Health technology assessment

2018/0018(COD) - 14/02/2019 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution on the proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

Parliament’s position adopted at first reading under the ordinary legislative procedure amended the Commission proposal as follows:

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.

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

Independence and transparency

Cooperation should be based on the principle of good governance, which encompasses transparency, objectivity, independent experience and fair procedures. Members insisted that trust is a precondition for successful cooperation.

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.

Parliament stressed 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.

Joint clinical assessment report

The report shall be accompanied by a summary report, which shall contain at least the clinical data compared, the end-points, the comparators, the methodology, the clinical evidence used, and conclusions as regards efficacy, safety, and relative efficacy, the limits of the assessment, diverging views, a summary of the consultations carried out, and the observations made.

The report should be accompanied by a summary report including at least the following elements: (i) comparative clinical data, (ii) efficacy criteria, (iii) efficacy criteria, (iii) comparators, (iv) method, (iii) clinical data used, (iv) conclusions on effectiveness and safety, relative efficacy and evaluation limitations, (v) divergent positions, (vi) summary of consultations carried out and comments received.

The conclusions of the joint clinical assessment report shall include:

- an analysis of the relative effectiveness and safety of the health technology being assessed in terms of the clinical end-points relevant to the clinical entity and patient group chosen for the assessment, including mortality, morbidity and quality of life;

- the degree of certainty of relative effects based on the best available clinical data and compared to the best standard therapies.

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.

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.