European Commission - Press release

Health Technology Assessment: Commission welcomes the adoption of new rules to improve access to innovative technologies

Brussels, 13 December 2021

Today, the Regulation on Health Technology Assessment (HTA), a deliverable of the EU Pharmaceutical Strategy, has been adopted. The new rules will allow vital and innovative health technologies - such as innovative medicines, certain medical devices, medical equipment and prevention and treatment methods - to be more widely available. The Regulation will also ensure the efficient use of resources, strengthen the quality of HTA across the EU, and save national HTA bodies and industry from duplicating their efforts, reassure business and ensure the long-term sustainability of EU HTA cooperation.

Welcoming the adoption, Commissioner for Health and Food Safety, Stella **Kyriakides,** made the following statement:

"I am very pleased that today, after years of hard work, new rules to ensure that patients have better access to innovative medicines and medical devices will soon be a reality in the EU. The Regulation on Health Technology Assessment is a key deliverable of the European Pharmaceutical Strategy and an important building block for a European Health Union and our work to deliver concrete benefits to citizens in the area of health.

With COVID-19, we have seen the importance of producing safe and efficient treatments and medical devices for all Europeans. The new rules will secure inclusiveness and transparency in the assessment process and increase predictability for Member States' authorities and for the industry. Member States will be able to take more timely and evidence-based decisions on patient access to innovative technologies within their healthcare systems.

Now health experts, the producers, and most importantly of all – patients, will have a new framework that will help us to address unmet medical needs and facilitate access to innovative medicines and some high-risk medical devices. This is about patients and improving access to life saving innovative technologies. It is also about building a new way of cooperating on health in the EU.

Its implementation will be crucial not only in order to reach the objectives of EU's Pharmaceutical Strategy and Europe's Beating Cancer Plan, but also to enhance coordination at EU level in the field of health. This is yet another step towards a stronger European Health Union."

The Regulation will apply from January 2025, but the implementing work starts now, including the setting up of the necessary governance structure and preparatory documents to ensure effective application from this date.

The Regulation supersedes the current system of EU-funded project-based cooperation between Member States on health technology assessment by introducing a permanent framework for joint work that will also cover joint scientific consultations, the identification of emerging health technologies, and voluntary cooperation, as well as work on joint clinical assessments.

The Regulation fully respects Member States' responsibility for the management of their health services, including pricing and reimbursement.

Next steps

The Regulation will enter into force 20 days after its publication in the Official Journal of the EU. The Regulation provides for a delayed application of three years, during which the Commission will:

- set up the Coordination Group. The Commission will soon invite Member States to nominate their members and the first meetings of the Coordination Group is tentatively scheduled for mid-2022;
- establish the Stakeholder Network;
- adopt the necessary implementing and delegated acts; and
- facilitate the development of methodology for joint HTA work by the Coordination Group as

required by the Regulation.

Background

The Commission's proposal for a Regulation on Health Technology Assessment (HTA) was adopted in January 2018. The European Parliament closed its first reading position in February 2019. The Council obtained a first partial mandate in March 2021 to start informal negotiations with the European Parliament, and a second mandate in June 2021 to secure the adoption of the file. The European Parliament closed its early second reading position in December 2021.

Both co-legislators and the Commission have been fully behind the work to achieve adoption of this very important file that will contribute to the objectives of the Pharmaceutical Strategy for Europe in terms of supporting innovation, addressing unmet medical needs and facilitating patient access to innovative medicines.

For More Information

Questions and Answers: Adoption of Regulation on Health Technology Assessment

More innovative health technologies for patients (europa.eu)

Commission website - Health technology assessment

Original Commission proposal, tabled in January 2018

Legislative observatory, European Parliament

IP/21/6771

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