



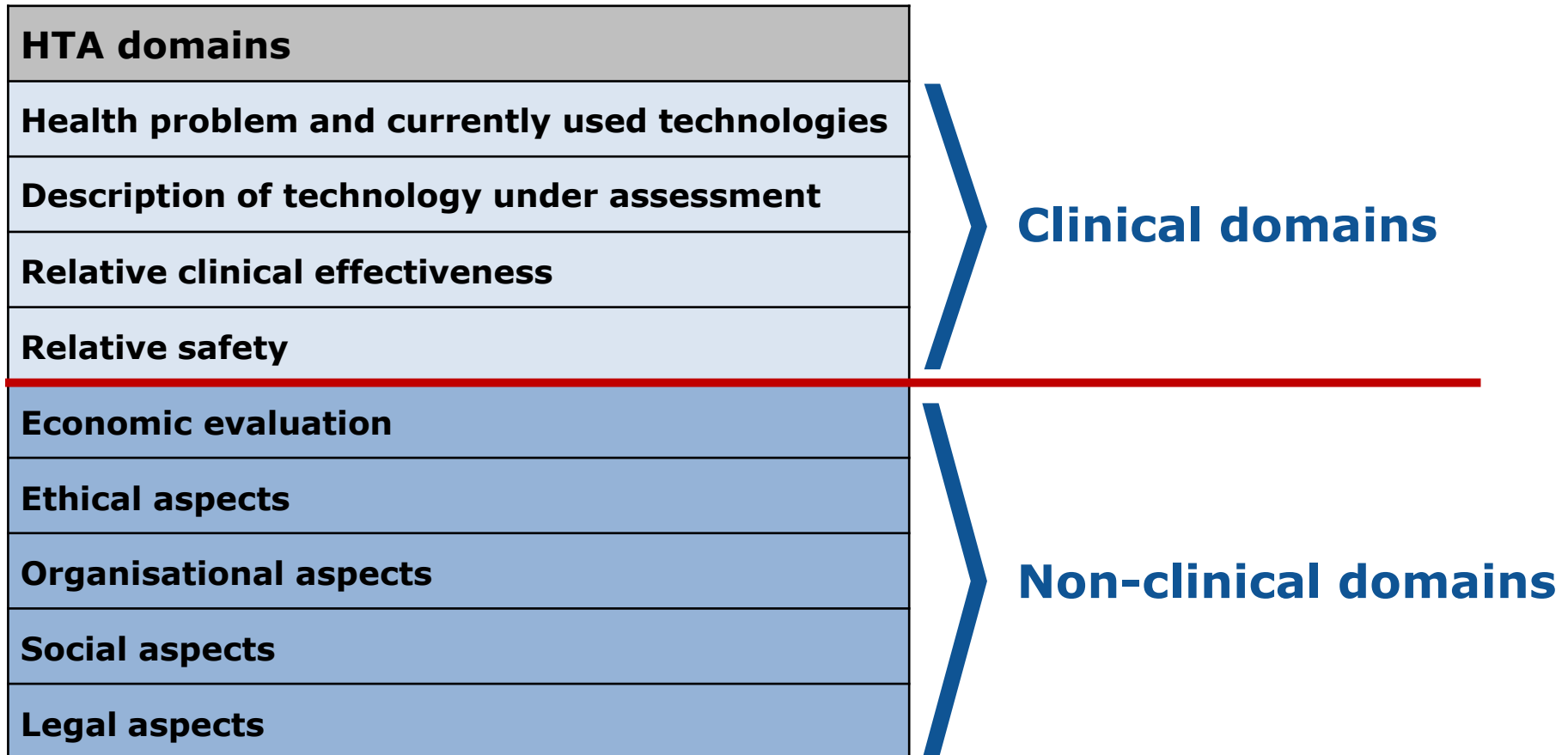
Proposal for a

**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

# 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](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

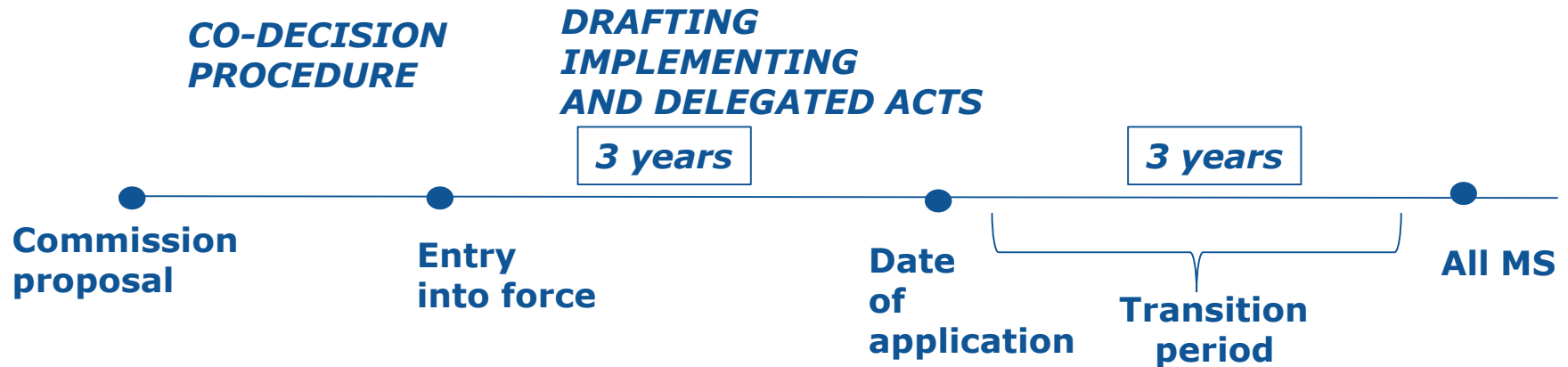
The Commission shall adopt **implementing acts** concerning **procedural rules** for the consultation of patients, clinical experts and other stakeholders

# 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

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