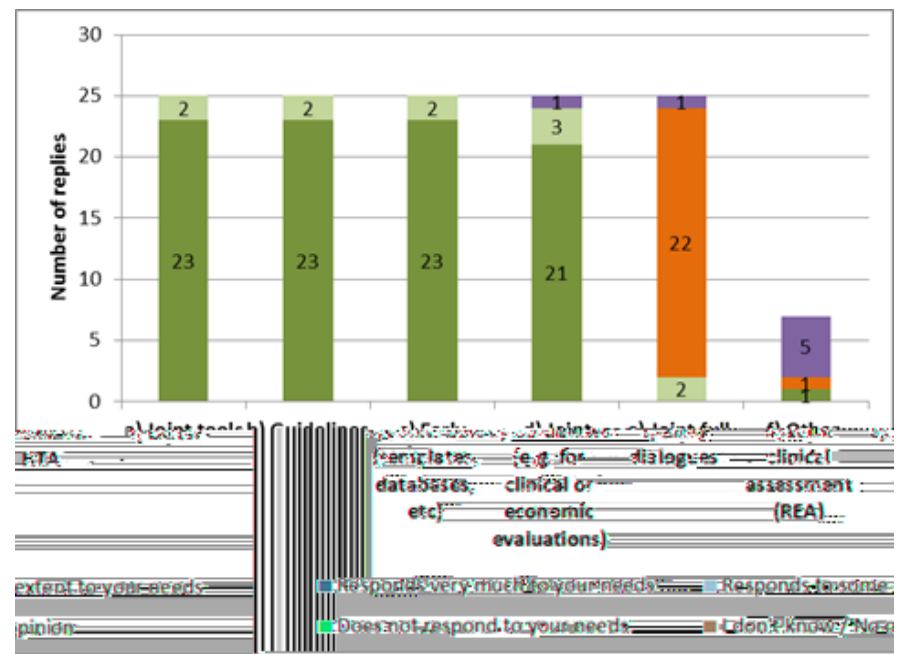
EU cooperation beyond 2020

Different needs for EU joint activities

Public administration



Pharmaceutical industry



- **Publication of the public consultation report** – 2nd quarter 2017
- **Conclusion of studies supporting the impact assessment** – 2nd quarter 2017
- **Consultation meetings** (Member States authorities, HTA Network, EUnetHTA, stakeholders) – on a continuous basis
- **Impact assessment**
- **Proposal**



Thank you for your attention!

Ioana-Raluca.Siska@ec.europa.eu

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