Health technology assessment

2018/0018(COD) - 31/01/2018 - Legislative proposal

PURPOSE: foster cooperation between EU Member States in health technology assessment.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: Parliament decides in accordance with the ordinary legislative procedure on an equal footing with Council.

BACKGROUND: health technology assessment (HTA) is a multidisciplinary process (covering medical, social, economic and ethical issues) and an evidence-based process that **independently and objectively assesses a new or existing technology** and compares it with other health technologies and / or the current standard of care.

Following the adoption of the Cross-Border Healthcare Directive (Directive 2011/24/EU), a **voluntary European network** of HTAs composed of national HTA agencies or bodies was set up (in 2013) to provide strategic and political guidance to the scientific and technical cooperation at Union-level.

While Member States have carried out some joint assessments within the framework of the EU co-funded joint actions, **the production of output has been inefficient**. Use of the results of the joint actions, including their joint clinical assessments, at Member State-level has remained low. The duplication of assessments on the same health technology by HTA authorities and bodies in different Member States within identical or similar timeframes has not been sufficiently addressed.

The European Parliament, in its resolution of 2 March 2017 called on the Commission to propose legislation on a European system for health technology assessment and to harmonise transparent health technology assessment criteria in order to assess the added therapeutic value of medicines.

IMPACT ASSESSMENT: four policy options were analysed. The preferred option is based on Option 4 (**permanent cooperation on common tools, procedures, early dialogues and joint clinical assessments**), integrating certain elements of Option 2 (project-based cooperation on HTA activities) as well as some adjustments (e.g. transitional arrangements for Member States and progressive implementation of the product scope for joint clinical assessments).

CONTENT: the proposed regulation aims to **provide the basis for permanent and sustainable cooperation** at the EU level for joint clinical assessments of new medicines and certain new medical devices. Its general objectives are to ensure a better functioning of the internal market and to contribute to a high level of protection of human health. The specific objectives are to improve the availability of innovative health technologies for EU patients, to ensure an efficient use of resources and to improve the quality of HTA across th EU, and to improve business predictability.

Member States will be able to use common HTA tools, methodologies and procedures across the EU, working together in four main areas:

1) **Joint clinical assessments:** these focus on the **most innovative health technologies** with the most Union-wide and public health impact. These assessments are limited to:

- medicinal products undergoing the central marketing authorisation procedure, new active substances and existing products for which the marketing authorisation is extended to a new therapeutic indication; and
- certain classes of medical devices and in vitro diagnostic medical devices which have been selected by the Coordination Group set up under the Regulation.

Following the end of a **transitional period**, participation in the assessments and use of the joint clinical assessment reports at Member State level will be mandatory. Member States will continue to carry out **non-clinical assessments** (e.g. economic, organisational, ethical) of health technologies and make decisions on pricing and reimbursement.

2) Joint scientific consultations: these allow a developer in the development phase of a health technology to seek the advice of HTA authorities and bodies on the data and evidence likely to be required as part of a potential future joint clinical assessment.

3) Identification of emerging health technologies: This exercise will act as a key input for the annual work programmes, helping to identify at an early stage of their development, the health technologies expected to have a major impact on patients. The Coordination Group will fully consult with all relevant interest groups during this exercise.

4) Voluntary cooperation in other areas: this cooperation could include the assessment of health technologies other than medicinal products or medical devices, non-clinical assessments or collaborative assessments of medical devices not subject to common clinical assessments.

Lastly, the proposal lays down **common implementing rules** in order to ensure harmonisation of the way in which Member States carry out clinical assessments. A key objective of these rules will be to ensure that clinical assessments, whether at EU or at Member State level, are carried out in an independent and transparent manner, free from conflicts of interests.

BUDGETARY IMPLICATIONS: the implementation of the proposal has **no impact** on the current Multiannual Financial Framework 2014-2020 as the current cooperation on HTA is financed by the Public Health Programme. The financial impact on the EU budget post-2020 will be part of the Commission's proposals for the next Multiannual Financial Framework.

DELEGATED ACTS: the proposal contains provisions empowering the Commission to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union.