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The European Council approves the final version of the Regulation on Health Technology Assessment

European assessment processes will be created to support budgetary decision-marking in healthcare

Background and scope

On 9 November, the European Council gave its final go-ahead to the proposal for a Regulation on Health Technology Assessment (HTA), which the European Commission presented in January 2018 and was particularly promoted during the Portuguese Presidency in the first semester of 2021. The Regulation still needs to be adopted by the European Parliament before being published in the EU Official Journal. It is foreseen that it will be applicable three years after its entry into force.

As regards medicinal products for human use, the Regulation will affect products that may only be authorized via the centralised procedure (Annex I of Regulation 726/2004) or those which authorisation may be submitted via the centralised procedure, provided that they are innovative and are based on a full dossier. The Regulation will also apply to authorisations of new indications for existing products, provided that a European Public Assessment Report has been published.

In addition, the Regulation will apply to certain medical devices of Class IIb and Class III, as well as to certain in vitro diagnostic medical devices selected by the European Commission based on criteria relating to their potential impact on patients or healthcare systems, their intended use or whether they incorporate software that uses artificial intelligence.

More and better cooperation at European level

The Regulation will implement joint clinical assessment processes, and hence replace the current system of cooperation between Member States with a permanent cooperation structure. The Regulation also covers joint scientific consultations for the purposes of sharing information with health technology developers as regards the development plans of a given health technology, the identification of emerging health technologies, and voluntary cooperation.

To this end, the Regulation will establish an HTA Coordination Group, which, among other functions, will oversee the implementation of assessments. The Regulation also sets out detailed rules on the procedure to be followed, and highlights the need to ensure that patients, clinical experts and other relevant experts are given opportunities to provide input to draft assessments. The developer of the health technology under assessment will also be able to participate, albeit on a limited basis, by alerting on technical or factual errors or on the confidential nature of any information contained in the project, justifying the reason it is commercially sensitive information.

In a nutshell, this is a clear step forward in European cooperation in this sector and we will continue to report on it.