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
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
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
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 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)
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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
Key elements (1)

1. Member State driven
   • **MS → scientific work**
2. Focus on clinical assessment
   • **no joint appraisal**
   • **no joint 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)
   - Technical support (e.g. secretariat to assessors, quality management)
   - IT support (e.g. submission system, databases)
   - Support voluntary cooperation (e.g. notification, adaptation common tools)

9. Pragmatic approach → phase-in approach
Key element 1 – Member State driven

→ 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**

- **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

**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**

(Articles 3-4)

**Stakeholder Network**
Key element 2 – Focus on clinical assessment (no appraisal, no economic assessment)

Scope of Joint Clinical Assessments (JCA)

- **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

- 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.
Prioritisation of JCA

→ For medical devices and IVDS
→ For medicinal products, but only in the transition period

Criteria:

- unmet medical needs;
- potential impact on patients, public health, or healthcare systems;
- significant cross-border dimension;
- major Union-wide added value;
- the available resources.
Key element 3 - High quality and timely output

- Build on already achieved work
- Synergies, but not delay or interfere with regulatory processes
- High quality and timely results
- Technical and scientific expertise
Key element 4 - 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)

+ Recital 16
Key element 5 – Fit for purpose

Medicinal products

• "Aligned" with MA process (Recital 17)
• Prioritisation only during transition period (Article 10a.ii)
• Joint work carried out by MS experts – CG Sub-group dedicated to medicinal products (Article 3.9)
• Common procedural and methodological framework for CA, JCA, JSC (Article 20,22,23)

Medical devices

• At/After market launch (Recital 18)
• Prioritisation also after the transition period (Article 5.2)
• Joint work carried out by MS experts – CG Sub-group dedicated to medical devices (Article 3.9)
• Common procedural and methodological framework for CA, JCA, JSC (Article 11,22,23)

Recital 25
Where appropriate, distinct rules should be developed for medicinal products and medical devices.
Key element 6 – Transparency

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 element 7 – Areas of joint work

WP 4
Joint REA

WP 5
Data generation

WP 4
Horizon scanning

WP 4
Collaborative assessments
Non-clinical assessments...

Chapter II
Joint Work on HTA at Union Level

Joint clinical assessments

Joint scientific consultations

Emerging health technologies

Voluntary cooperation

Section 1
Articless 5-11

Section 2
Articles 12-17

Section 3
Articles 18

Section 4
Articles 19
Preparation of Joint Clinical Assessment Reports

Health technology developer → Submission → Coordination Group → Joint clinical assessment (JCA) SG → Assessor & co-assessor → JCA SG → Coordination Group

On request from assessors:
- Provides additional data
- Provides comments to draft JCA report

- Analyse the data submitted
- Incorporates input from stakeholders (patients, healthcare professionals)
- Prepare draft report of JCA

Submits draft report

I. JCA SG Provides comments to draft report
II. Coordination Group approves final JCA report

Publication by EC
Preparation of Joint Clinical Assessment Reports

6.5. The conclusions of the joint clinical assessment report shall be limited to the following:

(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.
Joint Scientific Consultations

Health technology developer

Submission

Coordination Group

Joint scientific consultation (JSC) Subgroup

Assessor & co-assessor
- Analyse the data submitted
- Incorporates input from stakeholders (patients, healthcare professionals)
- Prepare draft recommendations

Submits draft

JSC SG

Provides comments to draft

Submits final draft

Coordination Group

Approval

European Medicines Agency

Regulatory Scientific advice

Coordination Group

HTA Joint scientific consultation

Parallel regulatory -HTA

Articles 12-17
Emerging Health Technologies

• The CG shall prepare **annually a study 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;
  - the EMA;
  - the Medical Devices Coordination Group

• The conclusions of the studies shall be summarised in the CG's annual reports + **taken into account for the annual work programmes**.
Voluntary Cooperation on HTA

• The Commission shall support and **facilitate cooperation** and the exchange of scientific information among Member States on:
  
  (a) non-clinical assessments on health technologies;
  (b) collaborative assessments on medical devices;
  (c) health technology assessments on health technologies other than medicinal products or medical devices;
  (d) the provision of additional evidence necessary to support health technology assessments.

• The CG shall be used to facilitate the cooperation

• May be carried out using the common rules and procedures and included in the work programmes
EU funding

- For the financing of the work of the CG and its sub-groups and activities in support of that work involving its cooperation with the Commission, with the EMA, and with the stakeholder network.
- Shall include funding for the participation of MS' designated HTA authorities and bodies in support of the work on JCA and JSC.

→ Assessor and co-assessors shall be entitled to a special allowance compensating them for their work on JCA and JSC in accordance with internal Commission provisions.
Key element 8 – Governance

Commission Support for the Coordination Group

- **host** on its premises and co-chair the meetings of the CG;
- provide the **secretariat** for the CG and provide **administrative, scientific and IT support**
- **publish on the IT platform** the CG's annual work programmes, annual reports, summary minutes of its meetings, and reports and summary reports of joint clinical assessments;
- **verify** that the work of the CG is carried out in an **independent and transparent manner**;
- **facilitate cooperation with the EMA** on the joint work on medicinal products including the sharing of confidential information;
- **facilitate cooperation with the relevant Union level bodies** on the joint work on **medical devices** including the sharing of confidential information.
Key element 9 – Phase-in approach

Timeline

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

**CO-DECISION PROCEDURE**

**DRAFTING IMPLEMENTING AND DELEGATED ACTS**

- **3 years**

- **3 years**

- **+ 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

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