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.

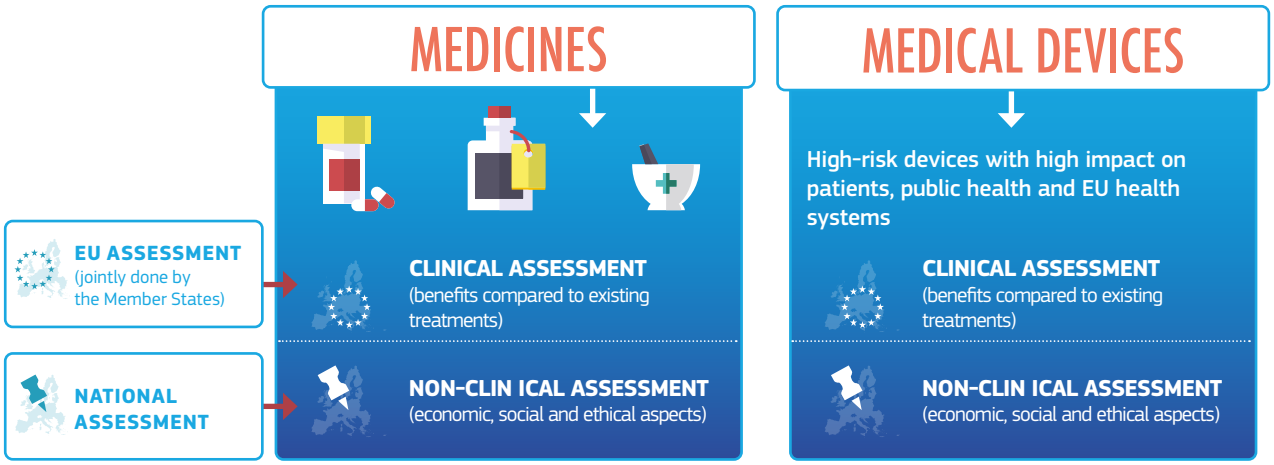
KEY PRINCIPLES OF THE HTA REGULATION

- 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.

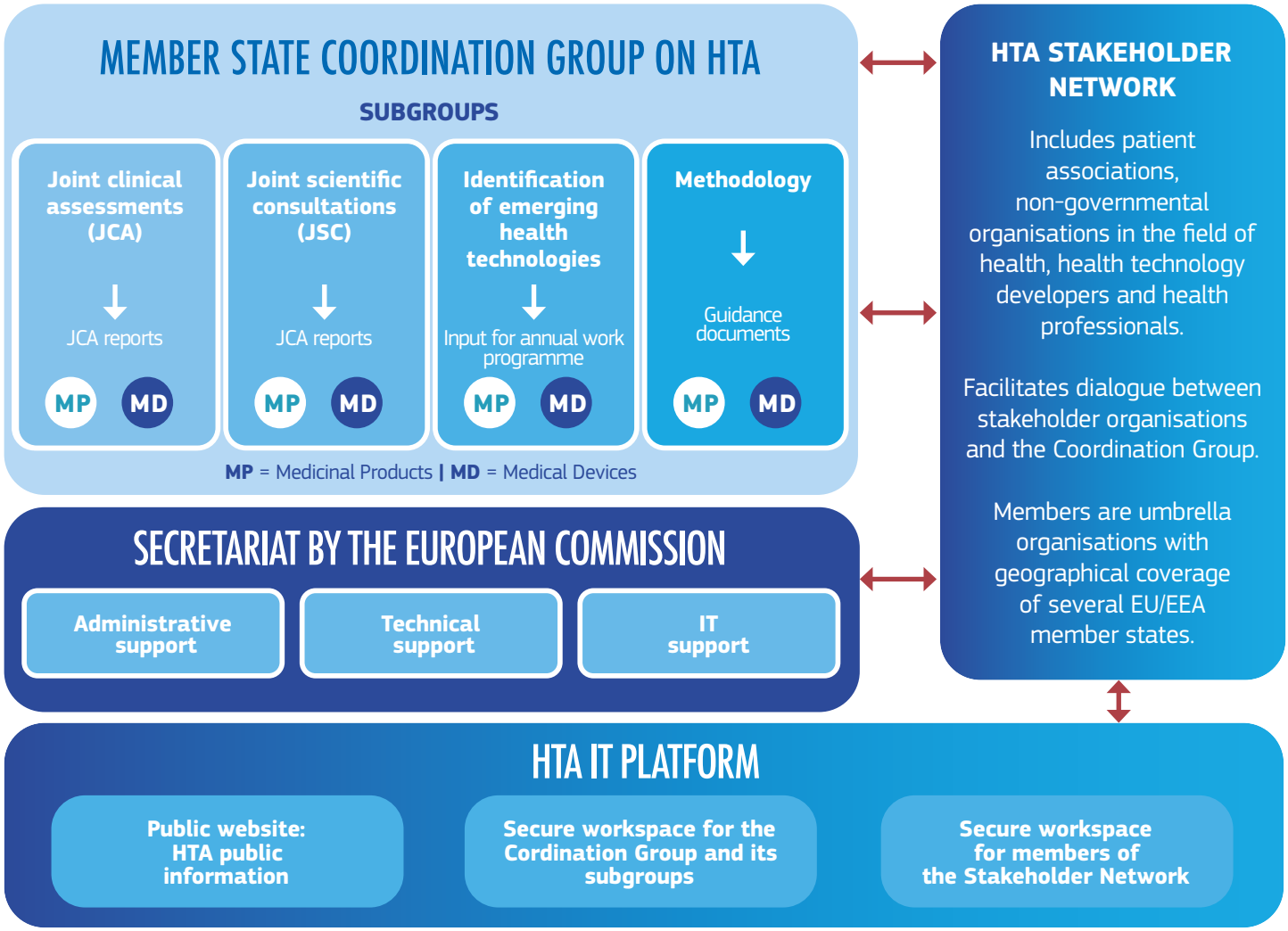
TIMELINE FOR MEDICINES

- 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.

WHAT WILL BE ASSESSED AT EU AND AT NATIONAL LEVEL?



GOVERNANCE STRUCTURE



TIMELINE

JAN 2022	MAR 2022	NOV 2022	APRIL 2023	JUNE 2023
Entry into force	Coordination Group established	Election of Chair and Co-chairs of the Coordination Group	All sub-groups established	Stakeholder Network established

2023 – 2024	12 JAN 2025
Adoption of implementing acts, and methodological and procedural guidance	Application

EUnetHTA 21

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/

#HealthUnion

For more information scan the QR code:
https://health.ec.europa.eu/health-technology-assessment_en

PDF ISBN 978-92-68-03348-7 doi:10.2875/246730 EW-07-23-200-EN-N