Regulation (EU) 2021/2282 of the European Parliament and of the Council on the assessment of health technologies

Regulation (EU) 2021/2282 of the European Parliament and the Council on the assessment of health technologies (hereinafter referred to as the "Regulation") was published on 22 December, which will enter into force on 12 January 2022.

The Regulation is the result of the recognition of the crucial role of health technology assessment (hereinafter referred to as "HTA" *) as an instrument of health policies to support choices based on concrete, sustainable data and equitable in the field of healthcare and health technologies for the benefit of patients. The purpose of the Regulation is to strengthen the joint work between Member States on HTA, so that opportunities for cooperation in the exchange of information between competent bodies are explored.

The Regulation establishes a support scheme and cooperation procedures at Union level between Member States on health technologies; a mechanism providing that any information, data, analyses and other evidence necessary for the joint clinical assessment of health technologies should be submitted by the creator of health technologies only once at Union level; and common rules and methodologies for the joint clinical assessment of health technologies.

The Regulation does not affect the competence of Member States to draw conclusions on the relative effectiveness of health technologies or to take decisions on the use of health technologies in their specific national health context. It does not interfere with the exclusive national competence of the Member States, including the competence relating to national decisions on pricing and contributions, nor does it affect any other competences relating to the management and provision of health services or medical care by Member States, or the allocation of the resources assigned to them.

Under the Regulation, a gradual approach to which health technologies shall be subject to joint clinical assessment is adopted, covering for the time being:

a) Medicinal products subject to the centralised procedure pursuant to Regulation (EC) No 726/2004 and others provided for in the same regulation;

b) Medicinal products authorised in the Union for which a joint clinical assessment report has been published, where authorisation is granted under the applicable regulations, to amend an existing marketing authorisation corresponding to a new therapeutic indication;

c) Medical devices classified in classes IIb or III in accordance with Article 51. of Regulation (EU) 2017/745 for which the relevant expert panels have delivered a scientific opinion under the procedure for consultation on clinical assessment pursuant to Article 54 of that regulation, and subject to selection in accordance with Article 7(4) of the Regulation;

d) In vitro diagnostic medical devices classified in class D in accordance with Article 47. of Regulation (EU) 2017/746 for which the relevant expert panels have submitted their observations under the procedure provided for in Article 48(6) of that regulation and are subject to selection pursuant to Article 7(4) of the Regulation.

The Regulation will apply from 12 January 2025.

* Health technology assessment (HTA) is a multidisciplinary process that sums up information on medical, social and patient-related aspects, as well as economic and ethical issues related to the use of health technology in a systematic, transparent, impartial and rigorous manner.

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