Health technology assessment

2018/0018(COD) - 13/12/2021 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a legislative resolution **approving**, without amendment, the Council's position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

The proposed regulation includes provisions on the use of common methods, procedures and tools for health technology assessment throughout the EU. Health technology assessment (HTA) is an evidence-based scientific process that enables competent authorities to assess the relative effectiveness of new or existing health technologies. HTA focuses in particular on the added value of a health technology compared to other new or existing technologies.

Purpose of the Regulation

The new rules provide for **Member States to cooperate in conducting joint clinical assessments and joint scientific consultations**. They will also join forces to identify emerging health technologies.

The regulation establishes:

- a support framework and procedures for cooperation between Member States on health technologies at EU level;

- a mechanism whereby all information, analysis and evidence required for the common clinical assessment of health technologies is **submitted by the health technology developer only once at EU level**;

- common rules and methods for the common clinical evaluation of health technologies.

Scope and timeframe

Advanced **therapy medicinal products** would be subject to a joint clinical assessment at the date of application of the regulation, as would medicinal products containing new active substances for the treatment of **cancer**. In addition, **orphan medicinal products** and all remaining medicinal products within the scope of the Regulation would be added three and five years respectively after the date of application of the Regulation.

Coordination group

The Member States Coordination Group on Health Technology Assessment will be established.

The Council's position provides for the use of different types of majorities, depending on the type of decisions adopted. The default rule would be that, where consensus cannot be reached, decisions of the Coordination Group would be adopted by **simple majority**. By way of derogation, a qualified majority would be required for the adoption of the annual work programme and the annual report, as well as for the definition of the strategic direction to be given to the work of the sub-groups.

The Coordination Group will ensure that the joint work carried out is of the highest quality, meets international standards of evidence-based medicine and is timely. It will operate in an independent, impartial and transparent manner.

Completion of the joint clinical evaluation

Upon receipt of the draft common clinical assessment reports and revised summary reports, the coordination group should review them. The coordination group should seek to approve the revised draft reports by consensus. Diverging scientific opinions, including the scientific basis for these opinions, should be included in the reports.

Obligations on Member States

Member States should '**give due consideration**' to the joint clinical assessment reports. A certain number of safeguards were introduced to strengthen obligations on Member States, namely the requirement to annex the joint clinical assessment report to the national health technology assessment and to report on how each joint clinical assessment report was given due consideration in the health technology assessment at national level.

Stakeholder involvement

The Council position states that the subgroups should ensure that patients, clinical experts and other relevant experts participate in the assessment by having the opportunity to provide input on the draft reports. Provisions were also agreed to ensure transparency and absence of conflict of interest during the joint work.