Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

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

12th November 2018

Mapping – medical devices HTA

Sample:

15 medical device and 5 other technology-indications pairs –

46 HTA reports for medical devices and 31 for other technologies

six agencies with at least four countries evaluating the same medical device

Economic model:

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

Looking at the 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

Background

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)

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.

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

PROPOSAL

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.*

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**

PROPOSAL

Key elements

- Enable **synergies** between regulatory and HTA issues **Articles 11, 16**

- **Defined areas of join work**:
  - Joint clinical assessments/JCA (REA) **Articles 5-11**
  - Joint scientific consultations/JSC (early dialogues) **Articles 12-17**
  - Horizon scanning/Emerging health technologies **Article 18**
  - Voluntary cooperation **Article 19**

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
- Pragmatic **phase-in** approach — Articles 33, 36

Article 19 – Voluntary cooperation

(a) non-clinical assessments on health technologies;

(b) collaborative assessments on medical devices;

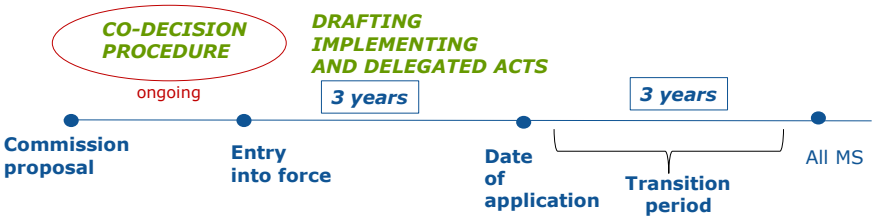
(c) health technology assessments on health technologies other than medicinal products or medical devices;

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

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

Thank you!

Contact: SANTE-HTA@ec.europa.eu

Assessment vs appraisal

Joint clinical assessment — EU

Conclusions limited to:

(a) an analysis of the **relative effects** of the health technology being assessed on the patient-relevant **health outcomes** chosen for the assessment

(b) the **degree of certainty** on the relative effects based on the available evidence.

1

NATIONAL APPRAISAL — NATIONAL

of joint clinical assessment and additional context-specific considerations (e.g. number of patients affected in MS, how patients are currently treated in the healthcare system, costs) +/- economic, ethical organisational, legal

Conclusions on added value
(e.g. added therapeutic value, cost-effectiveness…)

28

NATIONAL DECISION MAKING (e.g. P&R)