Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

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

Lisbon, 30 November 2018
Why an HTA initiative?

More than 20 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
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.

**Member States** remain **responsible for**
- Drawing the overall **conclusions on added value** in the context of their healthcare system
- Taking subsequent **decisions on pricing & reimbursement**
Key elements (1)

- Well defined scope

**Article 5**

- **Medicinal products with central marketing authorisation**
  - New active substances
  - New therapeutic indications for existing substances

- **Selection of medical devices & in vitro diagnostic medical devices**
Key elements (2)

Focus on CLINICAL aspects:

- Joint clinical assessments/JCA (REA)
- Joint scientific consultations/JSC (early dialogues)
- Emerging health technologies/Horizon scanning
- **Voluntary cooperation**
Key elements (3)

- **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, technical, IT)
  - EC to publish the joint reports/liable
Key elements (4)

- **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
  - Procedures for involving stakeholders and additional experts
- Pragmatic **phase-in** approach
Key elements (5)

- Enable **synergies** between regulatory and HTA issues ➔ Secure exchange of Information

- Horizon scanning
- Definition of the WP
- Parallel Joint Scientific Consultation
- Preparation of Joint Clinical assessment ➔ POST CHMP opinion (PHARMA)
Member State-driven approach

HTA Coordination Group (CG)

Joint work carried out by MS experts

CG Sub-groups

- Joint clinical assessments (JCA) → JCA reports
- Joint scientific consultations (JSC) → JSC reports
- Identification of emerging health technologies → Input for annual work programme
- Voluntary Cooperation → Collaborative assessments / non-clinical domains

Preparation of the annual work programme/annual reports, updates of the common requirements and guidance documents

EC Secretariat

Administrative support (e.g. meetings, planning)

Scientific/technical support (e.g. scientific secretariat to rapporteurs, quality management)

IT support (submission system, databases, intranet)

Facilitate cooperation with EMA and other Union bodies

MP = medicinal products, MD = medical devices
Key elements (6)

- Pragmatic approach → phase-in approach

Possible prioritisation criteria – e.g.
- unmet medical needs
- potential impact on patients/public health/healthcare systems
- significant cross-border dimension
- major EU added value
- availability of resources
Use of Joint Clinical Assessments

Key principles:

- **Non-duplication**, i.e. not repeat work already done jointly
- **Use** of joint clinical assessment in national HTA process
Expected benefits of Commission proposal

**Member State decision-makers**
- High quality, timely scientific reports (pooling of HTA resources/expertise; better evidence base for HTA across EU)
- Supports evidence-based decision-making at national level

**Patients**
- Improved transparency and engagement in the HTA process for EU patients
- Contribute to improved availability of technologies with true added value for patients across the EU (due to more timely, evidence-based decision-making)

**Industry**
- Clearer evidence requirements/predictability
- More efficient evidence generation and submission
State of play on the HTA proposal at the European Parliament

- **Lead committee:** ENVI
- **Rapporteur:** Soledad Cabezon Ruiz (S&D, ES, ENVI)
- **Vote:**
  - Plenary adopted amendments on 3 October 2018 and referred back to ENVI (mandate for trialogues)
  - First reading is not finished yet

**Assessment of the EP amendments:**
EP is largely supportive and mainly remaining consistent with the original objectives of the proposal:
- Suggested a dual legal basis (Article 168(4) TFEU and Article 114 TFEU)
- EP maintains the Commission's approach on "use" and **non-duplication** of Joint Clinical Assessment (Art 8) **BUT** opens the possibilities to complement the JCA by the MS → FLEXIBILITY
- Adds details on COI, transparency, role of the Coordination Group etc.
State of play on the HTA proposal at the Council

- **BG Presidency:**
  3 WP meetings + policy debate in EPSCO

- **AT Presidency:**
  7 WP meetings – revised presidency text (Articles 1-8)
  EPSCO 7/12 – progress report (AOB)

- **RO Presidency:**
  First WP meeting on 8 January 2019, (several meetings planned)

---

Compromise text from AT Presidency (Art 1→8) In line with EP proposals but more detailed
- Maintain Commission's approach on “use” and “non-duplication” of Joint Clinical Assessment (Art 8) **BUT changes** approach as it defines what MS can add on the JCA – **INCREASE FLEXIBILITY and CERTAINTY** → no consensus among MS
- Strengthen MS driven approach: strengthen role and responsibilities of Coordination Group, reduced role for EC
- Reduce IA and DA: more “details” in main act, e.g. quality, independence, COI, transparency, timing → **work ongoing**
Thank you!

Contact: SANTE-HTA@ec.europa.eu
Joint clinical assessment

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 (end points).

**NATIONAL APPRAISAL**

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...)

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