New EU rules on Health Technology Assessment open up a new era for patient access to innovation

Health treatment of patients

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The new rules create an EU framework for the assessment of health technologies, such as medicines and medical devices, by fostering collaboration and coordination between EU Member States. This will help national authorities to make more timely and informed decisions on the pricing and reimbursement of health technologies and streamline the procedure for health technology developers. This will contribute to faster and wider access to new and more effective innovative products for patients.

The rules will apply to companies seeking marketing authorisation for their products by introducing a new and permanent EU framework for Health Technology Assessment, including through:

introducing a single EU-level submission file for joint clinical assessments in order to ensure pooling of resources at the EU level and strengthening the scientific quality of HTA across the EU whileavoiding duplication of assessments at national level.

establishing faster procedures requiring Joint Clinical Assessments to be completed within 30 days after the authorisation of the medicine;

the systematic consultation of patients and clinicians during the preparation of the assessments as well as the involvement and consultation of the HTA stakeholders.

As a first step, starting on 12 January, these new rules will apply to marketing authorisation applications for a new cancer medicine or an advanced therapy medicinal product (ATMP). The rules will be extended to orphan medicines in January 2028 and will as of 2030 cover all new medicinal products. Selected high-risk medical devices will also be assessed as of 2026.

The new EU framework replaces the long standing EU-funded project-based cooperation between Member States on health technology assessment, while fully respecting Member States' responsibility for the management of their health services as their national context requires.

Background

Health technology assessment is a scientific, evidence-based process that aims to inform the creation of safe and effective health policies by summarising information about the medical, social, economic and ethical issues related to the use of a health technology.

The European Commission adopted its proposal for a Regulation on Health Technology Assessment on 31 January 2018. Adopted in December 2021, the Regulation, a key deliverable of the EU Pharmaceutical Strategy, entered into force in January 2022. It applies from 12 January 2025. During this three-year transitional period, the Commission and the Member States prepared by seting up the necessary governance structure and drafted preparatory documents to support an effective application.