European Commission

IMPLEMENTING THE EU HEALTH TECHNOLOGY ASSESSMENT REGULATION

WHAT IS HTA?

HEALTH TECHNOLOGY ASSESSMENT:

Procedure for assessing the added value, effectiveness, costs and broader impact of health care interventions including medicines, medical devices and procedures.

- Is a new medicine more effective in treating a certain disease?
- Do expected costs and benefits present sufficient value-for-money when compared to alternative healthcare interventions?
- How to compare a new medicine to an existing one considering patients, the disease, and the outcome for the patient?
- Will the use of a new medical device result in better diagnosis or treatment?

HTA DOMAINS

CLINICAL DOMAINS

- Health problems and currently used health technologies (e.g. medicines, medical devices, surgical procedures).
- Description of health technology under assessment.
- Relative clinical effectiveness.
- Relative safety.

NON-CLINICAL DOMAINS

- Economic evaluation.
- Ethical aspects.
- Organisational aspects.
- Social aspects.
- Legal aspects.

WHAT'S IN THE EU HTA REGULATION?

FRAMEWORK FOR JOINT HTA COOPERATION

- Joint clinical assessments (JCAs).
- Joint scientific consultations (JSCs).
- Identification of emerging health technologies.
- Common procedures and methodologies across the EU.

KEY PRINCIPLES OF THE HTA REGULATION

- Only on clinical domains of the assessment: No economic assessment or any conclusion on pricing and reimbursement.
- Driven by EU HTA bodies who remain responsible for drawing conclusions on added value for their health systems.
- High quality, timeliness and transparency.
- Use of joint work in national HTA processes.
- Input from independent experts.
- Stakeholder engagement and inclusiveness.
- Progressive implementation.

TIMELINE FOR MEDICINES

- 12 January 2025: New oncology medicines and advanced therapy medicinal products will be assessed at EU level.
- 13 January 2028: Orphan medicinal products to be added to the joint work.
- 13 January 2030: All new medicines will come under the scope of the regulation.