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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Medical Products: safety, quality, innovation

Pharma Committee meeting, 8 March 2018
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
Key milestones

- Inception impact assessment (IIA)
  - Published September 2016
- Consultation
  - Online public consultation – Report May 2017
  - Meetings with EUnetHTA JA3 and HTA Network
  - Discussions with stakeholders
- Studies to support the IA process
- Impact assessment – finalised October 2017
- Commission legal proposal – 31 January 2018
Specific objectives

- Improve the availability of innovative health technologies for EU patients
- Ensure efficient use of resources and strengthen the quality of HTA across the EU
- Improve business predictability

Operational objectives

- Promote convergence in HTA tools, procedures and methodologies
- Reduce duplication of efforts for HTA bodies and industry
- Ensure the uptake of joint outputs in Member States
- Ensure the long-term sustainability of EU cooperation
Expected benefits

**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)
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.
Key elements

- Member State driven approach
  - **MS → scientific work**
  - **EC → administrative, technical, IT support**
- Focus on clinical assessment
  - **no joint appraisal**
  - **no joint economic assessment**
- High quality and timely output
- Use of joint work → **no duplication at national level**
- Transparency and independence → **publication of reports + appropriate stakeholders' involvement**
- **Synergies** between regulatory and HTA issues
- Pragmatic approach → **phase-in approach**
Member State-driven approach

→ HTA Coordination Group (CG)

- Member State-led → members designated, one or more authority or body
- Will manage the overall governance of the joint work
- Will meet regularly to provide guidance and steer the cooperation.
- Will work based on an annual work programme developed and adopted by the Group
### HTA Coordination Group (CG)

**Joint work carried out by MS experts**

#### CG Sub-groups

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<th>Joint scientific consultations (JSC)</th>
<th>Identification of emerging health technologies</th>
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<td>JCA reports</td>
<td>JSC reports</td>
<td>Input for annual work programme</td>
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**Preparation of the annual work programme/annual reports, updates** of the common requirements and guidance documents

#### Administrative support
- (e.g. meetings, planning)

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

#### IT support
- (submission system, databases, intranet)

**EC Secretariat**

**Stakeholder Network**

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Articles 3-4
Focus on clinical assessment

CLINICAL ASSESSMENT

- Description of the health problem addressed by the HT
- Relative clinical effectiveness of the HT

- Description and technical characterisation of the HT
- Relative safety of the HT

NON-CLINICAL ASSESSMENT

- ECONOMIC ASPECTS
- ORGANISATIONAL ASPECTS
- SOCIAL ASPECTS
- LEGAL ASPECTS
- ETHICAL ASPECTS
- OTHER ASPECTS

NATIONAL

NATIONAL APPRAISAL (e.g. added therapeutic value)
Focus on clinical assessment

**Product scope:**

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

- **Medical devices classified as class IIb and III** for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure

- **In vitro diagnostic medical devices - class D** for which the relevant expert panels have provided their views in the framework of the clinical evaluation consultation procedure
Use of joint work
No duplication at national level

Member States shall:

- **not carry out a clinical assessment or an equivalent assessment process on a health technology included in the List of Assessed Health Technologies** or for which a joint clinical assessment has been initiated;

- **apply joint clinical assessment reports, in their health technology assessments at Member State level.**

**Safeguard clause** – applicable in exceptional circumstances (Article 34)
Transparency and independence

Stakeholder Network (Article 26 + Article 22.a.iii)

The Commission shall adopt implementing acts concerning procedural rules for the consultation of patients, clinical experts, and other stakeholders in clinical assessments.

Publication of reports (Article 7.6)

- 'List of Assessed Health Technologies'
- JCA report + summary report

Conflict of interest (Article 22.a.i)

The Commission shall adopt implementing acts concerning procedural rules for ensuring that HTA authorities and bodies carry out clinical assessments in an independent and transparent manner, free from conflicts of interest.
Key elements relevant for the interaction regulators-HTA

- **Synergies between regulatory and HTA issues**
  - Emerging new technologies/Horizon scanning
    - For topic selections and prioritisation
    - Based on planned activity EMA-EUnetHTA
  - Joint parallel scientific consultations
    - Based on EMA-EUnetHTA Parallel Consultation procedure initiated in July 2017 + previous collaboration during the SEED project
  - Joint clinical assessments
    - Based on EMA-EUnetHTA collaboration – early confidential sharing of the final CHMP opinion before MA Decision is published by the Commission
Phase-in approach

Timeline

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

**3 years**

**CO-DECISION PROCEDURE**
**DRAFTING IMPLEMENTING AND DELEGATED ACTS**

+ 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!

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