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The European regulation on Health Technology Assessment Balancing European and National Levels

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In order to harmonize and optimize access to health technologies*, including gene and cell therapies, the European Union changed its legislation with the adoption of a new regulation on Health Technology Assessment (HTA) in December 2021.

*medicinal products, medical device or medical and surgical procedures, and measures for disease prevention, diagnosis or treatment used in healthcare

What is HTA? EU Regulation 2021/2282

“A multidisciplinary process that summarises information about the medical, patient and social aspects and the economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner.”

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HTA conducted at national level

+ EU initiative → EUnetHTA (2006-2021): joint action, voluntary cooperation between 25 States

Consequences

- Redundancy of evaluation process
- Misallocation of resources
- Inequitable access to new technologies

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Harmonization of procedure

Regulation: Rolling implementation plan, preparatory phase

- Setting up the **HTA Coordination Group (HTACG)** and the **Stakeholder Network**
- Drafting implementing & delegated acts, and guidance documents

+ New **EUnetHTA 21**: 13 States work to support the continuation of the HTA process at a European level

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Step-by-step implementation

2025

Advanced Therapy Medicinal Products, cancer drugs

2028

Orphan medicines

2030

All health technologies

National level

- **National bodies** provide expert views on HTA
- **Member States** remain responsible for:
 - drawing conclusions on added value of health technologies for their health system
 - taking decisions on their pricing & reimbursement

European level

- **HTACG** manages the HTA process:
 - Joint clinical assessment (JCA)
 - Identification of emerging technologies
 - Joint scientific consultations
 - Voluntary cooperation
- **Stakeholder network** also supports HTACG's work, through exchange of scientific information
- **European Commission** supports HTACG's work, as the secretariat

- Regulation increases quality of joint work, and joint work increases quality of assessment.
- Better allocation of resources: reduced expenses for national bodies and the EU
- Improved accessibility to all medicines in the EU at medium and long term
- Among all processes, only joint clinical assessment will have to be taken into consideration at the national level.

Remaining challenges

- Building EU processes from national HTA experiences and feedback from experts
- Training more external experts / organisations on HTA in general, and on EU procedure(s)