Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on health technology assessment and amending Directive 2011/24/EU
## Health Technology Assessment (HTA)

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Why an HTA initiative?

More than 10 years of cooperation: joint actions, projects

ACHIEVEMENTS

- **Trust** between HTA bodies
- **Capacity building**
- Development of **joint tools** (e.g. EUnetHTA Core Model, POP/EVIDENT databases, methodological guidelines)
- Piloting **joint work** (e.g. early dialogues, joint assessments)

LIMITATIONS

- Low uptake of joint work ⇒ duplication of work
- **Differences** in national legal/procedural HTA frameworks and administrative capacities of Member States
- **No sustainability** of current cooperation model
HTA initiative: key milestones

- **Inception impact assessment** (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)

https://ec.europa.eu/health/technology_assessment/eu_cooperation_en
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 outcomes

**Member States**
- Pooling of resources and expertise
- High quality and timely reports
- Support MS in evidence-based decision-making
- Contribution to sustainability of health systems

**Patients**
- Increased transparency
- Increased engagement in the HTA process
- Contribution to improved access to technologies with benefits for patients

**Industry**
- Positive impact on business predictability (innovation investments)
- Increased efficiency of evidence generation and submission (reduced duplication)
HTA Coordination Group

Joint work carried out by MS experts

Sub-groups

Joint clinical assessments
- Medicines
- Medical devices

Joint scientific consultations
- Medicines
- Medical devices

Identification of emerging health technologies
(input to work programme)

Voluntary cooperation
- Other health technologies
- Non-clinical HTA aspects

Preparation of annual work programme/reports,
Common guidance documents

EC Secretariat

Administrative support
(e.g. meeting logistics)

Scientific/technical support
(e.g. scientific secretariat to assessors, monitor quality/SOPs)

IT support
(e.g. databases, submission system)

Support/monitor uptake
(e.g. notification tools)
Joint Clinical Assessments: product scope

- **Medicinal products:** centrally authorised new active substances and new therapeutic indications

- **Medical devices:**
  - Medical devices classified as class IIb and III pursuant to Article 51 of Regulation (EU) 2017/745 for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure pursuant to Article 54 of that Regulation
  
  - **In vitro diagnostic** medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746 for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation
  
  - **Additional selection by HTA Coordination Group** based on criteria: Unmet medical needs; potential impact on patients, public health and healthcare systems; significant cross-border dimension; major Union-wide added value; the available resources.
Use of Joint Clinical Assessments

Member States shall:

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

Appraisal (i.e. conclusions on added value) remains at Member States level
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.

NATIONAL APPRAISAL
of joint clinical assessment and additional context-specific considerations (e.g. number of patients affected in Member State, how patients are currently treated in the healthcare system, costs)

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

Legal proposal
Article 6, Recital 16
Transparency and independence

Publication of joint clinical assessment reports
The Commission shall publish the approved joint clinical assessment report and summary report on the IT platform referred to in Article 27

Avoiding conflicts of interest
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
Involvement of patients and clinical experts

- **Joint Clinical Assessments**
  The designated sub-group shall ensure that stakeholders, including patients and clinical experts, are given an opportunity to provide comments during the preparation of the draft joint clinical assessment report.

- **Joint Scientific Consultation**
  The designated sub-group shall ensure that stakeholders, including patients and clinical experts are given an opportunity to provide comments during the preparation of the draft joint scientific consultation report.

- Consultation of patients and clinical experts in clinical assessments carried out by Member States
  The Commission shall adopt implementing acts concerning procedural rules for the consultation of patients, clinical experts and other stakeholders.
Stakeholder involvement

Stakeholder Network

- Established by the Commission through an open call for applications and a selection procedure (list of included stakeholder organisations is published)

- Meetings between Stakeholder Network and Coordination Group (updates and information exchange)

- Support Coordination Group in the identification of patient and clinical expertise for the work of ist subgroups
Phase-in approach

CO-DECISION PROCEDURE

Commission proposal

Entry into force

DRAFTING IMPLEMENTING AND DELEGATED ACTS

Date of application

Transition period

All MS

- Member States may delay their participation in the system of joint work until 3 years after the date of application
- Prioritisation of health technologies subject to joint work (progressive build-up of system)
Building on work of EUnetHTA JA3 (2016-2020)

**WP 4**
Joint REA (medicines, medical devices)

**WP 5**
Early dialogues

**WP 4**
Horizon scanning

**WP 4**
Joint REA (other health technologies)

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Legal proposal

- Joint clinical assessments
- Joint scientific consultations
- Emerging health technologies
- Voluntary cooperation on HTA
Summary of key principles

- **Member States driven**
  - MS → scientific work and decisions
  - EU → support function
- **Joint clinical assessments** (but non-clinical assessments and appraisal remain at MS level)
- **High quality** and timeliness of joint work
- Use of joint work (no duplication at national level)
- **Transparency**
- **Independence**
- **Stakeholder involvement**
- Progressive implementation (phase-in approach)
Thank you

Contact: SANTE-HTA@ec.europa.eu