Health technology assessment

2018/0018(COD) - 01/12/2021 - Committee recommendation tabled for plenary, 2nd reading

The Committee on the Environment, Public Health and Food Safety adopted the recommendation for second reading contained in the report by Tiemo WÖLKEN (S&D, DE), on 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 Council's position at first reading reflects the agreement reached between Parliament and the Council in the interinstitutional negotiations at early second reading stage.

As the committee responsible has already confirmed the outcome of these interinstitutional negotiations, it recommends that the plenary confirm the Council's position at first reading, without amendment.

The proposed regulation includes provisions on the **use of common methods, procedures and tools for health technology assessment** across the EU. It sets out four pillars around which Member States will work together at EU level, namely (1) joint clinical assessments, (2) joint scientific consultations, (3) identification of emerging health technologies, and (4) voluntary cooperation in areas outside the scope of mandatory cooperation.

The main points of the Council's position are as follows:

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.

Completion of the joint clinical assessment

With regard to the approval of the joint clinical assessment reports by the Coordination Group, the Council's position states that where consensus cannot be reached, the joint assessment should include the diverging scientific opinions and the scientific grounds on which these are based.

Voting regime of the Coordination Group

The Council 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 will be adopted by a 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.

Obligations on Member States

Member States will be required to “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.