Regulation (EU) 2021/2282 on HTA
Member States Coordination Group on HTA

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HTA Regulation - Key principles

- **Joint work** on common **scientific, clinical aspects** of HTA
- Joint work **driven by Member State HTA bodies**
- Ensure **high quality, timeliness and transparency**
- Ensure **use of joint work in national HTA processes**
- **Member States** remain responsible for:
  - Drawing **conclusions on added value** for their health system
  - Taking **decisions on pricing & reimbursement**
- **Addresses stakeholders' engagement in joint work**
- **Progressive implementation**

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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**

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HTA Regulation
Implementation rolling plan (living document)

Implementation of the Regulation on health technology assessment

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The Regulation (EU) 2021/2282 on health technology assessment (HTAR) entered into force on 11 January 2022 and will apply from 12 January 2025.

In the preparatory phase for the implementation of the HTAR (January 2022 – January 2025), this webpage aims at informing national authorities, health technology developers and stakeholders about the development of implementing legislation in accordance with the powers conferred to the Commission by the co-legislators. It will also inform about other activities related to the future application of the new legal provisions. This information will be part of the implementing rolling plan published on this page. After their setting up, this page will also include information about the Coordination Group and, at a later stage, about the Stakeholder Network.

In the implementation phase of the HTAR (beyond January 2025, when joint HTA work will start), this webpage will include all the information required by Article 30.3 of the HTAR.

NEW

Implementation rolling plan

The rolling plan below contains a list of key activities that the European Commission has carried out or intends to carry out in preparation for the implementation of Regulation (EU) 2021/2282. The plan is subject to regular review in order to provide national authorities, health technology developers and stakeholders with the most updated information.

- Rolling plan

https://ec.europa.eu/health/system/files/2022-03/hta_htar_rolling-plan_en.pdf

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HTA Regulation - Timeline of implementation

Adoption
December 2021

Entry into force
January 2022

Date of Application
January 2025

Joint Clinical Assessment Full Scope
January 2030

Preparatory phase

Implementation phase

- **Setting up of the EC Secretariat**
- **Setting up the Coordination Group/CG (EC)**
- **Setting up Stakeholders' Network (EC)**
- **Drafting implementing and delegated acts (EC)**
- **Drafting guidance documents (CG)**

eunethta

Service contract EUnetHTA21

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)

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HTA Regulation
Implementation of joint HTA work on medical devices

Implementing acts

+ methodological and procedural guidelines to be adopted by CG

Selection JCA medical devices – Art. 7.4

After the date of application of this Regulation, the Commission, after seeking recommendation of the Coordination Group, shall **select**, by way of implementing act and **at least every two years**, the **medical devices and in-vitro diagnostic medical devices** for joint clinical assessment based on one or more of the following criteria: unmet medical needs; first in class; potential impact on patients, public health or healthcare systems; incorporating software using artificial intelligence, machine learning technologies or algorithms; significant cross-border dimension; major Union-wide added value.

Input from EunetHTA21

JCA medical devices - Art. 15.1c, 26.1a, b and c, 25.1 a and b

(procedures, format and templates for the submission dossier, the format and templates for the JCA reports and summary JCA reports, rules for cooperation with regulators – e.g. expert panels, general procedural rules on the selection and consultation of stakeholder organisations and patients, clinical experts in JCA - in an independent and transparent manner, free from conflicts of interest)

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HTA Regulation
MS Coordination Group on HTA (Article 3)

Configurations:
- Medicinal products
- Medical devices (including IVDs)

- More than 1 member organisation/MS/configuration possible (1 representative +1 alternate/member organisation)
- Decision by consensus; if voting is necessary: 1 vote/ MS

+ Observers from EEA countries

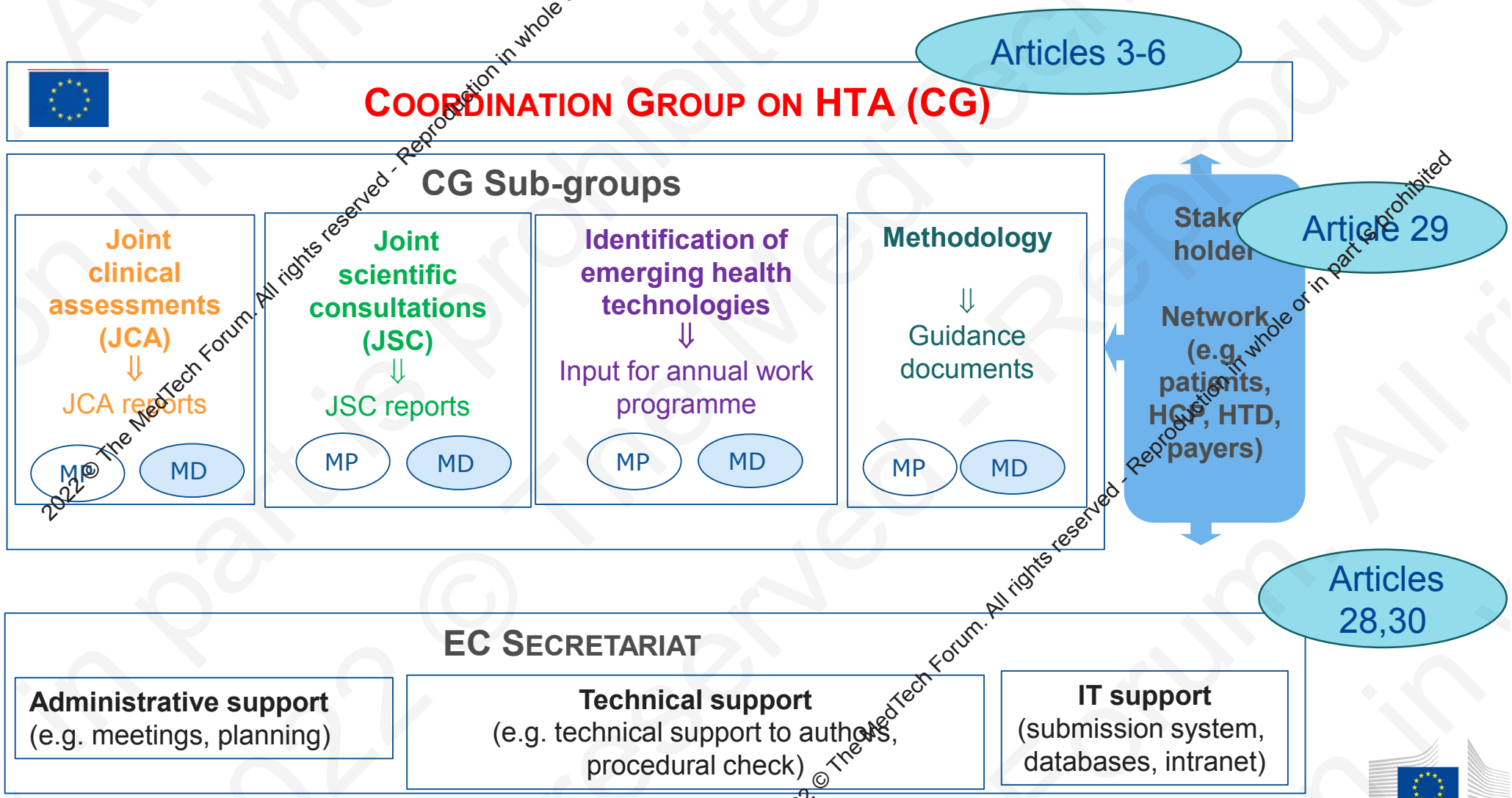
Elected chair and co-chair (from different MS)

First meeting 21 June 2022

EC Secretariat

European Commission

HTA Regulation
MS Coordination Group on HTA



MP = medicinal products, MD = medical devices, HCP = healthcare professionals, HTD = health technology developers

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HTA Regulation
MS Coordination Group on HTA (Article 3.7)

The Coordination Group shall:

- adopt its **annual work programme and annual report** pursuant to Article 6;
- provide **strategic direction for the work of its subgroups**;
- adopt **methodological guidance** on joint work following international standards of evidence-based medicine;
- adopt **detailed procedural steps and the timeframe** for the conduct of JCA and updates;
- adopt **detailed procedural steps and the timeframe** for the conduct of JSC
- adopt **guidance on the appointment of assessors and co-assessors** for JCA, JSC;
- **coordinate and approve the work of its subgroups**;
- **ensure cooperation with relevant Union level bodies (e.g. EMA, MDCG)**
- **ensure appropriate involvement of stakeholder organisations and experts** in its work;
- **establish subgroups**

Input from EunetHTA21

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Save the date: 22 June 2022, Brussels
One-day conference on the new Regulation on HTA)

- The main objective: to present the Commission's plans for the implementation of the new legal framework, and to stimulate a discussion with Member States authorities, HTA bodies, industry representatives, health professionals and patients on the opportunities and challenges of the next three years preparing for the implementation of the Regulation on HTA.
- The conference will include a plenary session hosted by European Commissioner for Health and Food Safety Stella Kyriakides, with participation of MEP Tiemo Wölken, and representatives of the Portuguese and French Presidencies.
- In the afternoon, the conference will adopt a participatory approach with parallel thematic breakout sessions organized by patients and healthcare professionals' organisations and HTA bodies respectively.

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Thank you

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