



Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

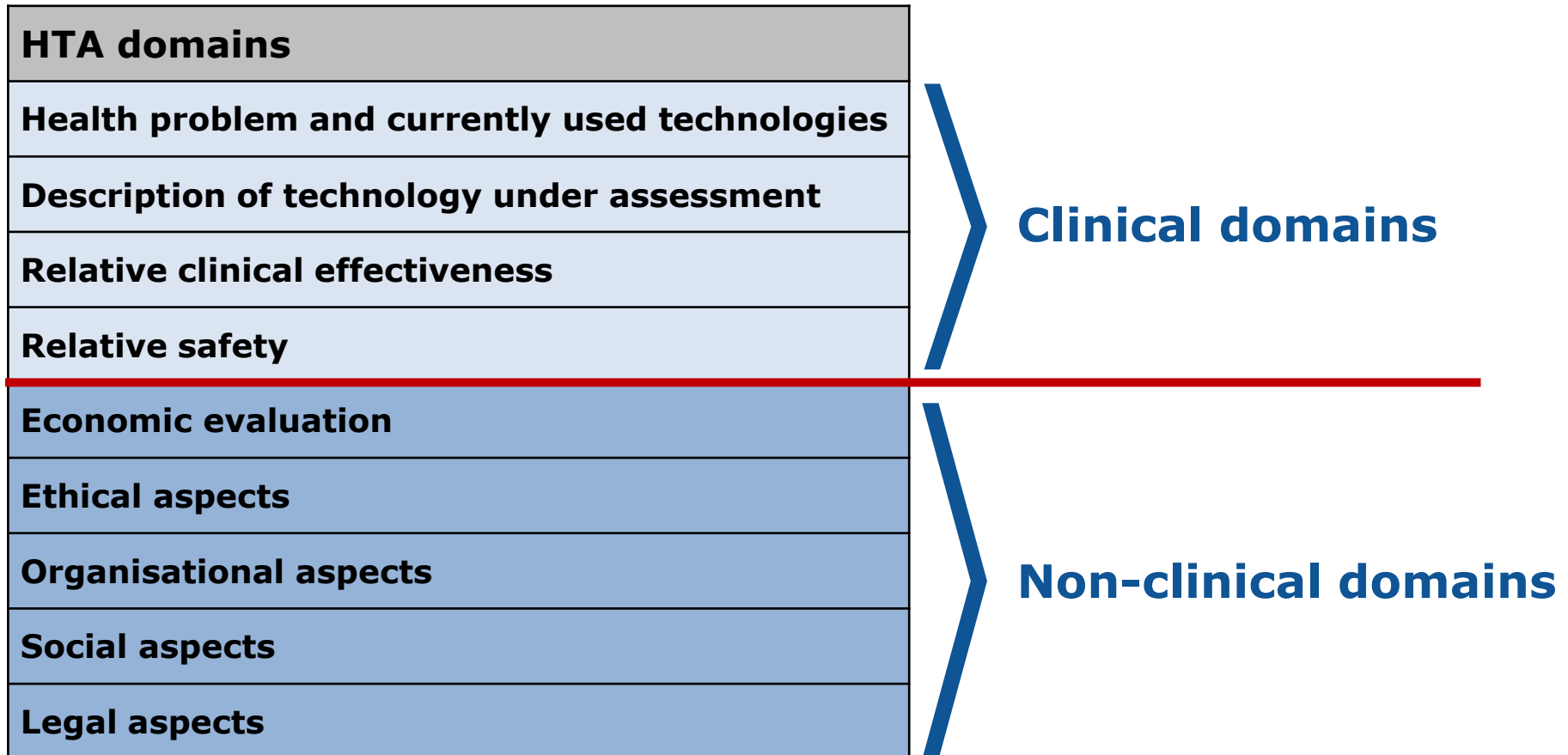
DG SANTE - Health Systems and Products
Medical Products: safety, quality, innovation



What is Health Technology Assessment?

- **"Health technology"** comprises:
 - medicines,
 - medical devices,
 - in vitro diagnostics devices,
 - medical and surgical procedures, measures for disease prevention, vaccination, treatments - used in healthcare.
- **HTA an evidence-based process that assesses the added value (relative effectiveness)** of a given health technology/health interventions and compares it with other health technologies and / or the current standard of care.
- **HTA can cover different aspects:** from clinical domains (e.g. safety, clinical effectiveness) to non-clinical domains (e.g. economic, ethical, organisational).

Health Technology Assessment (HTA)



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)



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Chapter I **General Provisions**

Chapter II **Joint Work on HTA at Union Level**

**Joint
clinical
assessments**

Section 1

**Joint
scientific
consultations**

Section 2

**Emerging
health
technologies**

Section 3

**Voluntary
cooperation
on HTA**

Section 4

Chapter III **Rules for Clinical Assessments**

Chapter IV **Support Framework**

Chapter V **Final Provisions**



Key elements

- Member State driven approach
 - **MS → scientific work**
 - **EC → administrative, technical, IT support**
- Focus on clinical aspects
 - **no joint appraisal**
 - **no joint economic assessment**
- High quality and timely output
- Use of joint work → **no duplication at national level**
- Fit for purpose → **pharma vs medtech**
- Transparency and independence → **publication of reports + appropriate stakeholders' involvement**
- Pragmatic approach → **phase-in approach**

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

Stakeholder Network

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)

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

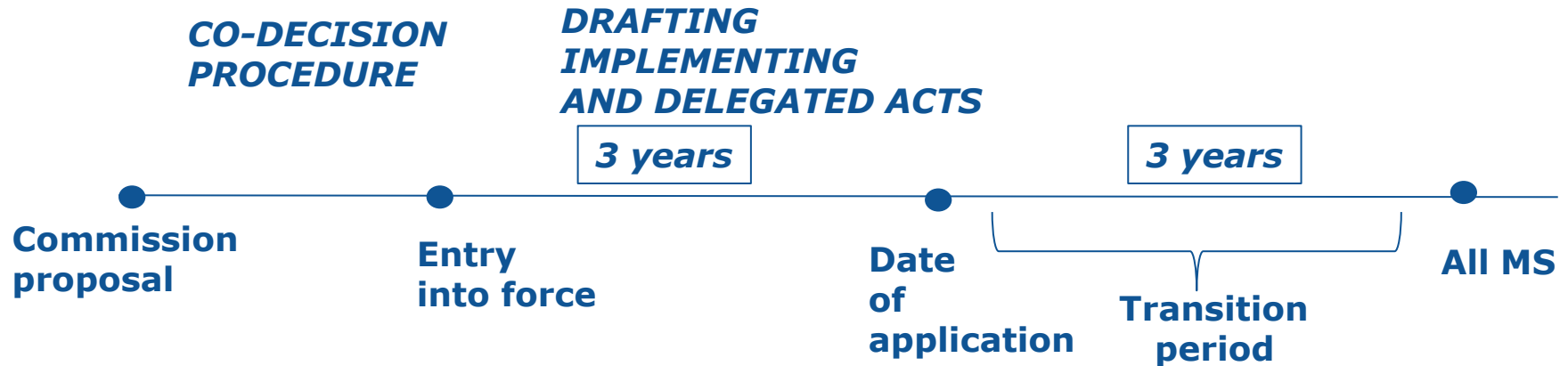
The Commission shall adopt **implementing acts** concerning **procedural rules** for the consultation of patients, clinical experts and other stakeholders

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 its 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)



Thank you

Contact: SANTE-HTA@ec.europa.eu