Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

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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

PROPOSAL

European Commission

Proposal for a

Article 1

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.

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**

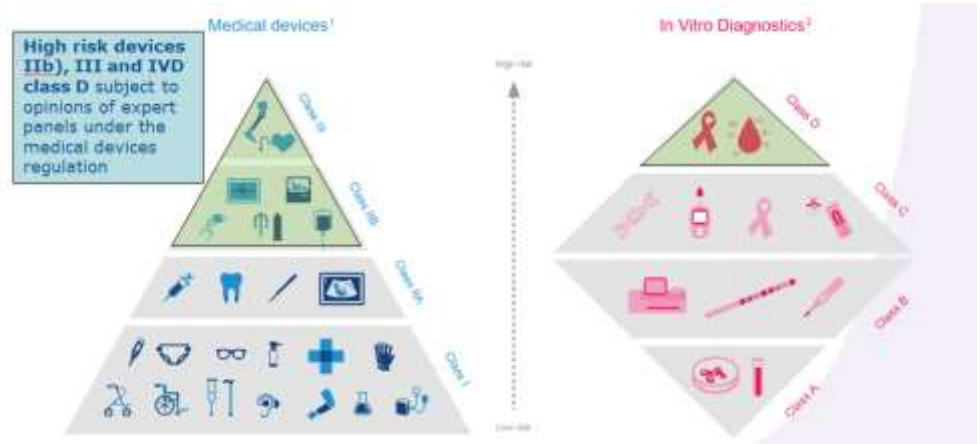
Article 5

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**:

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

Key elements (3)

- **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, technical, IT) — **Article 25**
  - EC to publish the joint reports/liable — **Articles 7, 27**

Key elements (4)

- **High quality** – Member States experts

Art 3,6, 11,12 …)

- **Timely output**
  - **For medicinal products** → by the time of publication of the EC Decision granting marketing authorisation

Recitals 17-18

  - **For medical devices** → flexible timeline (at or after market launch)
- **Transparency and independence**

Article 22.1.

  - Publication of reports
  - Conflict of interest procedures
  - Procedures for involving stakeholders and additional experts
- Pragmatic **phase-in** approach

Articles 33, 36

Key elements (5)

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

Articles 4, 6,12,18

  - Horizon scanning
  - Definition of the WP
  - Parallel Joint Scientific Consultation
  - Preparation of Joint Clinical assessment → POST CHMP opinion (PHARMA)

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 (6)

- Pragmatic approach → phase-in approach

Regional cooperation

BeNeLuxA
La Valletta
Nordic Council/FINOSE
Visegrád Group

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

Art 8

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 → **FLEXIBILTY**
- 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!

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Article 6, 8, and Recital 16

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).

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NATIONAL

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…)

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