HTA CG

MEMBER STATE COORDINATION GROUP
ON HEALTH TECHNOLOGY ASSESSMENT

The EU regulation on health technology assessment: History and status quo

HTA information day,
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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.

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

EU HTA vs National

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

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

HTA Regulation

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

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: new 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* diagnostic medical devices**

Joint Scientific Consultations (JSC)

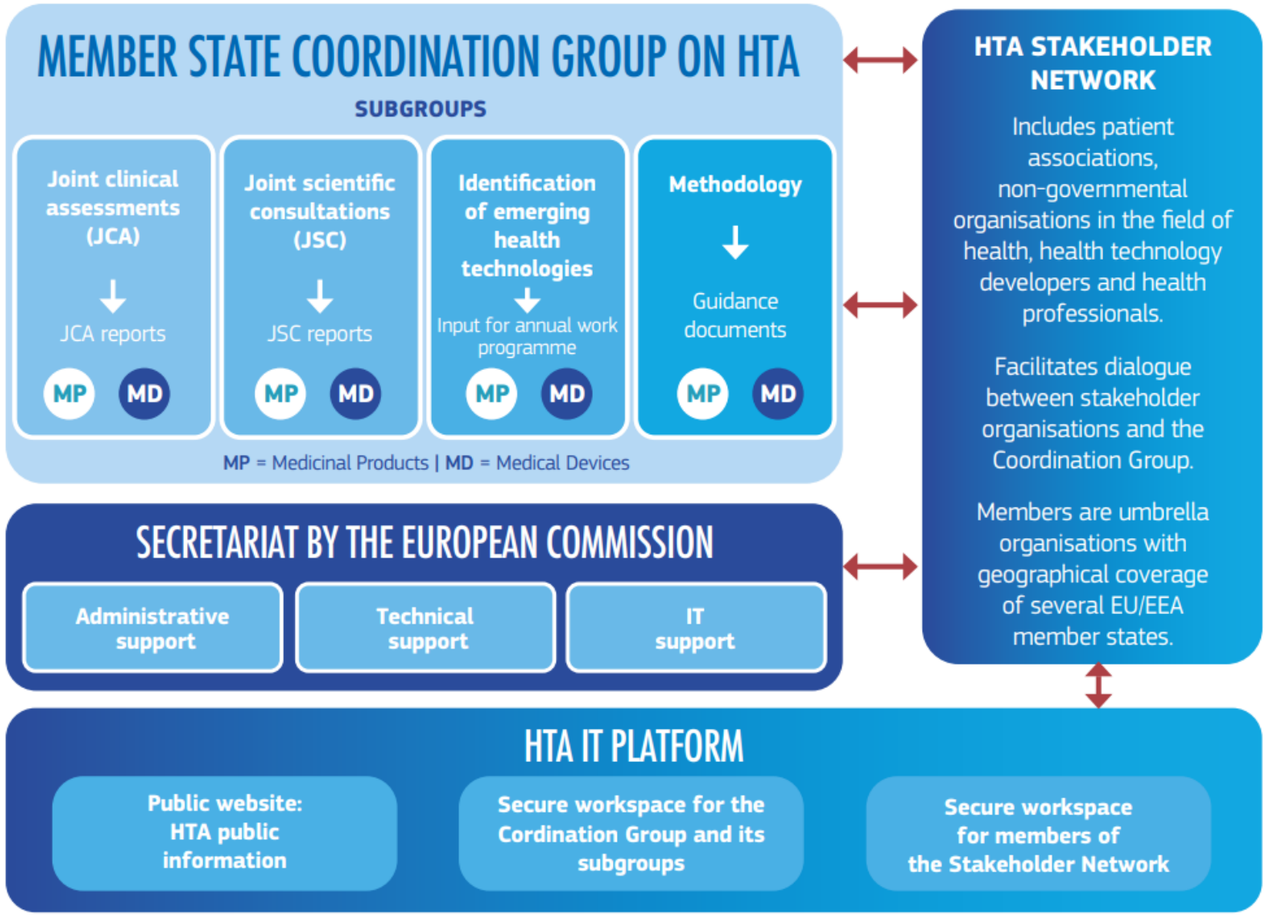
- in parallel with the European Medicines Agency

Emerging Health Technologies

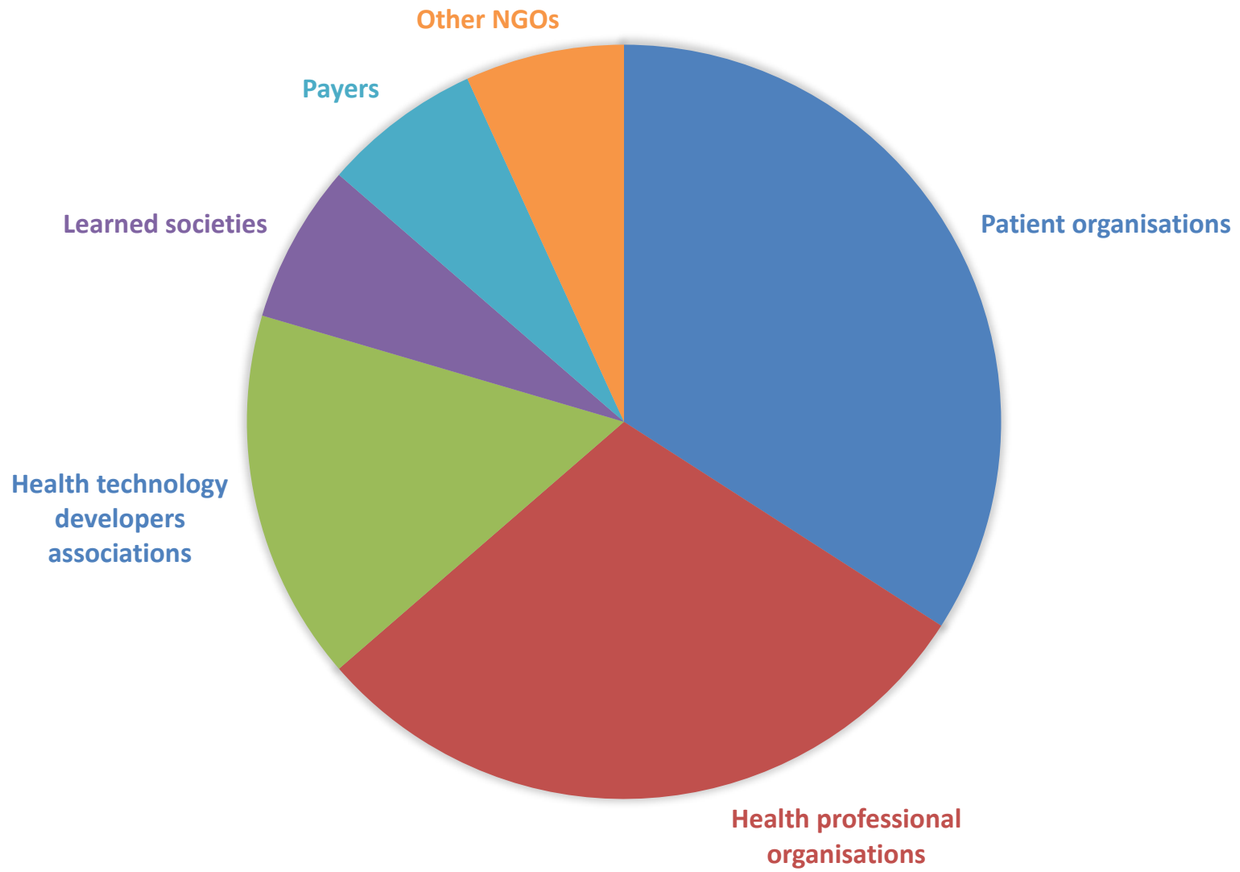
Methodology for joint HTA work

Voluntary cooperation

Governance


MEMBER STATE COORDINATION GROUP ON HTA
SUBGROUPS
Joint clinical assessments (JCA)
JCA reports
MP
MD
Joint scientific consultations (JSC)
JSC reports
MP
MD
Identification of emerging health technologies
Input for annual work programme
MP
MD
Methodology
Guidance documents
MP
MD
MP = Medicinal Products | MD = Medical Devices
HTA STAKEHOLDER NETWORK
Includes patient associations, non-governmental organisations in the field of health, health technology developers and health professionals.
Facilitates dialogue between stakeholder organisations and the Coordination Group.
Members are umbrella organisations with geographical coverage of several EU/EEA member states.
SECRETARIAT BY THE EUROPEAN COMMISSION
Administrative support
Technical support
IT support
HTA IT PLATFORM
Public website: HTA public information
Secure workspace for the Cordination Group and its subgroups
Secure workspace for members of the Stakeholder Network

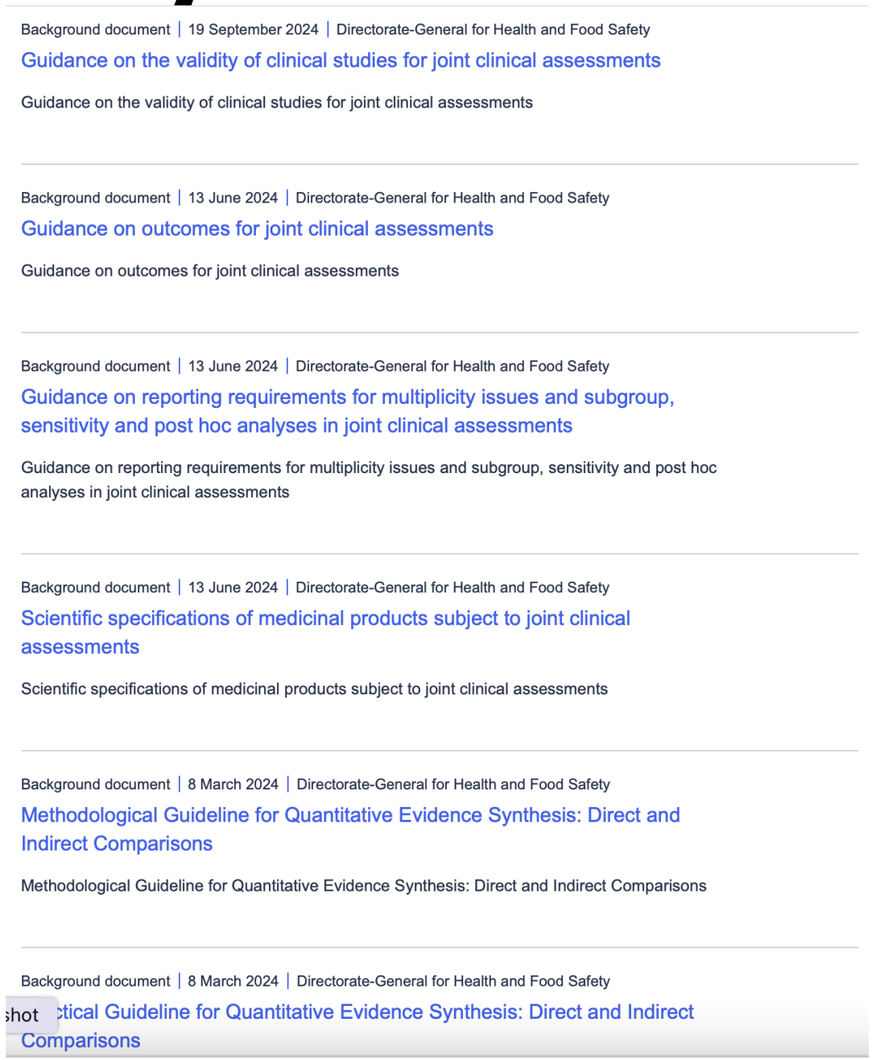
Type of organisations in the HTA Stakeholder Network



Implementing acts – Led by EC, supported by HTA Committee (MS)

• Procedural rules for JCA of medicinal products	Adopted
• Procedural rules for the management of conflict of interest	Publication in coming weeks
• Rules on cooperation by exchange of information with the EMA	Publication in coming weeks
• Procedural rules for JSC of medicinal products	Q4 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

Guidance by the HTA Coordination Group



Background document | 19 September 2024 | Directorate-General for Health and Food Safety

Guidance on the validity of clinical studies for joint clinical assessments

Guidance on the validity of clinical studies for joint clinical assessments

Background document | 13 June 2024 | Directorate-General for Health and Food Safety

Guidance on outcomes for joint clinical assessments

Guidance on outcomes for joint clinical assessments

Background document | 13 June 2024 | Directorate-General for Health and Food Safety

Guidance on reporting requirements for multiplicity issues and subgroup, sensitivity and post hoc analyses in joint clinical assessments

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Background document | 13 June 2024 | Directorate-General for Health and Food Safety

Scientific specifications of medicinal products subject to joint clinical assessments

Scientific specifications of medicinal products subject to joint clinical assessments

Background document | 8 March 2024 | Directorate-General for Health and Food Safety

Methodological Guideline for Quantitative Evidence Synthesis: Direct and Indirect Comparisons

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Background document | 8 March 2024 | Directorate-General for Health and Food Safety

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- 6 Scientific Guidance adopted and published
- Rolling Implementation plan published

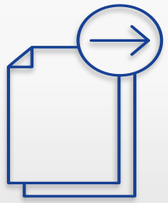
https://health.ec.europa.eu/health-technology-assessment_en

Collaboration with the EMA under the HTA Regulation

Life-cycle evidence planning

Communication and training

Research projects and policy initiatives



Processes under the Regulation

Awareness – HTA information events raising

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

~3 months left until the application

HTA CG

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Thank you

Any questions?