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.
WHAT WILL BE ASSESSED AT EU AND AT NATIONAL LEVEL?

**MEDICINES**
- **EU ASSESSMENT** (jointly done by the Member States)
- **CLINICAL ASSESSMENT** (benefits compared to existing treatments)
- **NON-CLINICAL ASSESSMENT** (economic, social and ethical aspects)

**MEDICAL DEVICES**
- **EU ASSESSMENT** (jointly done by the Member States)
- **CLINICAL ASSESSMENT** (benefits compared to existing treatments)
- **NON-CLINICAL ASSESSMENT** (economic, social and ethical aspects)

GOVERNANCE STRUCTURE

**MEMBER STATE COORDINATION GROUP ON HTA**
- **SUBGROUPS**
  - Joint clinical assessments (JCA)
  - Joint scientific consultations (JSC)
  - Identification of emerging health technologies
  - Methodology

**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
EUnetHTA 21 was set up as a joint consortium of national HTA agencies from 12 EU countries, working under a service contract of the European Commission. Their work, financed by the Third Health Programme, builds on the achievements of over 10 years of cooperation in the EUnetHTA Joint Actions. The work of the consortium focuses on supporting a future EU HTA system under the HTA Regulation.

All deliverables produced by EUnetHTA 21 can be found here: https://www.eunethta.eu/jointhtawork/