Implementation of the Regulation (EU) 2021/2282 on Health Technology Assessment

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"HTA Regulation: What's next ?" 22 June 2022

Regulation (EU) 2021/2282
Key principles

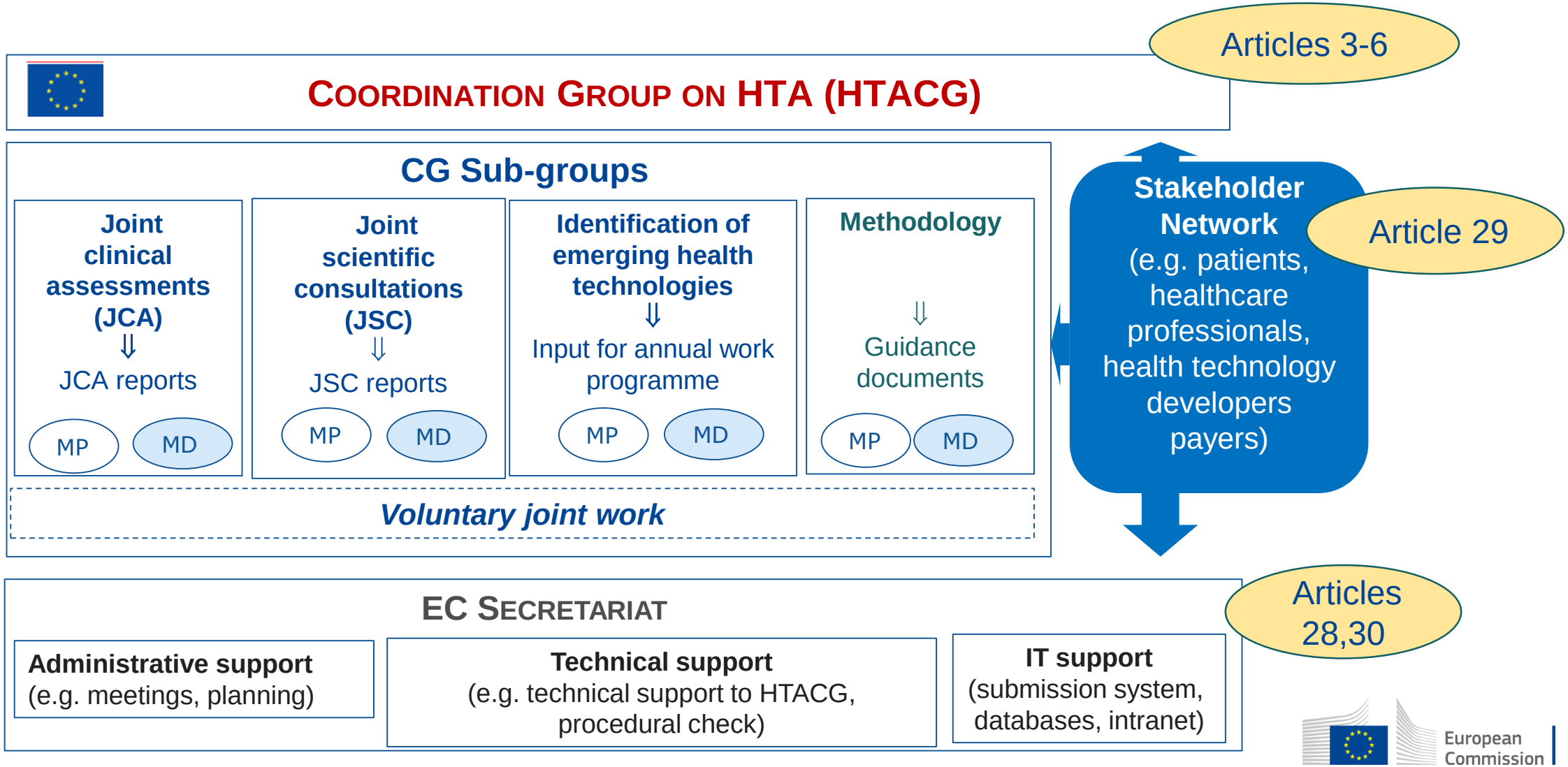
Joint HTA work

- Common scientific, clinical aspects of HTA
- Driven/carried out by Member States' Authorities
- High quality and timely reports for national HTA processes
- Transparent procedures/processes
- Engaging stakeholders
- Progressive implementation

➢ **Member States** remain responsible for:

- Drawing **conclusions on added value** for their health system
- Taking **decisions on pricing & reimbursement**

HTA Regulation
MS Coordination Group on HTA



MP = medicinal products, MD = medical devices

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HTA Regulation – Joint HTA activities

- **Joint Clinical Assessments/JCA** on:
  - **medicines** (first 3 years: oncology medicines and ATMP;

    following 2 years: + orphan drugs; after 5 years: full scope)
  - **a selection of high-risk implantable medical devices classified as class IIb or 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
- **Joint Scientific Consultations/JSC**
  - HTA only
  - in parallel with regulators
- **Emerging Health Technologies**/Horizon scanning
- **Methodology for joint HTA work**

HTA Regulation Implementation timeline

Adoption

December 2021

Entry into force

January 2022

Date of Application

January 2025

Joint Clinical Assessment Full Scope

January 2030

Preparatory phase

Implementation phase

Part of rolling Implementation plan

- **Setting up the Coordination Group/HTACG (EC)**
- **Setting up the Stakeholder Network (EC)**
- **Drafting implementing and delegated acts (EC)**
- **Drafting guidance documents (CG)**

Joint Scientific Consultations (JSC)

+

Stepwise build-up of Joint Clinical Assessments (JCA) scope for medicines:

- ***From Jan. 2025****: cancer drugs, ATMPs*

(from date of application)

- ***From Jan. 2028****: orphan drugs*

(3 years after date of application)

eunethta

Service contract EUnetHTA21

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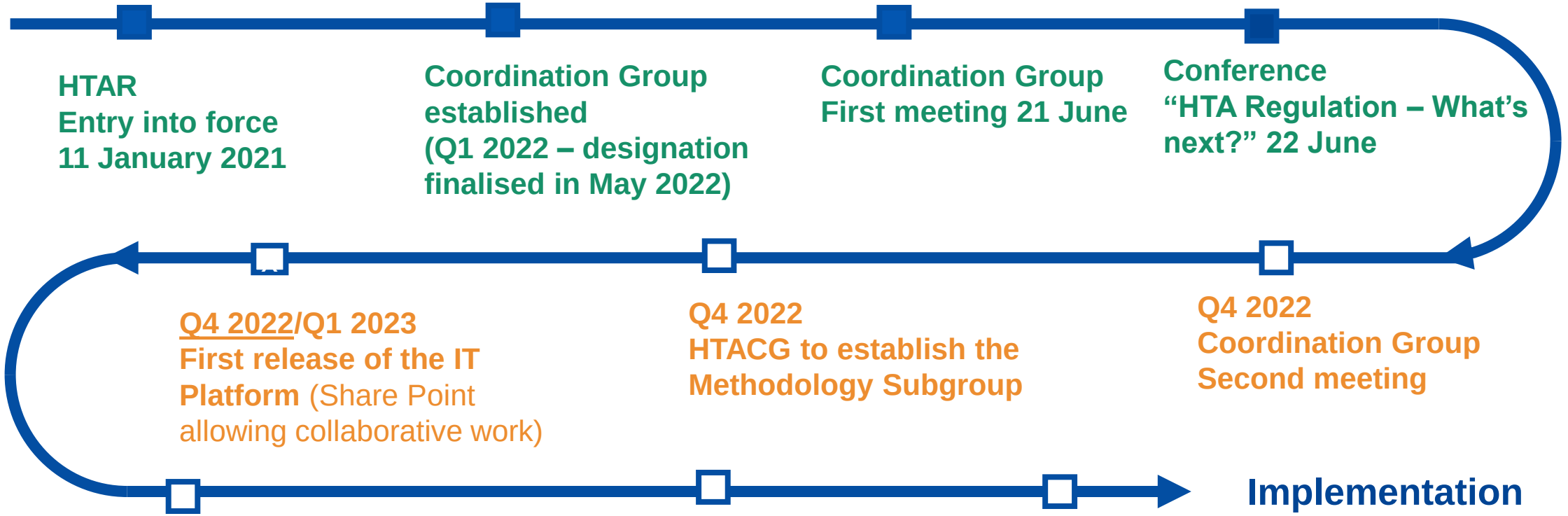
HTA Regulation
Implementation rolling plan

- Living document, public
- Aim: to provide national authorities, health technology developers and stakeholders with the most updated information regarding the implementation of HTAR
- Content
  - key activities that the European Commission has carried out or intends to carry out in preparation for the implementation of HTAR
  - key activities that the HTACG intends to carry out in preparation for the implementation of HTAR
- First version: March 2022
- Updated: May 2022

European Commission

HTA Regulation
Implementation rolling plan



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Joint efforts and shared commitment

- Commitment of **Member States and stakeholders** is essential to secure smooth implementation
  - Raise awareness
  - Adapt your process/procedures
  - Think “joint work”

- Implementation of the HTAR **is a priority for the Commission**
  - Establishing governance and operational structures
  - Support the HTACG in delivering methodological guidelines
  - Drafting and adoption of implementing legislation

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Thank you

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