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Developments in Life Sciences & Healthcare Legislation

An overview of provisions of the Health Technology Assessment Regulation which apply from 1 January 2025

In This Issue

A. Scope: Key points

1. EU Regulation 2021/2282[1] on Health Technology Assessment (the **HTA Regulation**) amending the provisions of Directive 2011/24/EU applies from 1 January 2025[2] and relates to health technology assessments (**HTAs**).
2. The aim of the HTA Regulation is to ensure an efficient use of resources and strengthen the quality of HTAs across the EU.
3. The HTA Regulation applies to all health technologies, including medicinal products, medical devices, in-vitro medical devices, medical procedures and measures for disease prevention, diagnosis and treatment.
4. In addition to the mandatory scope of the HTA Regulation, Member States may also engage in further voluntary cooperation, for example on health technologies other than medicines and medical devices, or on economic aspects of HTAs.
5. The HTA Regulation does not affect Member States' competence 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.
6. The HTA Regulation does not interfere with the exclusive national competence of Member States, including those on national pricing and reimbursement decisions. It also does not affect any other competences relating to the management and delivery of health services or medical care by Member States, or the allocation of resources assigned to them.
7. The HTA Regulation establishes a support framework and procedures for the cooperation of Member States on health technologies at an EU level. It introduces a mechanism whereby any information, data, analyses and other evidence required for the joint clinical assessment of health technologies are submitted by the health technology developer only once at EU level. It also lays out common rules and methodologies for the joint clinical assessment of health technologies.
8. Cooperation in relation to HTAs at an EU-level was launched in the 1980s. Three Joint Actions (EUnetHTA JA) were carried out comprising several projects. Directive 2011/24/EU (known as the Cross-Border Healthcare Directive) established the HTA Network in 2013 to provide strategic and political guidance on scientific and technical cooperation at an EU level.
9. The HTA Regulation replaces:

[1] Of the European Parliament and the Council of 15 December 2021

[2] Depending on the different categories of products in scope or the existence of unmet medical needs, effective date may vary (Article 7 of the HTA Regulation)

a. the current system based on the voluntary network of national authorities (HTA Network); and
b. the EU-funded project-based cooperation (Joint Actions EUnetHTA) with a permanent framework for joint work.

B. Means of Implementation: How it Works

1. The implementation of the HTA Regulation is entrusted to the following bodies:
   a. The Coordination Group (**CG**) which:
      i. runs and monitors the Joint Clinical Assessment (**JCA**) of the technologies within the scope of the HTA Regulation;
      ii. consists of Representatives from each Member State;
      iii. is responsible for Supervision of national representatives' work; and
      iv. is assisted by experts (patients and clinicians);
   b. The Stakeholder Network which:
      i. boosts negotiations between European stakeholders and the CG; and
      ii. drafts guidance documents supported by European stakeholders.
   c. The European Commission (EC) which:
      i. safeguards observance of the Regulation's procedures and timelines;
      ii. ensures transparency;
      iii. ensures dissemination of information to all stakeholders involved (eg the European Medicines Agency); and
      iv. ensures that important data from Joint Clinical Assessment Reports (JCRs) is uploaded to the relevant platform.
2. The HTA Regulation relies upon the adoption of several acts:
   a. detailed procedural rules for joint clinical assessments (Article 15 of the HTA Regulation);
   b. detailed procedural rules for joint scientific consultations (Article 20 of the HTA Regulation);
   c. general procedural rules (Article 25 of the HTA Regulation); and
   d. format and templates of submission and report documents (Article 26 of the HTA Regulation).

C. Intended Benefits

1. The **General** objectives of the HTA Regulation are to:
   a. ensure a better functioning of the internal market of health technologies; and
   b. contribute to a high level of human health protection.
2. The **Specific** objectives of the HTA Regulation are to:
   a. promote convergence in HTA tools, procedures and methodologies;
   b. ensure efficient use of resources; and
   c. strengthen the quality of HTAs across the EU and improve business predictability.[3]
3. Joint clinical assessments are anticipated to yield long term benefits such as economies of scale, greater business predictability, increased quality and consistency and improved transparency for patients.[4]

[3] https://health.ec.europa.eu/system/files/2018-02/2018_ia_exefinal_en_0.pdf

[4] https://health.ec.europa.eu/system/files/2018-02/2018_ia_exefinal_en_0.pdf

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