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

21 March 2018

Health Technology Assessment (HTA)

HTA domains
Health problem and currently used technologies
Description of technology under assessment
Relative clinical effectiveness
Relative safety
Economic evaluation
Ethical aspects
Organisational aspects
Social aspects
Legal aspects

Clinical domains

Non-clinical domains

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

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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)

Legal proposal
Article 3

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HTA Coordination Group

Joint work carried out by MS experts

Sub-groups

Joint clinical assessments	**Joint scientific consultations**	**Identification of emerging health technologies**	**Voluntary cooperation**
- Medicines - Medical devices	- Medicines - Medical devices	(input to work programme)	- Other health technologies - Non-clinical HTA aspects

Preparation of annual work programme/reports,
Common guidance documents

Stake-holder Network

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)

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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

Legal proposal
Article 6, Recital 16

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

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…)

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

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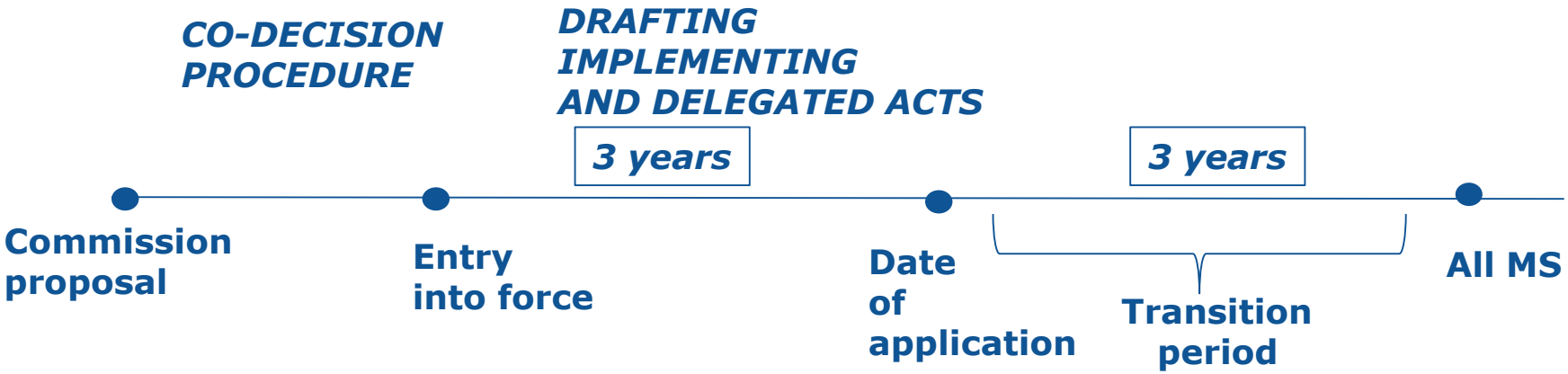
Stakeholder involvement

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



- 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)
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

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