



KEY ASPECTS IN THE EU HTA REGULATION

WHAT IS HEALTH TECHNOLOGY ASSESSMENT (HTA)?

HTA is a scientific, evidence-based, multidisciplinary process that evaluates new health technologies (pharmaceuticals, medical devices and procedures) to determine added value of a health technology in comparison with other new or existing health technologies.

WHAT IS THE EU HTA REGULATION (EU HTAR)?

The **EU regulation on HTA (Regulation 2021/2282)** applies from 12 January 2025. It provides a transparent and inclusive framework for Member States to work together at EU level on the clinical aspects of new health technologies coming to the market.

Expected impact:

- Increasing availability of innovative health technologies;
- Ensuring efficient use of resources;
- Strengthening the quality of HTA across EU Member States;
- Reducing duplications of efforts for national HTA authorities and Health Technology Developers (HTDs);
- Facilitating business predictability;
- Long-term sustainability of EU HTA cooperation.

WHAT HEALTH TECHNOLOGIES ARE UNDER CONSIDERATION?

Medicinal products and high-risk medical devices with high impact on patients, public health and health systems.

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Pillars of activities

- **Joint Clinical Assessment (JCA)** supports member states' national HTA processes, by providing a scientific analysis of clinical evidence on the relative effects of a medicinal product or a medical device on health outcomes.
- **Joint Scientific Consultation (JSC)** enables HTDs to obtain scientific consultation by HTA agencies alone or with EMA during the planning of the development plan and clinical investigations of a health technology on the information and evidence needed for a subsequent JCA.
- **Emerging Health technologies (EHT)**, also known as 'horizon scanning', consists of the early identification of new and emerging health technologies and trends that may have an impact on patient outcomes, clinical care or costs.
- **Voluntary cooperation** among Member States on clinical and/or non-clinical assessment on health technologies which are not in scope of joint clinical assessment.

HORIZONTAL ACTIVITY ACROSS PILLARS

Common procedures and methodologies: they represent a cornerstone of joint work in JCAs and JSCs as they are instrumental to the harmonization of procedures and methods for the joint work.

WHO IS INVOLVED?



- **Members State Coordination Group on HTA (HTACG)**: all EU Member States are represented. It includes subgroups for JCA, JSC, EHT, and procedures and methods. Each subgroup has a track for medicinal products and medical devices.
- **HTA Stakeholder Network**: it includes patient organisations, non-governmental organisations in the field of health, HTDs and health professionals.
- **Individual Experts** (patients, clinical experts and other relevant experts).
- **HTA Secretariat hosted by the European Commission (EC), DG SANTE** ensuring that procedures are followed, and joint work is produced in a timely and transparent manner.
- **European Medicines Agency (EMA)**: EMA collaborates with the EC and the HTACG by providing specific information as required by the EU HTAR and may participate in JSC. The aim is to support the work of the HTACG.

ROLE OF PATIENTS

Patient involvement is crucial in ensuring a successful implementation of the EU HTAR.

Alongside clinical experts, selected patients bring their expertise and lived experience to contribute their input to the joint work, including the assessment framework that defines the clinical research questions, known as PICO (Population, Intervention, Comparator, and Outcome).

Priority is given to patients:

- with expertise,
- covering several Member States in the therapeutic area, and
- complying with conflict-of-interest rules.

They will provide their input through interviews or in written format, on:

- impact of the condition,
- experiences with currently available health technologies,
- expectations from the new health technology being assessed, and
- experience with the new health technology being assessed.

In JSC, they provide their expectations and indicate perceived limitations on the clinical development plan for proposed clinical trials.

Patient organisations involved in the HTA Stakeholder Network also play a role. They provide input to the annual work programme and help to identify experts for joint work. Other patient organisations at the national and European level may support and inform the PICO definition.



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