HTA Regulation
State of play for medical devices

Medical Device Coordination Group

15 October 2024

DG SANTE.C2 / HTA team

Regulation on Health Technology Assessment (HTA)

- Adoption 15/12/2021; in force 11/01/2022; in application **12/01/2025**
- Establishing: **a support framework and procedures** for cooperation of Member States on health technologies assessment at Union level; **a mechanism for submission of evidence** for joint clinical assessments only once at Union level; **common rules and methodologies** for joint clinical assessments.
- Vision: improve **patient access** to innovative technologies, strengthen the **quality** of HTA across the EU, avoid duplication of assessments, ensure **efficiency** and secure the **long-term sustainability** of EU HTA cooperation.

HTA Regulation - Key elements

- **Joint work** at EU level limited to the **clinical aspects** of HTA:
  - **Joint Clinical Assessment (JCA)** -> assessment of the relative effectiveness/performance and relative safety of a product compare to other products available on the market
  - **Joint Scientific Consultation (JSC)** -> advice to manufacturers on their plan to generate clinical data in view of future JCA
- Joint work **carried out by Member State HTA bodies** with input from **individual experts**
- **Member States** remain responsible for:
  - Drawing **conclusions on added value** for their health system
  - Taking decisions on pricing and reimbursement
- Ensure **use of joint work in national HTA processes**

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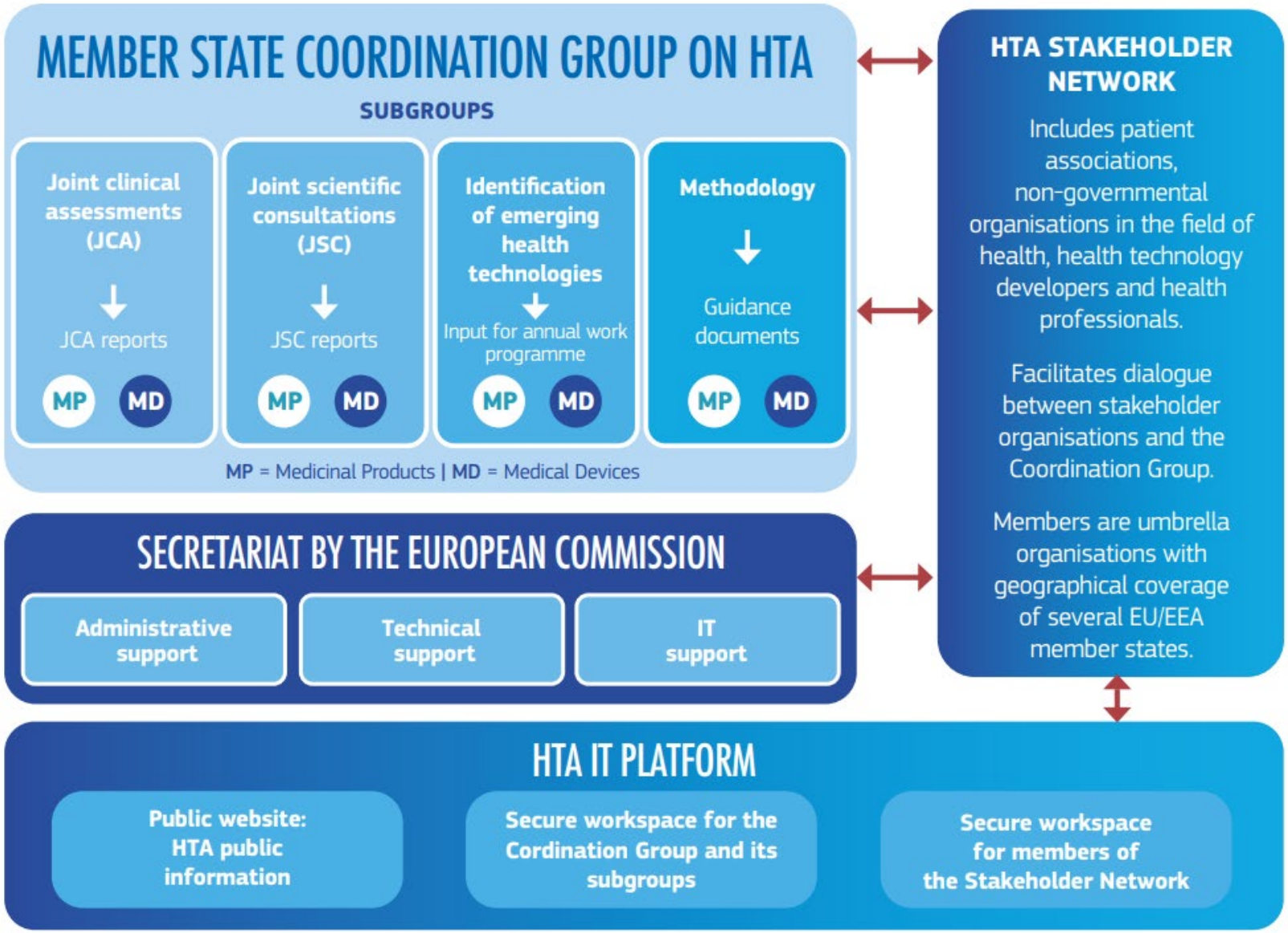
Joint HTA activities

- **Joint Clinical Assessments (JCA)** on:
  - **medicines** with a staggered approach (first 3 years: cancer medicines and advanced therapy medicinal products, from Jan 2028: + orphan medicines, from 2030: full scope)
  - **Selection of high-risk MDs and IVDs with expert panel opinions/views**
- **Joint Scientific Consultations (JSC)**
  - in parallel with the European Medicines Agency (medicines) / expert panels (MDs)
- **Identification of Emerging Health Technologies (EHT) with major impact**
- **Methodology for joint HTA work**
- **Voluntary cooperation** [Article 23 of the HTAR]

Governance



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MDs and IVDs in mandatory scope

Class III and class IIb **MDs** and class D **IVDs** that received an **expert panel opinion/views** AND subject to **selection** based on criteria listed in Article 7(4) of the HTAR

- **Selection criteria**: a) unmet medical needs; b) first in class; c) potential impact on patients, public health or healthcare systems; d) incorporation of software using artificial intelligence, machine learning technologies or algorithms; e) significant cross-border dimension; f) major Union-wide added value.
- Selection by means of an implementing decision by the Commission following HTA Coordination Group (HTACG) recommendation

Interaction with MDR and IVDR

- **Mandatory scope of devices** subject to joint work defined by the availability of an expert panel opinion/views
- **Joint scientific consultation**: possibility for the manufacturer to request an advice from the expert panels in parallel of a joint scientific consultation
- **Joint clinical assessment**: possibility for the HTA Coordination Group to request information to the notified body in view of the preparation and update of joint clinical assessment
- **Identification of emerging health technologies (EHT):** the reports on EHT shall consider information from relevant sources including the MDCG

Implementing acts on MDs and IVDs

3 implementing acts	Date of COM adoption
Implementing Regulation on JSC for MDs and IVDs Detailed procedural rules (Art. 20, HTAR) - Submission of requests from health technology developers (HTDs) - Selection and consultation of stakeholder organisations and patients, clinical experts and other relevant experts in JSC - Cooperation with the expert panels on JSCs on MDs in case of parallel consultation	**by 12 Jan 2025**
Implementing Regulation on JCAs for MDs and IVDs Detailed procedural rules (Art. 15, HTAR) - Cooperation with notified bodies and expert panels for preparation and update of JCAs - Interaction with and between HTACG, subgroups and HTDs, patients, clinical experts and other relevant experts during JCAs and updates Format and templates (Art. 26, HTAR) - Dossiers to be provided by HTDs for JCAs - JCA reports and summary JCA reports.	**by 12 Jan 2025**
Implementing Decision on MDs and IVDs subject to JCA following recommendations of the HTACG (Art. 7(4), HTAR)	**After 12 Jan 2025** Update min every 2 years

State of play of the preparation of the joint work on medical devices

- **Joint Scientific Consultations (JSC) of MDs and IVDs**
  - Activity expected to start 2nd half 2025
  - Draft Implementing Regulation on MD JSC: public feedback to be launched mid-end October
- **Joint Clinical Assessments (JCA) of MDs and IVDs**
  - Activity expected to start in 2026
  - Draft Implementing Regulation on MD JCA in preparation
    - **Input from notified bodies, industry and Member States**
    - **Selection of devices for JCA**: Member States to work on the methodology incl. interpretation of criteria

Thank you

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