Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

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

9 February 2018
More than 10 years of cooperation: projects, joint actions

EUnetHTA JAs (2010-2020)

Research projects

AdhopHTA
MedtecHTA
INTEGRATE-HTA
ADVANCE-HTA
Calls to strengthen EU cooperation on HTA

Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States (June 2016)

→ EU cooperation on HTA can support the decision-making of MS
→ Commission was asked to reflect about the future of this cooperation beyond 2020 when the current EUnetHTA JA comes to an end.

European Parliament Report on EU options for improving access to medicines (2016/2057(INI))

→ highlighted the potential of joint assessments for avoiding the duplication of efforts and the misallocation of resources across the EU and urged the Commission to propose legislation on a European system for HTA.
Key milestones

- Inception impact assessment (IIA)
  - Published September 2016

- Consultation
  - Online public consultation – Report May 2017

- Meetings with EUnetHTA JA3
  - Discussions with stakeholders

- Studies to support the IA process

- Impact assessment – finalised October 2017

- Commission legal proposal – 31 January 2018
Online public consultation

EU cooperation beyond 2020:

- supported by **87%** of all respondents

- Scope (useful and to some extent useful)
  - Pharmaceuticals **80%**
  - Medical devices **72%**
  - Other **54%**
Discussions with stakeholders

Open and constructive meetings

9 meetings
Patients and consumers

8 meetings
Healthcare professionals

20 meetings
Pharmaceutical industry

5 meetings
Medtech industry

Payers
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General objectives
- Ensure a better functioning of the internal market
- Contribute to a high level of human health protection

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 (more pronounced for the pharmaceutical industry)
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Chapter I  General Provisions

Chapter II  Joint Work on HTA at Union Level

Joint clinical assessments
Joint scientific consultations
Emerging health technologies
Voluntary cooperation

Section 1  Section 2  Section 3  Section 4

Chapter III  Requirements for Clinical Assessments

Chapter IV  Support Framework

Chapter V  Final Provisions
The Regulation establishes:

- a support framework and procedures for cooperation on health technology assessment at Union level;
- common rules for the 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 (1)

1. Member State driven
   • MS → scientific work and decisions
   • EU → support function

2. Focus on clinical assessment
   • no common appraisal
   • no common economic assessment

3. High quality and timely output

4. Use of joint work → no duplication at national level

5. Fit for purpose → pharma vs medtech

6. Transparency → stakeholders' involvement
Key elements (2)

7. Areas of joint work
   - Common tools and methodologies
   - Emerging new technologies/Horizon scanning
   - Joint scientific consultations (JSC)
   - Joint clinical assessments (JCA)

8. Governance → stable secretariat
   - Administrative support (e.g. meetings, planning)
   - Scientific/technical support (e.g. scientific secretariat to rapporteurs, quality management)
   - IT support (e.g. submission system, databases)
   - Support voluntary cooperation (e.g. notification, adaptation common tools)

9. Pragmatic approach → phase-in approach
HTA Coordination Group (CG)

CG Sub-groups

- **Joint clinical assessments (JCA)**
  - JCA reports
  - MP
  - MD

- **Joint scientific consultations (JSC)**
  - JSC reports
  - MP
  - MD

- **Identification of emerging health technologies**
  - Input for annual work programme
  - MP
  - MD

- **Voluntary Cooperation**
  - Collaborative assessments / non-clinical domains

Joint work carried out by MS experts

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)

Support and monitor uptake (notification, adaptation common tools/brokering)

Stakeholder Network
Key elements relevant to stakeholders (1)

**Article 3.8.d** - Coordination Group on Health Technology Assessment shall ensure appropriate involvement of stakeholders in its work

**Recital 24**

In order to ensure the inclusiveness and transparency of the joint work, the Coordination Group should engage and consult widely with interested parties and stakeholders. However, in order to preserve the integrity of the joint work, rules should be developed to ensure the independence and impartiality of the joint work and ensure that such consultation does not give rise to any conflicts of interest.
Key elements relevant stakeholders (2)

- **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 and the summary report and set a time-frame in which they may submit comments (Article 6.9)

- **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 and set a time-frame in which they may submit comments. (Article 13.8)
Key elements relevant stakeholders (3)

• **Identification of Emerging Health Technologies/Horizon scanning (Article 18)**
  - **Annual study prepared by the CG** on emerging health technologies expected to have a major impact on patients, public health or healthcare systems.

  - In the preparation of the study, the **CG shall consult**: health technology developers, patient organisations, clinical experts, EMA, Medical Devices Coordination Group
Key elements relevant stakeholders (4)

Stakeholder Network (Article 26)

- Established by the Commission through an open call for applications and a selection procedure

- **Provide support to the Coordination Group** in the identification of patient and clinical expertise for the work of its sub-groups

- **Observers to meetings of the Coordination Group**.

- Ad-hoc meetings between the stakeholder Network and the Coordination Group

- Covered from EU budget (Article 24)
Key elements relevant stakeholders (5)

- **Implementing acts**
  - Detailed Procedural Rules for JCA (Article 11)
  - Detailed Procedural Rules for JSC (Article 16)
  - Common Procedural Rules and Methodology (Article 22)
    - procedural rules for:
      - ensuring that HTA authorities and bodies carry out clinical assessments in an independent and transparent manner, free from conflicts of interest;
      - the mechanisms for the interaction between health technology bodies and health technology developers during clinical assessments;
      - the consultation of patients, clinical experts, and other stakeholders in clinical assessments.
    - methodologies used to formulate the contents and design of clinical assessments.
Key elements relevant stakeholders (6)

➢ **Delegated acts**
Documentation and Rules for Selecting Stakeholders for JSC *(Article 17)*

→ *rules for determining the stakeholders to be consulted*

Contents of Submission and Report Documents and Rules for Selecting Stakeholders – JCA *(Article 23)*

→ *rules for determining the stakeholders to be consulted*

➢ **Implementing acts**
Common Procedural Rules and Methodology *(Article 22)*

- procedural rules for [...]:
  - the *consultation of patients, clinical experts, and other stakeholders in clinical assessments.*
Timeline

**CO-DECISION PROCEDURE**

Commission proposal

**DRAFTING IMPLEMENTING LEGISLATION**

Entry into force

Date of application

Transition period

All MS

- 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
- **Expected number** of JCA/JSC per year = up to 65/40 by the end of the transition period
Thank you