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The new European regulation on Health Technology Assessment: what changes for Advanced Therapy Medicinal Products?

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Health Technology Assessment (HTA)?

“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.”

Article 2.5) EU Regulation 2021/2282

➔ Evidence-based process enabling relative effectiveness assessment of new/ existing technologies

Health technology?

“A medicinal product, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare.”

Article 3.1) Directive 2011/24/EU

➔ ATMPs are included

PAST

- Independent assessments from national HTA bodies
- EUnetHTA (2006-2021): joint action, voluntary cooperation

BUT

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

PRESENT (2022)

Rolling implementation plan: preparatory phase

- Setting up the Coordination Group and the Stakeholder Network
- Drafting implementing & delegated acts, and guidance documents
- 2021-23: New EUnetHTA (2021)
- 2023-25: Member States remain responsible for drawing conclusions on added value for their health system and taking decisions on pricing & reimbursement. They can give additional multinational or simultaneous national scientific advice on a voluntary basis.

FUTURE (from 2025)

Application of Joint Clinical Assessments:

- 2025: ATMPs, cancer drugs
- 2028: orphan drugs
- 2030: all medicines covered by Regulation scope

New HTA process:

- New **Coordination Group** managing HTA process
- **Secretariat** provided by the European Commission
- **National bodies** providing expert views on HTA
- Exchange of information with **stakeholder network**

- Increased quality of joint work
- Better allocation of resources: reduced expenses for national bodies and the EU
- Improved accessibility to ATMPs in the EU

Clinical and non-clinical assessments

Joint Clinical Assessments

➔ To be considered for any HTA at Member States level

Description	Goal
Collection and analysis of clinical evidence about a health technology to determine its therapeutic value compared to other technologies already available or not.	Quality, common source for States to determine pricing and reimbursement of health technology: ATMPs⁺⁺⁺

Voluntary Cooperation to exchange information, e.g., on non-clinical assessments

Description	Goal
Allowing States to exchange information on non-clinical areas, for examples on organizational, ethical, legal, and economic matters, or on health technologies other than medicines and medical devices	Going beyond the clinical scope: ATMPs⁺⁺⁺

Joint Scientific Consultations

➔ No legal effects on Member States

Description	Goal
Early exchanges between industry and the Coordination Group.	Advising on clinical studies designs to generate appropriate evidence: ATMPs⁺⁺⁺

Identification of Emerging Technologies (ATMPs)

➔ Coordination Group's Initiative

Description	Goal
Reports on new technologies with potentially significant impact on patients, public health and healthcare systems.	Anticipating issues to improve patient access: ATMPs⁺⁺⁺

Complementary tools

Support to industry

Support to national governments

Remaining challenges:

- Building EU processes from national HTA experiences and feedback from experts
- Training more external expert / organisations on HTA in general, and on EU procedure(s)
- Organising HTA registries, raising awareness, collecting experiences
- Identifying / involving clinicians or patients (organisations' membership list, social networks, European Reference Networks, clinics in Pubmed...)