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

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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

Expected outcomes

Member States

- High quality and timely reports
- Pooling of expertise → specialisation of HTA bodies
- Better allocation of resources
- Savings in the long run, contribution to sustainability of healthcare systems

Patients

- Increased transparency
- Increased engagement in the HTA process at national and EU level
- Potential faster access across EU

Industry

- Positive impact on business predictability, competitiveness and innovation
- Savings (reduced duplication)

PROPOSAL

Article 1

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.

Key elements (1)

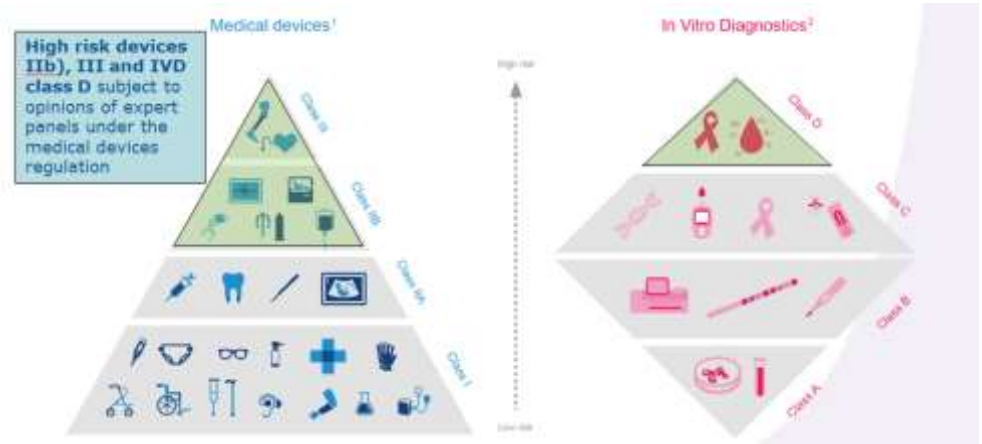
- **Provides support framework** and procedures for EU cooperation on HTA
- **Well defined scope** **Article 5**

Selection during the transition period

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

Selection permanent

- ***Selection of medical devices & in vitro diagnostic medical devices***



Key elements (2)

- 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**

European Commission

Member State-driven approach

Articles 3-4

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
MP MD	MP MD	MP MD	

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

Article 26

Stake-holder Network

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 (3)

- 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**

Joint clinical assessments (JCA)

- Based on **obligatory submission** by industry to the Coordination Group
- Analysis by the JCA Sub-group, led by Assessor and Co-assessor chosen based on **their expertise and experience**
- **Patients and clinical experts asked to provide input**
- Draft report submitted by assessor to the Coordination group
- Approval by the Coordination Group
- **Publication by EC of the full report on the IT Platform**

Joint scientific consultations (JSC)

- Based on request from company interested in receiving advice on study design + data to be collected for (regulatory and) HTA purposes (*for medicinal products 6-8 years before application for marketing authorisation*)
- Analysis by the JCA Sub-group, led by Assessor and Co-assessor chosen based on their expertise and experience
- **Patients and clinical experts asked to provide input**
- Draft report submitted by assessor to the Coordination group
- Approval by the Coordination Group
- Overview of JSCs **published in the annual report** of the Coordination Group

Horizon scanning/ Emerging new technologies

Potential candidates for joint clinical assessments

- Annual report prepared by the Coordination Group
- Input from stakeholders

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)

Recitals 17-18

- **Transparency and independence**
  - Publication of reports
  - Conflict of interest procedures
  - Clear procedures for involving stakeholders

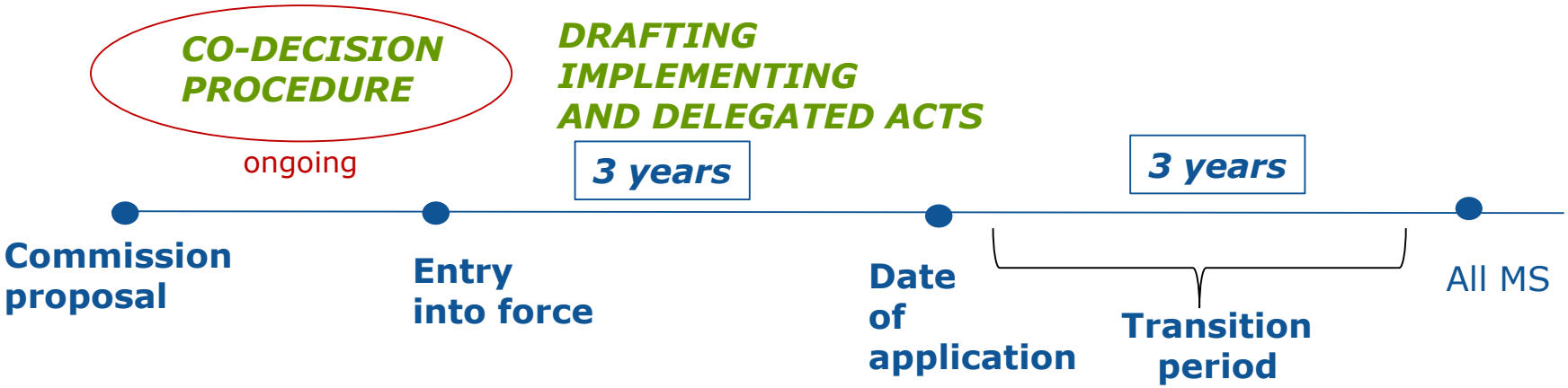
Article 22.1.

- 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

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
- Adds details on COI, transparency, role of the Coordination Group etc.
- Removes harmonisation of national rules and procedures

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, from Article 12 until the end (8 meetings planned)

The Council WP amendments and discussions:

Compromise text from AT Presidency (Art 1→8)

- ❑ MS agree with EP to use dual legal basis
- ❑ Maintain Commission's approach on "use" and "non-duplication" of Joint Clinical Assessment (Art 8) and clarifies what MS can add on the JCA – no consensus among MS
- ❑ MS driven approach, strengthen role of Coordination Group, reduced role for EC
- ❑ More substance in main act, e.g. quality, independence, COI, transparency, timing
- ❑ Removal of harmonisation of national rules and procedures

Next Steps

- FIN Presidency (second half 2019) stated the intention to continue discussion on the file, if not completed

- JA EUnetHTA ending June 2020 –request for extension

Thank you!

Contact: SANTE-HTA@ec.europa.eu