The EU regulation on health technology assessment: what's in it and why it matters?"

HTA information day, Riga
9 April 2024

Directorate-General for Health and Food Safety

European Commission

What is health technology assessment?

Health technology assessment (HTA) is the systematic evaluation of the properties, effects, or impact of a health technology in comparison to another health technology.

HTA considers evidence about medical, economic, social and ethical issues related to the use of a health technology.

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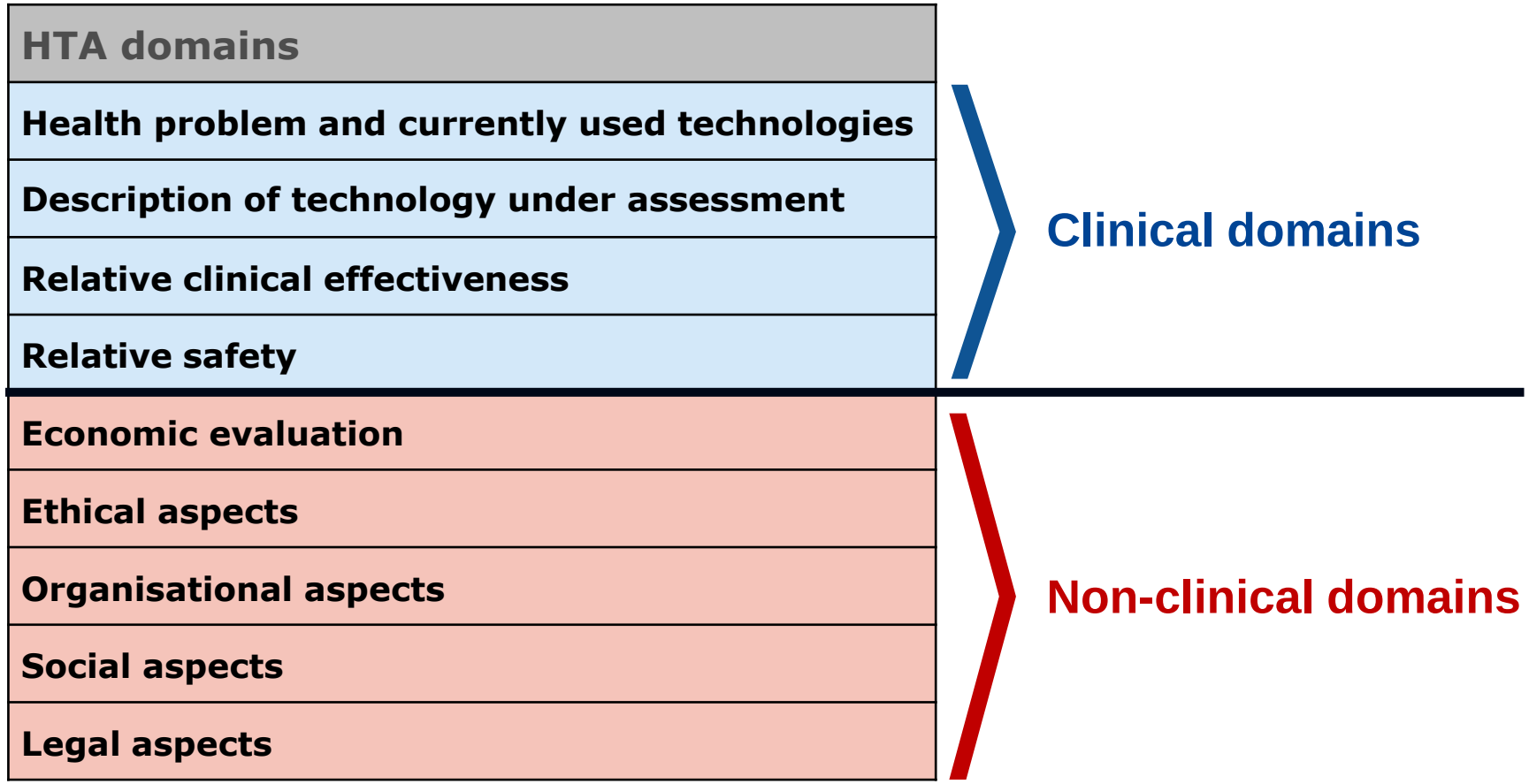
HTA domains


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

Regulatory process vs. HTA (current)

- Single licensing system
- EU legislation
- Well-defined and agreed assessment criteria

- All Member States have different HTA systems
- National legislation and procedures
- Different methodologies and assessment criteria

Regulatory process vs. HTA (HTA Reg.)

- Single licensing system
- EU legislation
- Well-defined and agreed assessment criteria

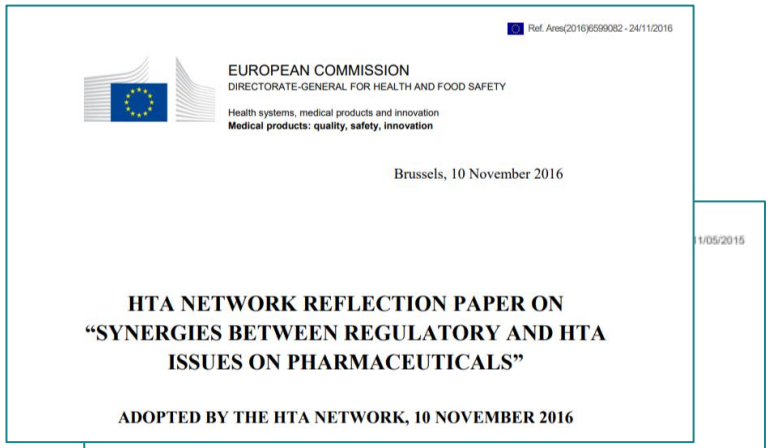
EU HTA Regulation

- Joint framework for clinical assessment
- Common methodology and approach for clinical assessments and scientific consultations

NATIONAL

- Use of joint clinical assessment in national decision-making
- Non-clinical assessments
- Decision making on pricing and reimbursements

Strengthening EU HTA cooperation


Ref. Ares(2016)6599082 - 24/11/2016

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical products: quality, safety, innovation

Brussels, 10 November 2016

HTA NETWORK REFLECTION PAPER ON "SYNERGIES BETWEEN REGULATORY AND HTA ISSUES ON PHARMACEUTICALS"

ADOPTED BY THE HTA NETWORK, 10 NOVEMBER 2016

HTA NETWORK REFLECTION PAPER ON "REUSE OF JOINT WORK IN NATIONAL HTA ACTIVITIES"

ADOPTED BY THE HTA NETWORK, APRIL 2015

JA1 (2010 – 2012)
JA2 (2012 – 2015)
JA3 (2016 – 2021)

HTA Regulation

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Regulation (EU) 2021/2282 on HTA

- Adoption 15 December **2021**
- Entry into force 11 January **2022**
- Entry into application 12 January **2025**
- **Main objectives**:
  - establishing a **support framework** and procedures **for cooperation** of Member States on health technologies at Union level
  - a mechanism for the **submission of evidence** for joint clinical assessments **only once** at Union level
  - **common rules and methodologies** for joint clinical assessments

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HTA Regulation – Key principles

- **Joint work on** common **scientific, clinical aspects** of HTA
- **Driven by Member State HTA bodies**
- Ensures **high quality, timeliness** and **transparency**
- **Inclusivity** by involving **all MSs**, **patients, clinical experts** and **stakeholders i**n the joint work
- **Roles of patients** and **clinical experts** embedded in the EU legislation
- Ensures **use of joint work in national HTA processes**
- **Member States** remain responsible for:
  - Drawing **conclusions on added value** for their health systems
  - Taking **decisions on pricing & reimbursement**
- **Progressive implementation**

Joint HTA activities

Joint Clinical Assessments (JCA) on:

- **medicines** first 3 years: cancer medicines and advanced therapy medicinal products

  from January 2028: + orphan medicinal products

  from 2030: all medicines
- **a selection of high-risk medical devices and in-vitro diagn. medical devices**

Joint Scientific Consultations (JSC)

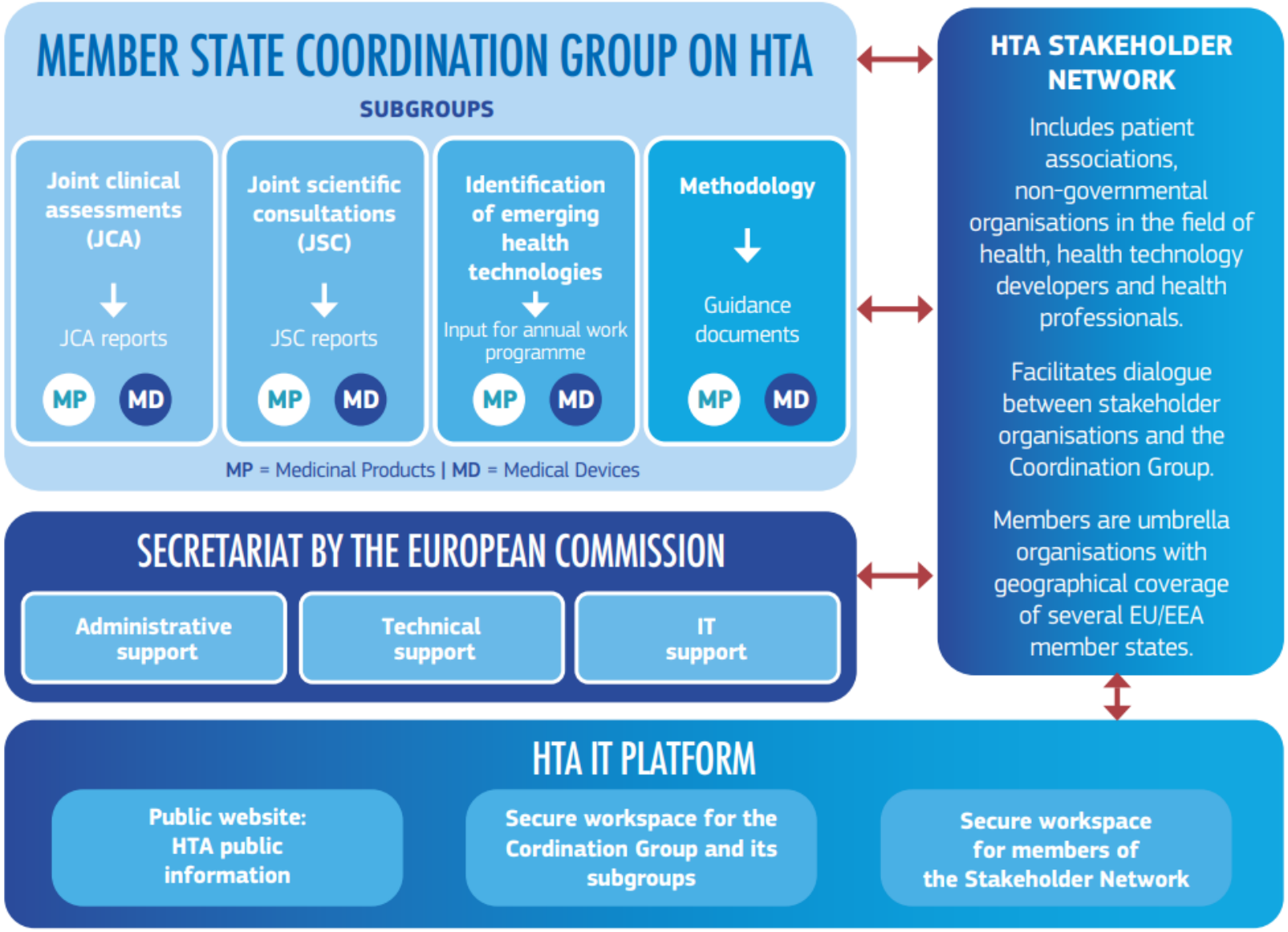
- in parallel with the European Medicines Agency

Emerging Health Technologies

Methodology for joint HTA work

Voluntary cooperation

Governance



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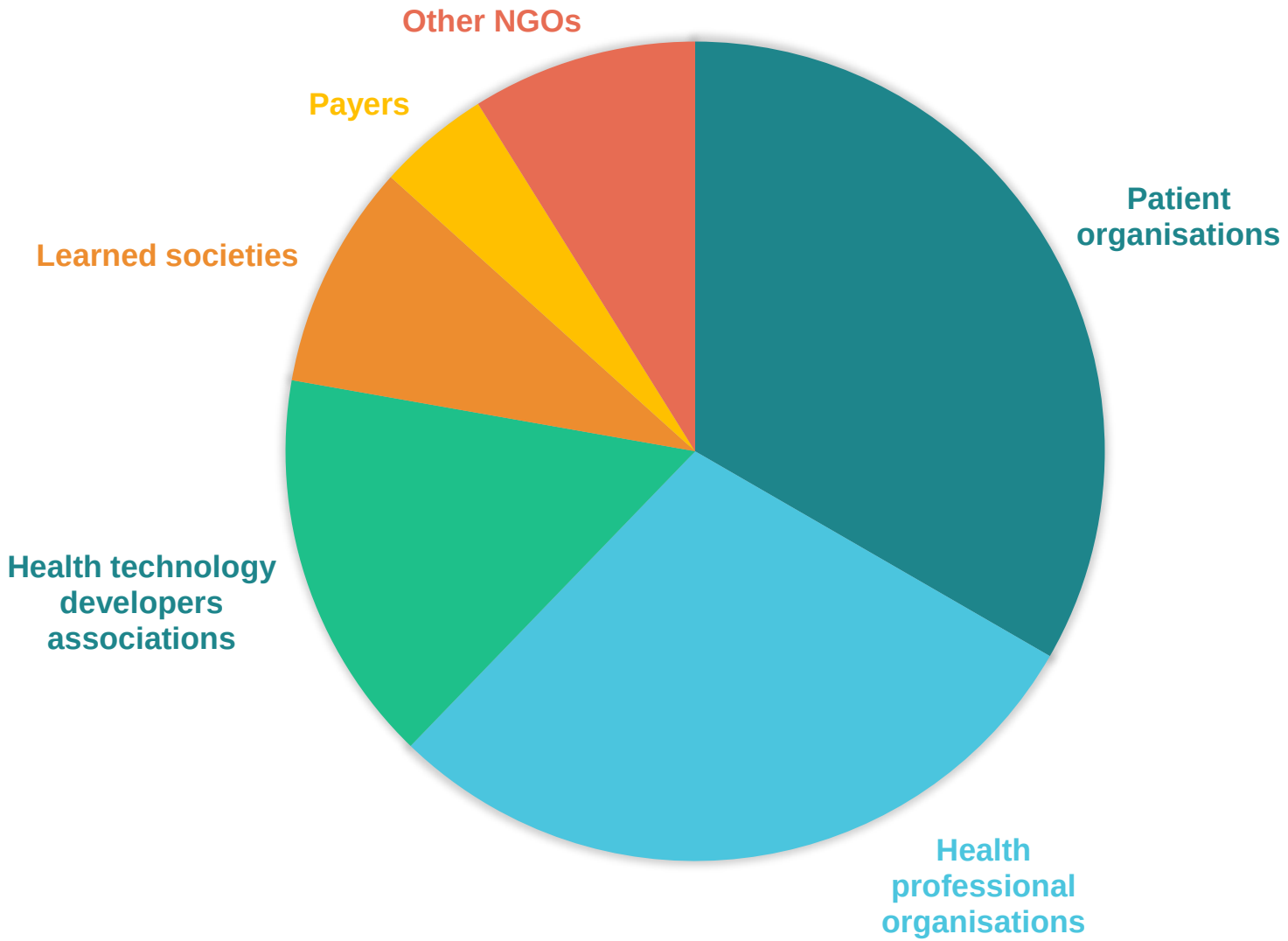
Type of organisations in the HTA Stakeholder Network



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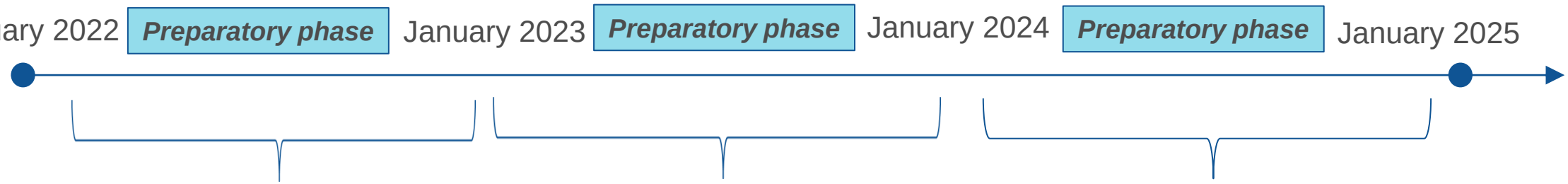
Final steps in the preparatory phase

Adoption
December 2021

Entry into force
January 2022

- **Developing the IT platform (EC)**

Application
January 2025



- **Setting up the Coordination Group (EC)**
- **Setting up the subgroups (EC)**
- **Setting up the Stakeholder Network (EC)**
- **Drafting implementing acts (EC)**
- **Drafting guidance and procedures (CG)**
- Training and capacity building
- **Awareness raising, incl. HTA information events (regional)**

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Service contract EUnetHTA21

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Implementing acts to be adopted by 2025

• Procedural rules for JCA of medicinal products	Q1-Q2 2024
• Procedural rules for the management of conflict of interest	Q2-Q3 2024
• Rules on cooperation by exchange of information with the EMA	Q2-Q3 2024
• Procedural rules for JSC of medicinal products	Q2-Q3 2024
• Procedural rules for JSC of medical devices and IVD medical devices	Q4 2024
• Procedural rules for JCA of medical devices and IVD medical devices	Q4 2024

Preparation, consultation and adoption of implementing acts

Early reflection
The Commission carries out appropriate consultations **during its preparatory work**

‘**Comitology**’ (examination) **procedure**

HTA Committee provides **opinion** on the draft text

Targeted consultation
Consultations with relevant stakeholders

Public consultation
Consultations with all stakeholders on Have your Say (4-week feedback period)

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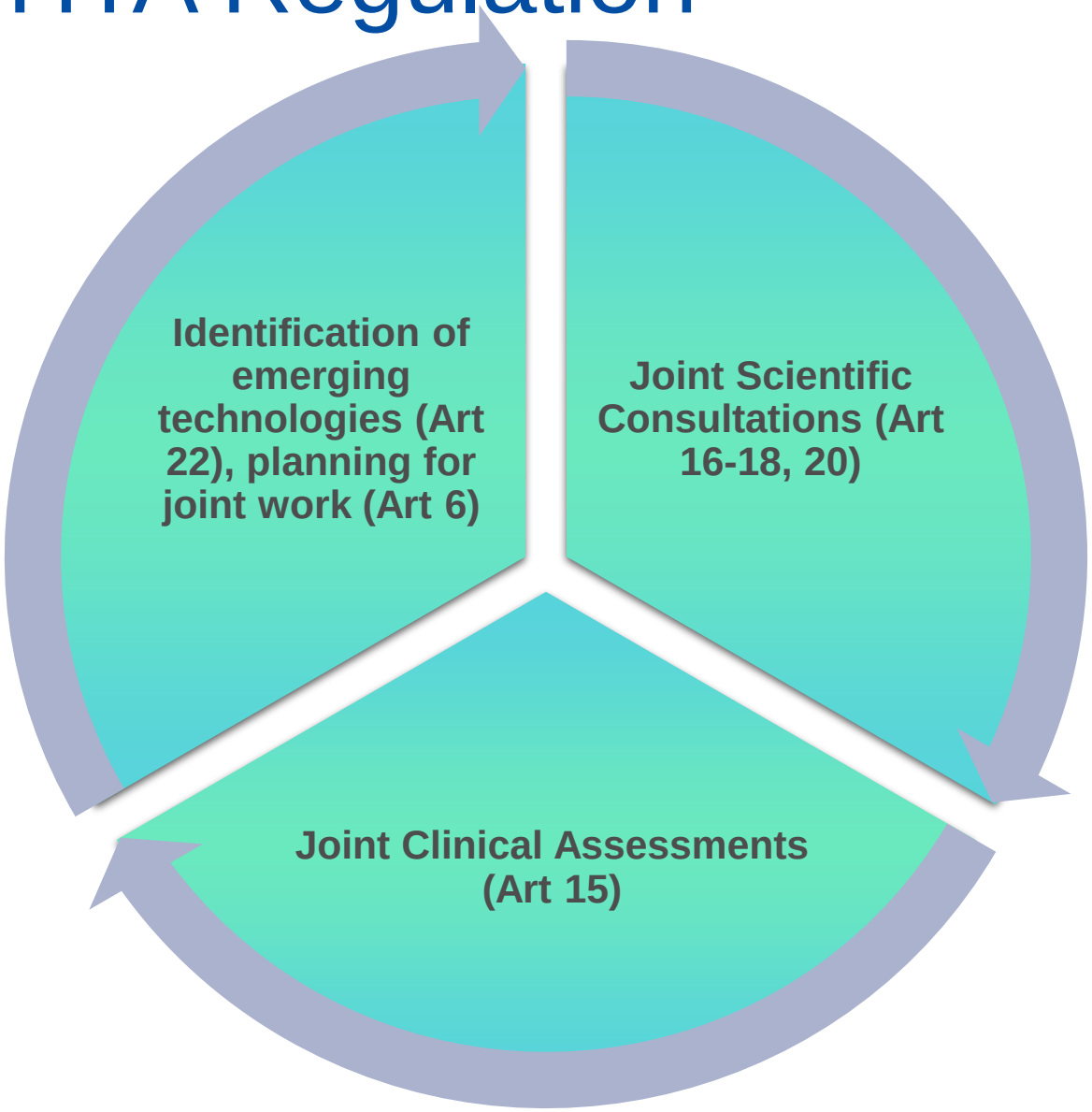
Collaboration with the EMA on the joint work under the HTA Regulation



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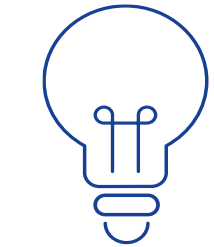
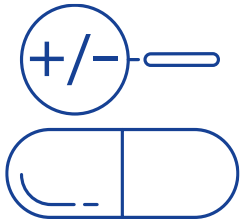
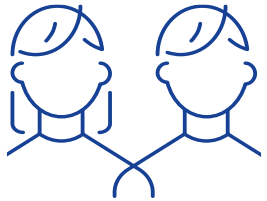


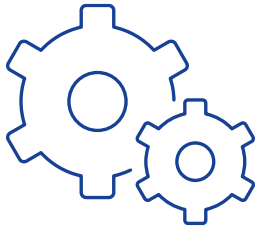
Life-cycle evidence planning



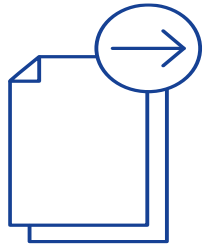
Cross-decision making collaboration



Communication and training



Research projects and policy initiatives



Processes under the Regulation

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Rolling plan regularly updated

IMPLEMENTATION ROLLING PLAN

2023-2024

REGULATION (EU) 2021/2282 ON HEALTH TECHNOLOGY ASSESSMENT

This rolling plan contains a list of key activities that the Commission has carried out or intends to carry out in preparation for the implementation of Regulation 2021/2282 on Health Technology Assessment (the "HTAR"). The plan is subject to regular review to provide national authorities and stakeholders with the most updated information.

The HTAR entered into force on January 11, 2022. It will be applicable as of January 12, 2025.

Latest update: February 2024

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
Member State Coordination Group on Health Technology Assessment (HTACG) HTAR Article 3				
Eighth meeting of the HTACG	HTAR Article 3		**8 March 2024**	In preparation
Eighth meeting of the subgroup for methodological and procedural guidance			19 February 2024	In preparation
Eighth meeting of the subgroup for joint Clinical Assessments			20 February 2024	In preparation
Fifth meeting of the subgroup for joint Scientific Consultations			21 February 2024	In preparation

https://health.ec.europa.eu/health-technology-assessment_en

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Awareness raising – HTA information events

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Conclusions: Co-creation of a new system

Quality, inclusivity and **transparency** as key principles of the joint work on HTA

Commitment of all Member States and all stakeholders is essential to secure smooth implementation

9 months left until the application

Thanks

Any questions?

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