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

EU cooperation on HTA

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**

eunethta

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 / *voluntary*		**Legislative / *voluntary* + *mandatory***		

+ Issues to be addressed

Scope

Funding mechanism

Coordination /secretariat

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

Public consultation

- 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

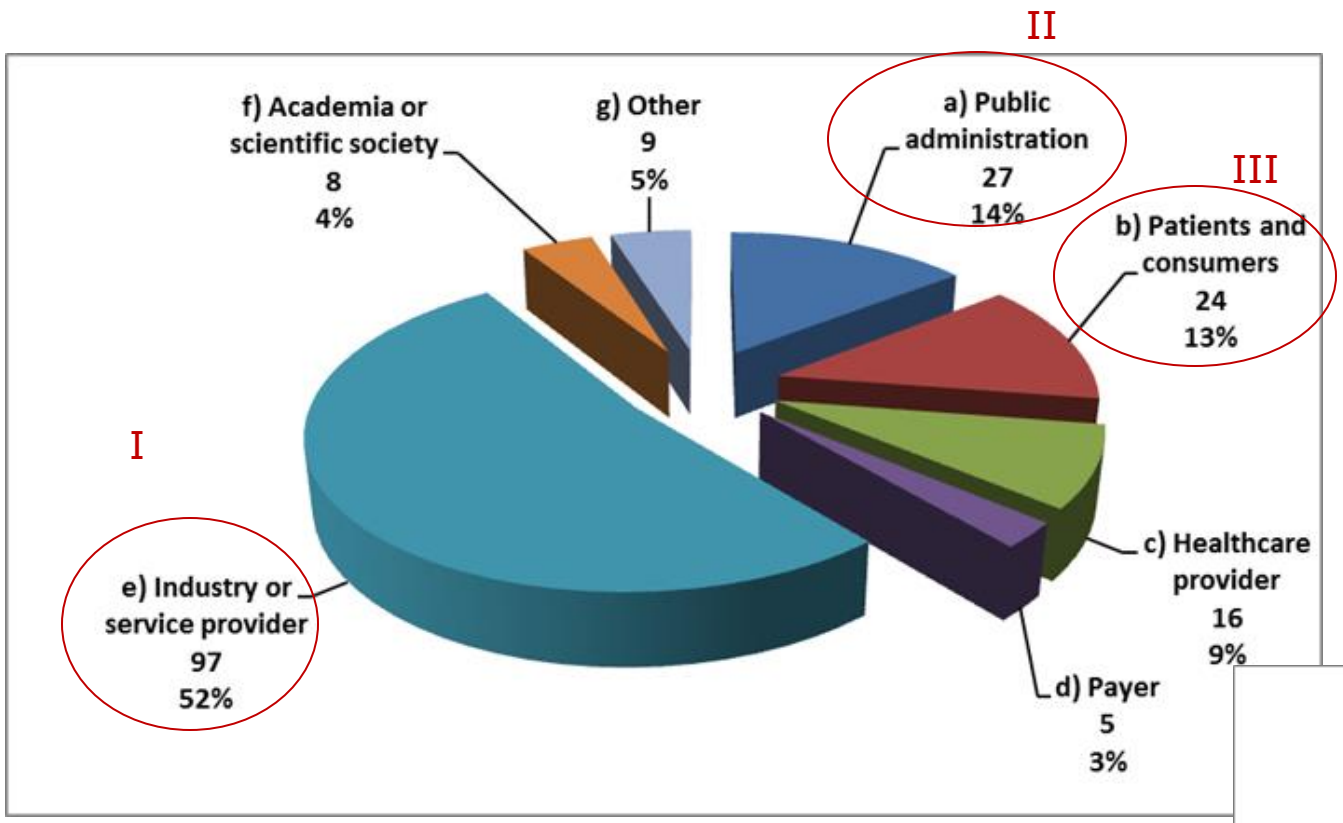
- **HTA information should be accessible to doctors and patients/patients' representatives**
- **57% consider that clinical assessment should not be performed in parallel by HTA bodies in the MS**

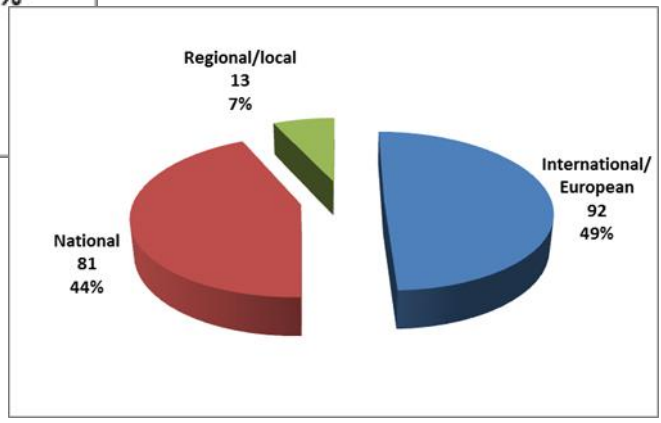
Administrations, associations, organisations (1)

European Commission

Public consultation

186 contributions





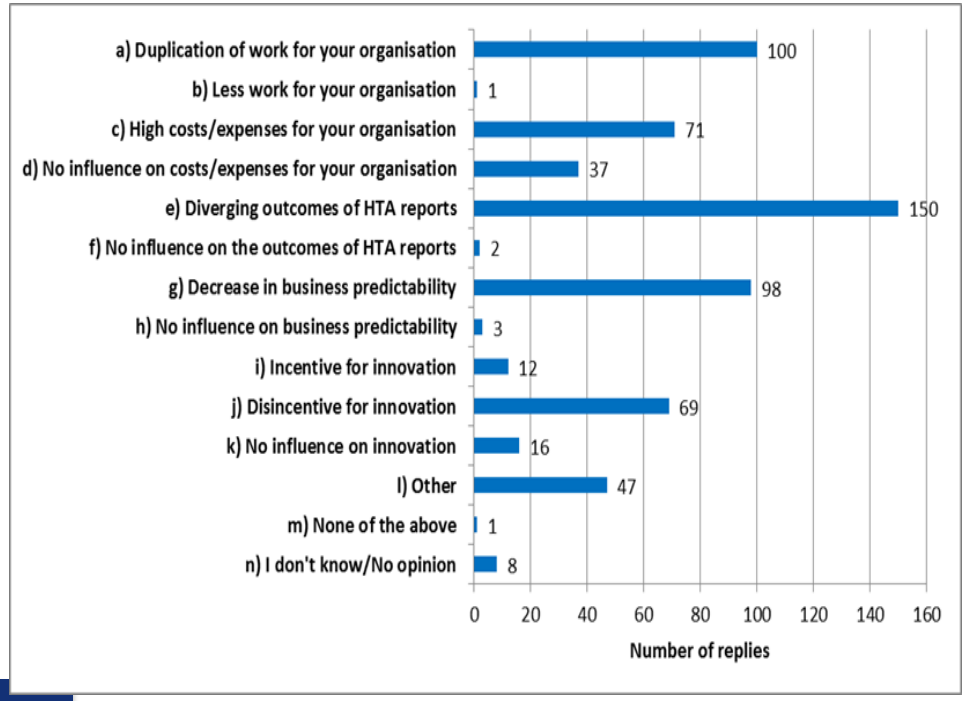
Differences between MS acknowledged by most respondents, including

(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**:

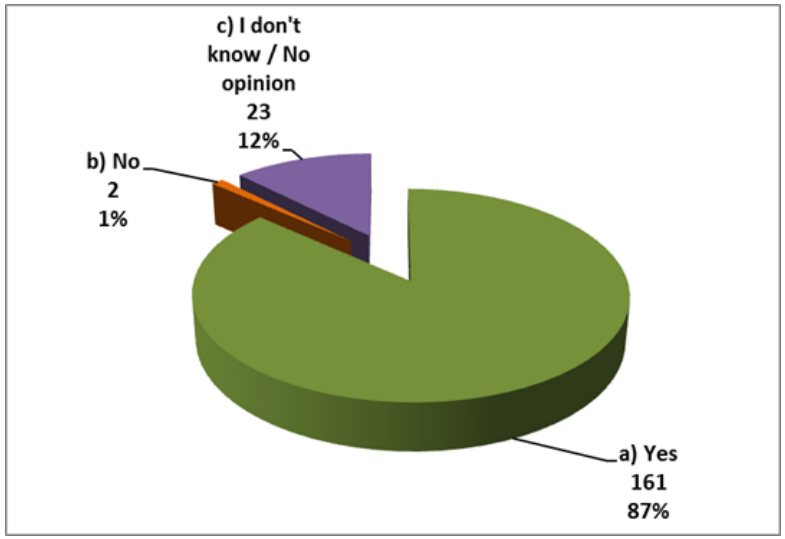
- Joint tools – 9/33%
- Guidelines – 9/32%
- Early dialogues – 11/23%
- Joint clinical assessments (REA) – 3/51%
- Joint full HTA (clinical + non-clinical/economic) – 1/21%

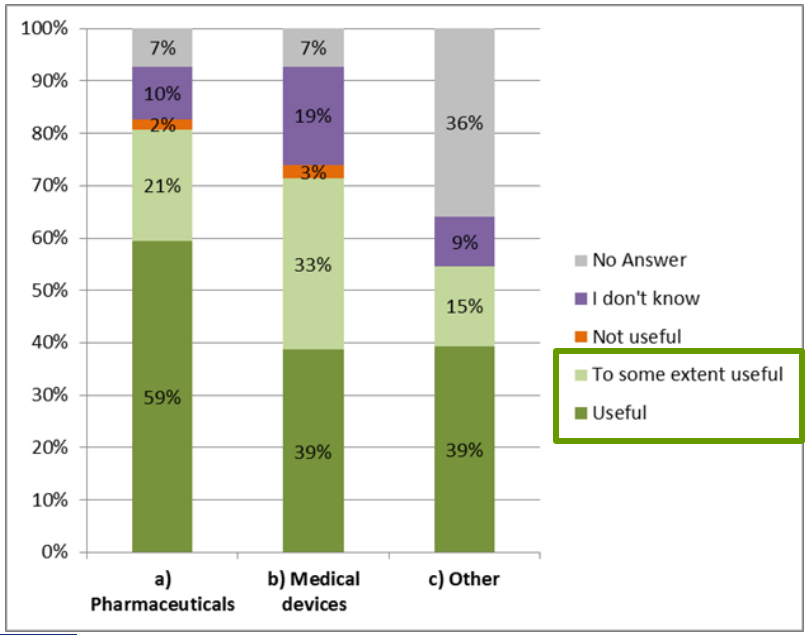
European Commission

Public consultation

- **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%



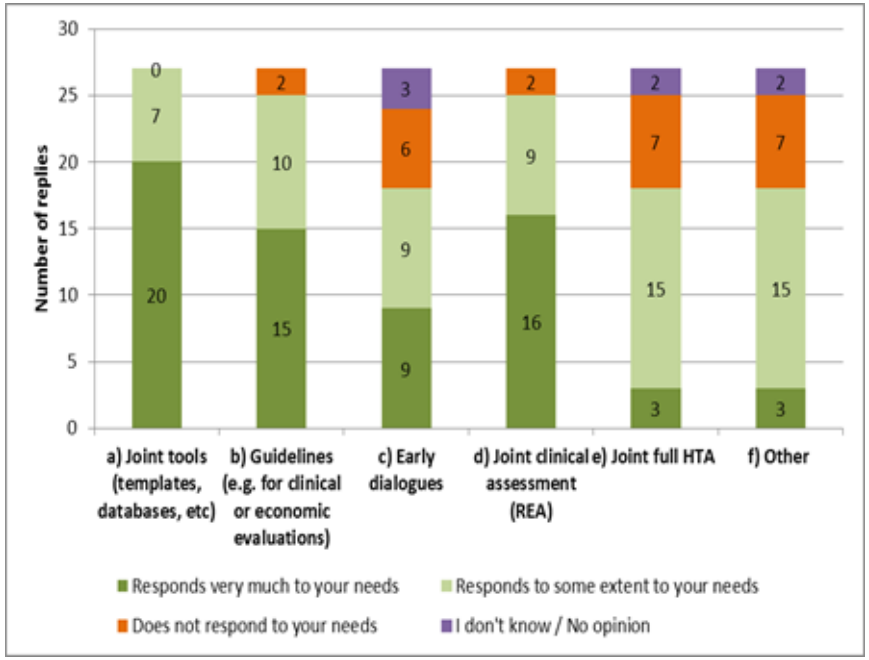


European Commission

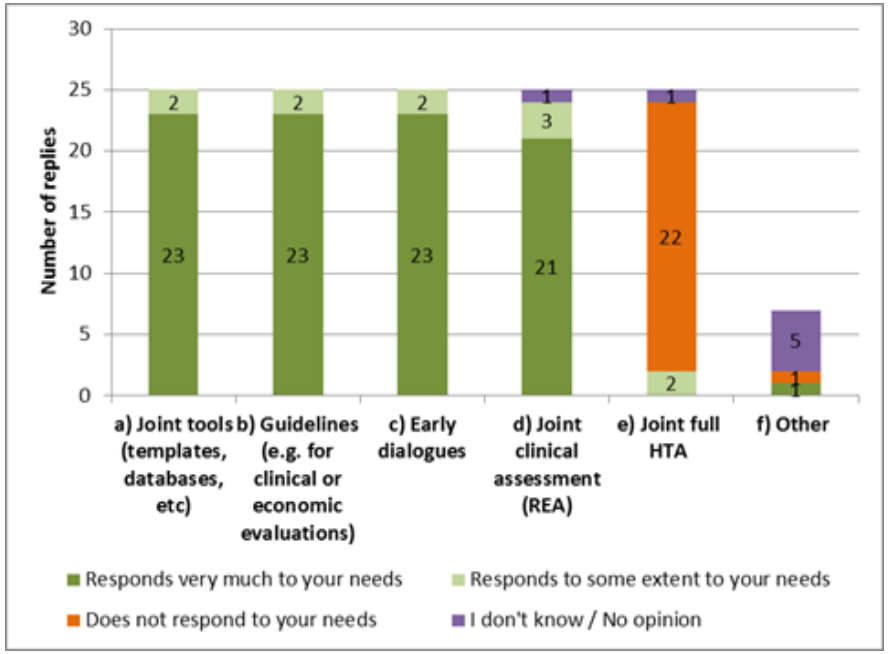
EU cooperation beyond 2020

Different needs for EU joint activities

Public administration



Pharmaceutical industry



Next steps

- **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