Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

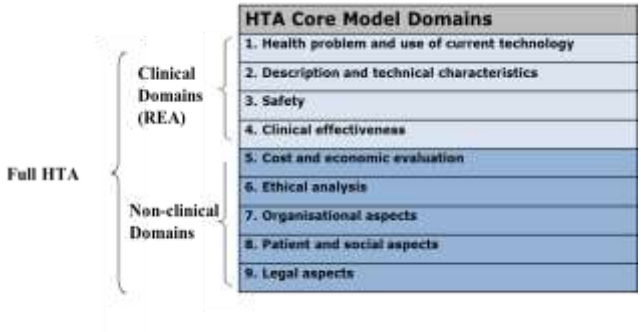
on health technology assessment and amending Directive 2011/24/EU

Orsi NAGY
DG SANTE - Health Systems and Products
Medical Products: safety, quality, innovation

13th November 2018

Background

HTA = "a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value" (as defined by EUnetHTA JA).



Background

HTA across EU

Differences in:
- Procedural framework
- Methodology

Scope
- Medicinal products

→ 26 MS and NO
- Medical devices

(same/dedicated HTA body)

→ 21 MS* and NO
- Under development

→ 2 MS

Overview of HTA activity

Key: N=31 countries with England, Scotland and Wales counted separately; red = no current HTA procedure; blue = pharmaceuticals only; yellow = both pharmaceuticals and non-pharmaceuticals

* In Wales HTA on medical devices is under development

(EUnetHTA, WP7 report, 2017)

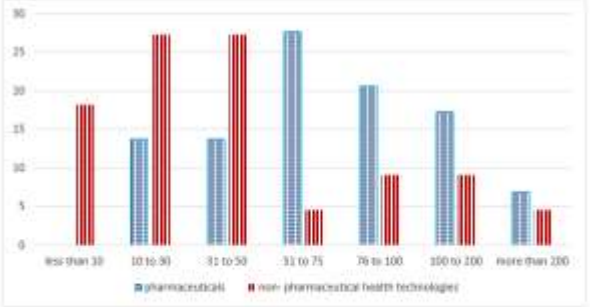
Background

HTA across EU

Number of assessments

The number of topics considered across the countries varies considerably (figure 4). The number of assessments or evaluations of pharmaceuticals ranges from approximately 20 per year to 500. For non-pharmaceutical health technologies the range is less than 10 per year to up to 400. In general, across countries a greater number of pharmaceutical than non-pharmaceutical HTAs are carried out. Among the regional agencies the number of assessments carried out ranges from an average of 3 (UETS Madrid, Spain), to 40 (AQuAS, Spain).

Figure 4: Number of topics considered in each country per year (% countries)



Key: Data for 29 countries (pharmaceuticals) and 22 countries (non-pharmaceutical health technologies)

(EUnetHTA, WP7 report, 2017)

Mapping – medical devices HTA

Sample:

15 medical device and 5 other technology-indications pairs

Findings:

- More fragmented market access path

- Higher variation of clinical evidence and methodologies used

BUT duplication exists

- Eight countries considered economic evaluation with an average number of studies 2.5 studies per technology.

- Type of economic evaluation,

- cost-utility studies
- cost comparisons
- budget impact analysis

Study on impact analysis of Policy Options for strengthened EU cooperation on Health Technology Assessment (GOEG, LSE)
https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2018_ia_policyoptions_en.pdf

Why an HTA initiative?

More than 10 years of cooperation: projects, joint actions

ACHIEVEMENTS

- **Trust** between HTA bodies
- **Capacity building**
- Development of **joint tools** (e.g. EUnetHTA Core Model, POP EVIDENT databases)
- Piloting **joint work** (e.g. early dialogues, joint assessments)
- **Collaborative assessments – involving few MS – on CLINICAL aspects**

LIMITATIONS

- **Low uptake of joint work** ⇒ duplication of work
- Differences in the **procedural framework** and administrative capacities of Member States
- Differences in national **methodologies**
- **No sustainability** of current cooperation model

PROPOSAL

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on health technology assessment and amending Directive 2011/24/EU

- The Regulation establishes:
  - **support framework and procedures for cooperation** on health technology assessment at Union level
  - **common rules for clinical assessment** of health technologies

The Regulation **shall <u>not</u> affect** the rights and obligations of Member States with regard to the organisation and delivery of health services and medical care and the allocation of resources assigned to them.

PROPOSAL

Outline of the proposal (1)

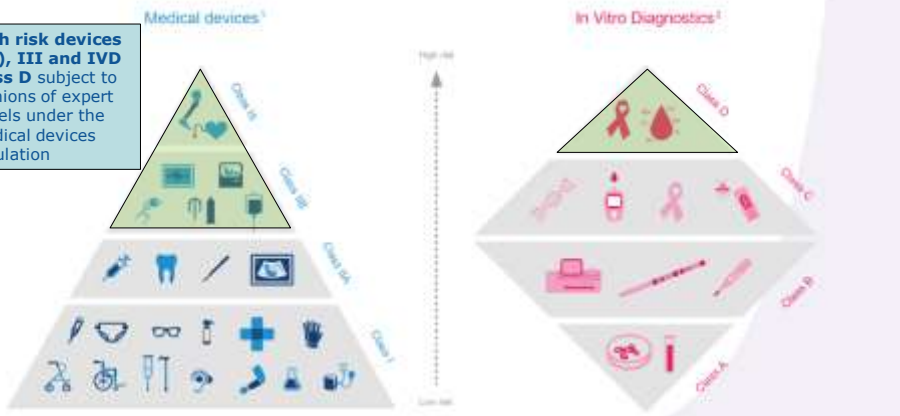
- **Provides support framework** and procedures for EU cooperation on HTA
- **Well defined scope** – E.g. **selection of medical devices**

(for which joint clinical assessments bring added value)

- ***MD class IIb and III*** for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure
- ***IVDs - class D*** for which the relevant expert panels have provided their views in the framework of the clinical evaluation consultation procedure

Examples of high-risk medical devices

High risk devices IIb), III and IVD class D subject to opinions of expert panels under the medical devices regulation



[1]*The classification of medical devices is a 'risk based' system based on the vulnerability of the human body taking account of the potential risks associated with the devices. The classification rules are based on different criteria such as the duration of contact with the patient, the degree of invasiveness and the part of the body affected by the use of the device.*
[2]*IVD classification is based on the degree of health risk posed to an individual and public, and is related to the risk of an incorrect result arising from the use of the IVD.*

PROPOSAL

Key elements

- Focus on **clinical** aspects
- **Member States** driven approach
  - National agencies to do scientific work — **Articles 6, 13**
  - Annual programme decided by the Coordination group — **Articles 3-4**
  - Approval of joint reports by Coordination Group — **Articles 6, 13**
  - EC to provide secretariat (administrative, scientific, IT) — **Article 25**
  - EC to publish the joint reports — **Articles 7, 27**

Key elements

- Enable **synergies** between regulatory and HTA issues, but maintain processes separate

Articles 11, 16

- **Defined areas of joint work – LIFE-CYCLE Approach**

Articles 5-11

- Joint clinical assessments/JCA (REA)

Articles 12-17

- Joint scientific consultations/JSC (early dialogues)
- Horizon scanning/Emerging health technologies

Article 18

- Voluntary cooperation

Article 19

Article 19 – Voluntary cooperation

(a) non-clinical assessments on health technologies;

(b) collaborative assessments on medical devices;

(c) health technology assessments on health technologies other than medicinal products or medical devices;

(d) the provision of additional evidence necessary to support health technology assessments.

Key elements

- **High quality** – Member States experts
- **Timely output** — Recitals 17-18
  - **For medicinal products –** by the time of publication of the EC Decision granting marketing authorisation
  - **For medical devices** → flexible timeline (at or after market launch)
- **Transparency and independence** — Article 22.1.
  - Publication of reports
  - Conflict of interest procedures
  - Clear procedures for involving stakeholders both on horizontal and product-specific issues
- Pragmatic **phase-in** approach — Articles 33, 36

Phase-in approach

Timeline

+ Recitals 29-30

- Member States **may delay their participation** in the system of JCA and JSC until **3 years after the date of application**
- **Prioritization** of health technologies subject to JCA, JSC

Proposition

European collaboration can help the development of HTA methodologies adapted to the specificities of medical devices

Thank you!

Contact: SANTE-HTA@ec.europa.eu