European Commission

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

eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

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.

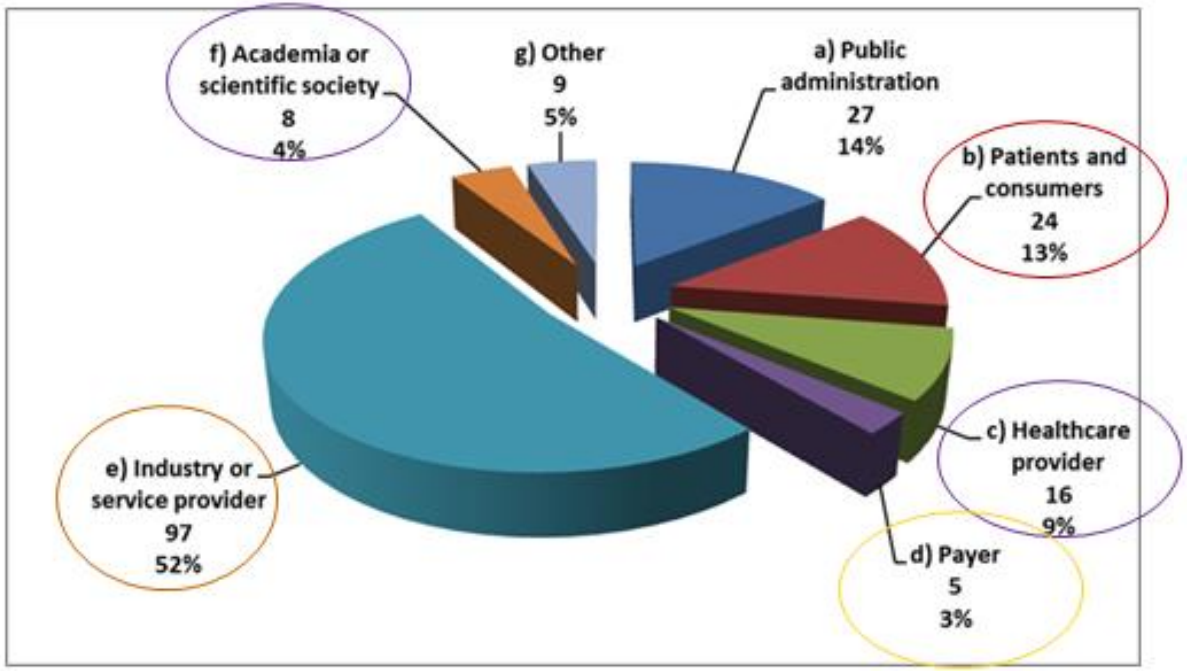
European Parliament Report on EU options for improving access to medicines (2016/2057(INI))

→ 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

HTA Network

Member States authorities

eunethta

Executive Board

9 meetings — Patients and consumers

8 meetings — Healthcare professionals


EUROPEAN COMMISSION

Brussels, 31.1.2018
COM(2018) 51 final

2018/0018 (COD)

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(Text with EEA relevance)

{SWD(2018) 41 final} - {SWD(2018) 42 final}

Pharmaceutical industry

Medtech industry

20 meetings

Payers — 5 meetings

Open and constructive meetings

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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

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- 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)

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

Stake-holder Network

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).

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*)

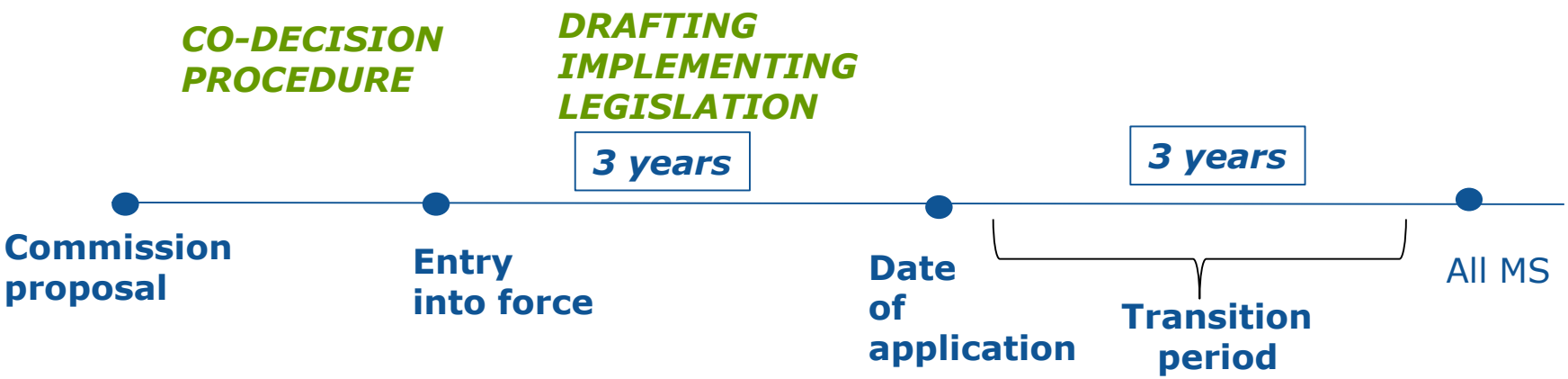
→ **rules for determining the stakeholders to be consulted**

➢ 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



- 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