Health technology assessment

2018/0018(COD) - 03/10/2018 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted, by 576 votes to 56 with 41 abstentions, **amendments** to the proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

The matter was referred to the committee for interinstitutional negotiations.

The main amendments to the Commission proposal adopted in plenary session concern the following points:

Purpose: the proposed Regulation shall define a support framework and procedures for cooperation on clinical assessment of health technologies at Union level and common methodologies for the clinical assessment of health technologies. Pricing and reimbursement of medicines shall fall within the exclusive national competence of the Member States.

Cooperation in the field of health technology assessment (HTA): Members considered that the cooperation between HTA authorities shall be based on the principle of **good governance**, objectivity, independence and transparency. They stressed that **trust** is a precondition for successful cooperation.

The amended text stipulated that HTA shall be used to **promote innovations that produce the best results for patients and society in general**. It should enable health professionals, patients and health institutions to know whether or not a new health technology represents an improvement on existing health technologies, in terms of benefits and risks.

Members therefore considered that joint clinical assessments should therefore aim to identify the **added therapeutic value** of new or existing health technologies in comparison with other new or existing health technologies, by undertaking a comparative assessment based on comparative trials.

Cooperation shall, *inter alia*:

- promote **high-quality innovation**, steering research towards addressing the unmet diagnostic, therapeutic or procedural needs of healthcare systems as well as steering clinical and social priorities;
- **improve scientific evidence** used to inform clinical decision-making, efficiency in use of resources, the sustainability of health systems, patient access to these health technologies, and the competitiveness of the sector through greater predictability and more efficient research;
- ensure that Member States **use the outcome** of HTA to augment the scientific evidence that informs decisions to introduce health technologies into their systems;
- play a role **throughout the health technology cycle**;
- help in decision-making on **divestment** in cases where a technology becomes obsolete;
- contribute to improving and harmonising **standards** of care as well as diagnostic and new-born screening practices across the Union;
- cover areas such as **diagnostics** used to supplement treatment, surgical procedures, prevention, screening and health promotion programmes, information and communications technology (ICT) tools.

In the absence of a **commonly agreed definition** of what constitutes a high-quality innovation or therapeutic added value, Members called for such definitions to be adopted at EU level.

Avoid duplication: in order for harmonised procedures to achieve their objective of the internal market and improving innovation and the quality of clinical evidence, Member States shall take account of the results of joint clinical assessments and not repeat them.

However, the amended text stated that according to national needs, Member States shall have the right to **complement the joint clinical assessments** with additional clinical evidence and analyses to account for differences in comparators or the national specific treatment setting. Such complementary clinical assessments shall be duly justified and proportionate and shall be notified to the Commission and the Coordination Group.

Independence and transparency: a **coordination group** composed of representatives from Member States' health technology assessment authorities and bodies should be established with responsibility and proven expertise for overseeing the carrying out of joint clinical assessments and other joint work within the scope of this Regulation.

In order to ensure high quality of work, members of the Coordination Group shall be drawn from **national or regional** health technology assessment agencies or bodies responsible for that field. Members serving in the Coordination Group, and experts and assessors in general, shall not have financial interests in any type of health technology developer industry or insurance company that may affect their impartiality. They shall undertake to act independently and in the **public interest** and shall make an annual declaration of interests. In the event of a conflict of interest, they shall withdraw from the meeting whilst the relevant agenda items are being discussed.

The coordination group shall ensure that **relevant stakeholders and experts** are consulted in its work.

In addition, in order to ensure transparency and public awareness of the process and to promote confidence in the system, all clinical data being evaluated shall have the **highest level of transparency and public communication**. Where data is confidential for commercial reasons, its confidentiality shall be clearly defined and justified and the confidential data shall be well delimitated and protected.

Membersstressed the need to ensure a **dialogue** between the coordination group and patient organisations, consumer organisations, non-governmental health organisations, experts and health professionals, in particular through a **stakeholder network**, whose independence, transparency and impartiality of decisions would be guaranteed.

Financing: in order to ensure the availability of sufficient resources for joint work and stable administrative support provided for in the Regulation, the Union shall ensure **stable and permanent public funding**, as provided for in the multiannual financial framework, for joint work and voluntary cooperation, as well as for the support framework for these activities. Member States shall also have the possibility to second national experts to the Commission in order to support the secretariat of the coordination group.