Health technology assessment

2018/0018(COD) - 24/09/2018 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Soledad CABEZÓN RUIZ (S&D, ES) on the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

The committee recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the Commission's proposal as follows.

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. It shall not interfere with the exclusive national competence of Member States for national pricing or reimbursement decisions.

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.

HTA shall be used to **promote innovations that produce the best results for patients and society in general**. Health professionals, patients and health institutions need 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.

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, 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.

Transparency: 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.

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.

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.