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

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)

---

**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 (LETS Madrid, Spain), to 40 (AQuAS, Spain).

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

(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)

Background

Why an HTA initiative?

More than 10 years of cooperation: projects, joint actions

<table>
<thead>
<tr>
<th>ACHIEVEMENTS</th>
<th>LIMITATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trust between HTA bodies</td>
<td>Low uptake of joint work ⇒ duplication of work</td>
</tr>
<tr>
<td>Capacity building</td>
<td>Differences in the procedural framework and administrative capacities of Member States</td>
</tr>
<tr>
<td>Development of joint tools (e.g. EUnetHTA Core Model, POP EVIDENT databases)</td>
<td>Differences in national methodologies</td>
</tr>
<tr>
<td>Piloting joint work (e.g. early dialogues, joint assessments)</td>
<td>No sustainability of current cooperation model</td>
</tr>
<tr>
<td>Collaborative assessments – involving few MS – on CLINICAL aspects</td>
<td></td>
</tr>
</tbody>
</table>
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 not 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.

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

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.

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.

Key elements

- Focus on **clinical** aspects
- **Member States** driven approach
  - National agencies to do scientific work
  - Annual programme decided by the Coordination group
  - Approval of joint reports by Coordination Group
  - EC to provide secretariat (administrative, scientific, IT)
  - EC to publish the joint reports
Key elements

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

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

- Joint clinical assessments/JCA (REA)
- Joint scientific consultations/JSC (early dialogues)
- Horizon scanning/Emerging health technologies
- Voluntary cooperation

**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**
  - 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**
  - Publication of reports
  - Conflict of interest procedures
  - Clear procedures for involving stakeholders both on horizontal and product-specific issues
- **Pragmatic phase-in approach**

### Phase-in approach

**Timeline**

- **Commission proposal**
- **Entry into force**
- **Date of application**
- **Transition period**
- **All MS**

- **CO-DECISION PROCEDURE**
  - ongoing

- **DRAFTING IMPLEMENTING AND DELEGATED ACTS**
  - 3 years

- **3 years**

- + **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

---

Recitals 17-18

Article 22.1.

Articles 33, 36
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