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Client Alert Commentary

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New Regulation on Health Technology Assessment Seeks to Facilitate EU-Level Joint Clinical Assessments From 2025

The regulation aims to harmonise clinical and scientific aspects of HTA to make innovative health technologies more widely available in the EU.

Health technology assessment (HTA) is a multidisciplinary evidence-based process that allows authorities to determine the relative effectiveness of new or existing health technologies (e.g., medicines and medical devices), focusing on the added value of a health technology. The outcome of an HTA typically influences the extent to which a given health technology is adopted and/or reimbursed by a given country's healthcare system.

At present, HTA procedures within the EU are conducted at a national or regional level, against the backdrop of some voluntary EU-funded project-based cooperation between Member States. Parallel assessments by multiple Member States, and divergences between national laws, regulations, and administrative provisions, can result in health technology developers facing multiple and divergent data requests — which can lead to duplication and variation in outcomes.

Following several years of deliberation, the Regulation on Health Technology Assessment (Regulation (EU) 2021/2282) (the HTA Regulation), a deliverable of the EC Pharmaceutical Strategy, was adopted in December 2021. In essence, the HTA Regulation for the first time introduces a permanent legal framework for joint HTA work that will cover joint clinical assessments (JCAs), joint scientific consultations, the identification of emerging health technologies, and voluntary cooperation between Member States.

Scope

The HTA Regulation aims to harmonise clinical and scientific aspects of HTA to make innovative health technologies more widely available in the EU. Such technologies include innovative medicines (e.g., cancer medicines, gene and cell therapies, and orphan medicines), certain high-risk medical devices and in vitro diagnostics (IVDs), medical equipment, and prevention and treatment methods. It seeks to ensure the efficient use of resources, strengthen the quality of HTA across the EU, and save national HTA bodies and industry from duplicating their efforts. However, Member States are to remain responsible for all non-clinical aspects of HTA, such as pricing and reimbursement, the use of a health technology in a specific health context, and the management and delivery of health services and medical care.

Key features

The HTA Regulation establishes a Member State Coordination Group composed of Member States' representatives, in particular from HTA authorities and bodies. The Coordination Group, which was formally established in June 2022, will oversee the joint technical work carried out by subgroups of national representatives for specific types of work (e.g., JCAs, joint scientific consultations, or methodological guidance documents). External experts, including clinicians and patients, will also be able to provide input during the preparation of certain joint work. In addition, stakeholder organisations will be able to provide input on non-product related matters, such as on the drafting and preparation of methodological guidance documents.

The HTA Regulation includes the following key planks:

1. JCA is to be conducted at the EU level on a strictly scientific basis, with the health bodies of Member States to give "due consideration" to the resulting report when carrying out their respective national or regional HTAs. Those health bodies are not permitted to request information, data, analyses, or other evidence at the national level that has been submitted by the health technology developer at the EU level. However, they may still perform complementary clinical analyses relating, *inter alia*, to patient groups, comparators, or health outcomes other than those included in the JCA report, or using a different methodology if that methodology would be required in the overall national HTA process of the relevant Member State.

2. The Coordination Group will engage in joint scientific consultations with health technology developers to advise them on clinical study designs that generate appropriate evidence for the purpose of JCAs.

3. The Coordination Group is to undertake "horizon scanning" exercises to identify, at an early stage, promising health technologies, to help health systems prepare for them.

4. Beyond the mandatory scope of the HTA Regulation, Member States may also engage in further voluntary cooperation, e.g., on health technologies other than medicines and medical devices, or on economic aspects of HTA.

Timing of application

While the HTA Regulation entered into force in January 2022, it will only begin to apply from January 2025, with preparatory and implementation-related steps to take place in the interim.

When it does apply, it will have a phased implementation:

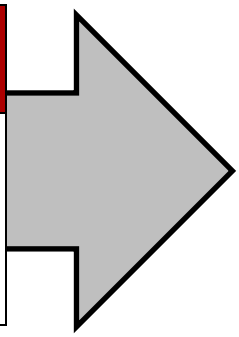
- From 12 January 2025, (i) medicinal products with new active substances for oncological indications, (ii) advanced therapy medicinal products (ATMPs) (i.e., gene, tissue, and cell therapy products), and (iii) certain high-risk medical devices and IVDs will be subject to JCA. These devices and IVDs will be selected at least every two years based on a number of criteria (e.g., unmet medical needs, first in class, potential impact on patients, incorporation of software using AI, EU-wide added value, and significant cross-border dimension).

- From 13 January 2028, the HTA Regulation's application will extend to orphan medicinal products.

- From 13 January 2030, various other medicinal products will be subject to the HTA Regulation.

Phased implementation of the HTA Regulation with respect to JCAs

11 January 2022 Entry into force	12 January 2025 Entry into application	13 January 2028 First extension	13 January 2030 Second extension
Preparatory steps Adoption of detailed procedural rules and measures to implement	**Technologies subject to JCA:** • Cancer medicines • ATMPs • Certain medical devices/IVDs	**Further technologies subject to JCA:** • Orphan medicinal products	**Further technologies subject to JCA:** • Various other medicinal products



Evaluation

The HTA Regulation will hopefully benefit health technology developers, including through greater predictability as to outcomes across the EU, greater clarity as to clinical evidence requirements, and efficiency gains with respect to documentary submissions.

At the same time, much remains to be seen as to the implementation and effectiveness of the HTA Regulation once operational. The final "compromise" text of the HTA Regulation only requires Member States to give "due consideration" to the EU JCA reports (unlike the original Commission proposal, which made their use mandatory). Therefore, an unpredictable system could result whereby Member States decide on a case-by-case basis if and how they commit to use these JCAs, thereby unnecessarily increasing regulatory and administrative red tape. In addition, performing complementary clinical analyses at a national level could necessitate multiple clinical submissions. Ultimately, since the Regulation will not address non-clinical considerations, HTA procedures will to some degree continue to be duplicated at national level. Stakeholders should therefore seek to establish the necessary safeguards to ensure that joint assessments cannot simply be ignored and that Member States remove inefficient duplicative parallel processes and limit time-consuming complementary clinical assessment activities.

Despite these potential challenges, the HTA Regulation represents a valuable opportunity for health technology developers to increase product access, amongst others through pooling resources and high-level expertise and joint early scientific dialogue, particularly as society moves towards increasingly complex and advanced health technologies and treatments.

Takeaway

Given that the HTA Regulation will only begin to apply from 2025, health technology developers and other relevant stakeholders do not need to take any immediate steps. However, they should continue to monitor the implementation of the HTA Regulation and familiarise themselves with the procedures it establishes. They may also wish to consider opportunities for stakeholders to engage under the HTA Regulation framework (such as with the Consultation Group) so that any input can be taken into consideration.

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