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

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European Commission

HTA information day, Seville
22 November 2023
Health technology assessment (HTA) is the systematic evaluation of the properties, effects, or impact of a health technology in comparison to another technology.

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

<table>
<thead>
<tr>
<th>HTA domains</th>
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<tbody>
<tr>
<td>Health problem and currently used technologies</td>
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<tr>
<td>Description of technology under assessment</td>
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<tr>
<td>Relative clinical effectiveness</td>
</tr>
<tr>
<td>Relative safety</td>
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<tr>
<td>Economic evaluation</td>
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<tr>
<td>Ethical aspects</td>
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<tr>
<td>Organisational aspects</td>
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<tr>
<td>Social aspects</td>
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<tr>
<td>Legal aspects</td>
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**Clinical domains**

**Non-clinical domains**
Regulatory process vs. HTA

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

• All Member States have different HTA systems
• National legislations and procedures
• Different methodologies and assessment criteria
Regulatory process vs. HTA

• Single licensing system
• Single 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
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**
- Ensure **high quality, timeliness and transparency**
- Ensure **involvement of stakeholders**
- 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 experts and stakeholders’ engagement in joint work**
- **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: full scope

- a selection of high-risk medical devices and in-vitro 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
- Joint scientific consultations (JSC)
  - JSC reports
- Identification of emerging health technologies
  - Input for annual work programme
- Methodology
  - Guidance documents

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 Coordination Group and its subgroups
- Secure workspace for members of the Stakeholder Network
Type of organisations in the HTA Stakeholder Network

- Patient organisations
- Health professional organisations
- Health technology developers associations
- Learned societies
- Payers
- Other NGOs
Halfway through the preparatory phase

Adoption
December 2021

Entry into force
January 2022

Preparatory phase
January 2023

Preparatory phase
January 2024

Preparatory phase
January 2025

Application

• Drafting guidance and procedures (CG)
  • Training and capacity building
  • Awareness raising, incl. HTA information events (regional)

• Developing the IT platform (EC)

• Drafting implementing acts (EC)

• Setting up the Coordination Group (EC)

• Setting up the subgroups (EC)

• Setting up the Stakeholder Network (EC)

Service contract EUnetHTA21

December 2021

January 2022

January 2023

January 2024

January 2025

Entry into force
## Implementing acts to be adopted by 2025

<table>
<thead>
<tr>
<th>Act</th>
<th>Date</th>
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<tbody>
<tr>
<td>Procedural rules for JCA medicinal products</td>
<td>Q4 2023</td>
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<tr>
<td>Procedural rules for the prevention of conflict of interest</td>
<td>Q1 2024</td>
</tr>
<tr>
<td>Cooperation by exchange of information with the EMA</td>
<td>Q1 2024</td>
</tr>
<tr>
<td>Procedural rules for JSC medicinal products</td>
<td>Q2 2024</td>
</tr>
<tr>
<td>Procedural rules for JCA medical devices and IVD medical devices</td>
<td>Q3 2024</td>
</tr>
<tr>
<td>Procedural rules for JSC medical devices and IVD medical devices</td>
<td>Q4 2024</td>
</tr>
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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)
Collaboration with EMA under the HTA regulation

- Identification of emerging technologies (Art 22)
- Joint Scientific Consultation (Art 16-18, 20)
- Joint Clinical Assessment (Art 15)
Collaboration with EMA under the HTA regulation

- Life-cycle evidence planning
- Cross-decision making collaboration
- Communication and training
- Research projects and policy initiatives
- Processes under the Regulation
Rolling plan regularly updated

Implementing 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: June 2023

<table>
<thead>
<tr>
<th>SUBJECT</th>
<th>LEGAL BASIS</th>
<th>DESCRIPTION</th>
<th>EXPECTED TIMELINE</th>
<th>STATUS</th>
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<tbody>
<tr>
<td>Fourth meeting of the HTACG</td>
<td>HTAR Article 3</td>
<td></td>
<td>13 June 2023</td>
<td>In preparation</td>
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<td>Third meeting of the subgroup on methodological and procedural guidance</td>
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<td></td>
<td>6 July 2023</td>
<td>In preparation</td>
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<tr>
<td>Third meeting of the subgroup on Joint Clinical Assessments</td>
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<td>7 July 2023</td>
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<tr>
<td>Third meeting of the subgroup on Joint Scientific Assessments</td>
<td></td>
<td></td>
<td>6 October 2023</td>
<td>In preparation</td>
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</table>

Awareness raising – HTA information events
Conclusions: Co-creation of a new system

Inclusiveness and transparency as key principles of the joint work

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

16 months left until application
Thank you for your attention

Any question?

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