HTA IN EUROPE: understanding the wider impact of the European Commission proposal

Recap: EU cooperation on HTA

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Health programme	**2005** Call for project proposals		**2009** Call for joint action	**2011** Call for joint action		**2014 - 2020** Financial support HTA
eunethta		**2006-2008** EUnetHTA Project	**2009** EUnetHTA Collaboration	**2010 - 2012** EUnetHTA Joint Action 1	**2012 - 2015** EUnetHTA Joint Action 2	**2016 - 2020** EUnetHTA Joint Action 3
Legislation			**2008-2011** Draft Cross Boarder Healthcare Directive. Article 15 HTA network	**2011-12** CBHC Directive now decided		**2013 & +** EU Cooperation on HTA Implenting Decision HTA Network
DG R&I				**2011 FP7 –** Health **2012 -** Innovation – 1 New methodologies for HTA		**Horizon 2020 Calls Health Care**

Recap: HTA Core Models Domains

	HTA Core Models DOMAINS
*Rapid REA**	1. Health problems and current use of technology
	2. Description and technical characteristics
	3. Safety
	4. Clinical effectiveness
Full HTA	5. Costs and economic evaluation
	6. Ethical analysis
	7. Organisational aspects
	8. Patients and social aspects
	9. Legal aspects

Source: EUnetHTA Joint Action definition.

*Rapid REA : Relative Effectiveness Assessment

Recap: EC Inception Impact Assessment 2016

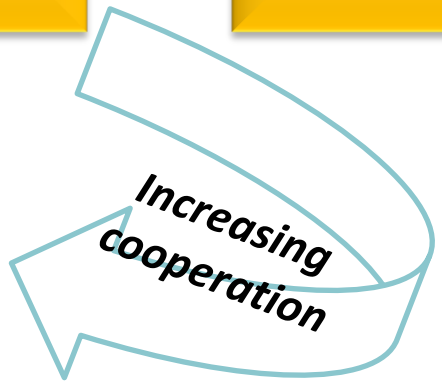
POLICY OPTIONS

OPTION 1

The status quo with Joint Action until 2020. HTA is regulated and organised at national/regional level. Voluntary cooperation mechanism through the current JA and the HTA Network until 2020.

OPTION 2

Long-term voluntary cooperation, financed by the EU **beyond 2020**. This option foresees the continuation of the current cooperation model, but on a longer-term basis.



OPTION 5

Cooperation on production of joint Full HTA reports and their uptake. **Joint production of Full HTA reports**, comprising not only the assessment of clinical/medical domains but also the assessment of economic, ethical, legal and organisational domains.

OPTION 3

Cooperation on collection, sharing and use of common tools and data. Introduction of a legal framework for HTA cooperation to enable the efforts by national bodies to be compatible, shared and used. This will ultimately allow for the production of **joint REA reports on a voluntary basis**.

OPTION 4

Cooperation on production of joint Relative Effectiveness Assessments (REA) reports and their uptake. **Mutual recognition of HTA assessment opinions applying joint REAs at national level.** Establishment of a **central structure** in charge of managing the preparation, coordination and follow-up reports.

The European Commission Proposal

January 31st 2018 - **Proposal for a "Regulation of the European Parliament and of the Council on Health Technology Assessment and amending Directive 2011/24/EU"**

Reinforcing cooperation amongst Member States

4 main pillars for joint work of Member States on which the proposal is built

1. **Joint clinical assessments** focusing on the most innovative and potentially impactful health technologies;

2. **Joint scientific consultations** whereby developers of a health technology can seek the advice of HTA authorities on what type of data and evidence is likely to be required in the submission for HTA;

3. **Identification** of **emerging health technologies** to help ensure that the most promising health technologies for patients and health systems are identified early and included in the joint work;

4. **Voluntary cooperation** in areas **outside** the scope of mandatory cooperation.

Main features of the EC proposal (1/3)

THE COORDINATIN GROUP

- A **Member State Coordination Group** on HTA composed of representatives from national HTA authorities and bodies will be responsible for overseeing the joint clinical assessments and other joint work;

- **National experts** organised in **sub-groups** dedicated to the specific types of joint work will carry out joint clinical assessments and other joint work (for example joint scientific consultation);

- The work of the **Coordination Group** will be supported by the European Commission, which will host the meetings of national HTA experts providing scientific, secretarial and IT support, and facilitating cooperation with other EU organisations.

- The Commission will be responsible for making sure that the work of the Coordination group is carried out **independently and transparently**, and the timing and quality of the joint work complies with the requirements set in the Regulation

Main features of the EC proposal (2/3)

JOINT SCIENTIFIC CONSULTATION (*early dialogues*)

- Allow a developer in the development phase of a health technology to **seek the advice of HTA authorities** and bodies on the **data and evidence** likely to be required as part of a **potential future joint clinical assessment** ;
- Health technology developers can make a **request to the Coordination Group** for a joint scientific consultation

EMERGING HEALTH TECHNOLOGY (*horizon scanning*)

- **Identification** of emerging health technologies (annual study under the responsibility of the Coordination Group);
- This exercise will act as a key input for the annual work programmes, helping to ensure that the **health technologies expected to have a major impact on patients**, public health or healthcare systems are **identified at an early stage** in their development and are included in the joint work of the Coordination Group.

VOLUNTARY COOPERATION

- Member States have the possibility to continue to cooperate on a **voluntary basis** at Union-level;
- This voluntary cooperation would allow for HTA on **health technologies** other than medicinal products or medical devices, non-clinical assessments, collaborative assessments on medical devices i.e. on medical devices **not selected for joint clinical assessment**, and cooperation on the provision of additional evidence which can facilitate HTA.

Main features of the EC proposal (3/3)

JOINT CLINICAL ASSESSMENTS

- Will be limited **to the most innovative technologies** with the highest potential impact on public health under the categories of **medicines and medical devices** (including in vitro diagnostic and medical devices which have received an opinion of relevant experts at EU-level under the new EU Regulations on medical devices);

- **Will not affect market approval**, indeed the joint clinical assessments will only be completed after the products have obtained a marketing authorisation or a CE marks, depending on the product;

- Will be used by Member States as part of their national HTA processes with the aim **not to repeat the joint clinical assessment**;

- **Can be completed** by Member States with assessments concerning non – clinical HTA domains;

- The **timing** of the procedure for joint clinical assessments will be coordinated with that of the central marketing authorization procedure (for medicines), and decided case by case for medical devices.

- The **number of joint clinical assessments** will increase gradually during the first 3 years after the date of publication, to reach (after 3 years) all medicines under the central marketing authorization approval procedure.

Main features of the EC proposal (3/3)

- ✓ **Harmonization of REA** - *Relative Effectiveness Assessment* - procedures among Member States for national HTAs agencies;

- ✓ **P&R and Access schemes** are left in the responsibilities of national regulatory organizations;

- ✓ Members States have the possibility **to use common instruments for the evaluation of safety and efficacy of innovative products** and the opportunity to create **early – dialogue meetings** between the technologies' producers and the Coordination Group during the development stage of the product which will undergo the evaluation;

- ✓ The attempt to **institutionalize the "cooperation"** between Member States and the EU Institutions trough the Coordination Group's activity, directly monitored and supported by the European Commission.

Key Questions

1. Do you think that the European Commission's proposal **satisfy the requests** of the different stakeholders, in particular the ones arising from the public consultations?

2. To what extent do you think that the EC proposal will help to **overcome the bottlenecks in the cooperation process** between Member States in the field of **relative effectiveness**?

3. Do you agree with the proposed creation of a **Coordination Group**, supported and supervised by the EC?

3. Do you agree with REA reports **not to affect market approval** at national level?

4. Do you think it will be possible in the future **to extend this model from REA to full HTA**? Do you think the direction is to link results of a full HTA reports with the decision of regulatory agencies at national level?

5. To what extent do you think the EC proposal will **ease and foster a wider access** to treatment, especially for **innovative** medicines and medical devices, for EU citizens?

Piazza dei Santi Apostoli 66
00187 Roma
tel. +39 06 4740746
fax + 39 06 40402523
info@i-com.it
www.i-com.it