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ANALYSIS - EVALUATION - OPPORTUNITIES - KEY DEVELOPMENTS

Impact of the New Regulations on the Health Technologies Evaluation

Regulation (EU) 2021/2282 harmonises health technology assessment across EU Member States through Joint Clinical Assessments, improving consistency, transparency and stakeholder involvement. It supports faster access to innovative health technologies while allowing national control over non-clinical evaluations and reimbursement decisions, aiming to strengthen evidence-based decision-making and healthcare system sustainability.

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key points

- The regulation harmonises health technology assessments across EU Member States.
- Joint Clinical Assessments aim to speed up access to innovative health technologies.
- National authorities retain control over reimbursement and non-clinical evaluations.
- The process ensures greater transparency and stakeholder participation.
- Consistent methods support evidence-based and equitable healthcare decisions.

Introduction

We all agree that the incorporation of health technologies is a fundamental pillar in the protection of citizens' health. However, their importance does not end with this role, which is so beneficial to health; technologies are also a source of knowledge, research and innovation and a driving force for industrial and economic development.

But what do we mean by health technology? This term includes medicines, medical devices, *in vitro* diagnostic tests, medical and surgical procedures, therapies and digital medical products, organisational models and measures for the prevention, diagnosis or treatment of diseases. In short, health technology is any instrument, procedure, medicine, organisational system or innovation applied to healthcare.

According to the World Health Organisation (WHO), health technology is "the application of organised knowledge and skills in the form of devices, drugs, vaccines, procedures and systems developed to solve a health problem and improve the quality of life".

However, each of these technologies has its own regulatory standards and requirements to be applied in clinical practice to ensure quality, safety and efficacy. In order to determine whether a health technology fulfils the purposes for which it was created, a scientific evaluation process based on verified data is required to allow health authorities to assess its efficacy and decide whether to incorporate it into the health system. This process is called Health Technology Assessment (HTA).

Background

So far, assessment processes in the EU are fragmented. Each Member State conducts its own assessments, leading to duplication of efforts, inconsistent results and delays in patient access to innovative therapies.

Furthermore, although the conceptual framework of the HTA is very similar across EU member states, the demand for and pace of uptake of different types of technology is very different across EU countries. For this reason, Regulation (EU) 2021/2282 aims to address

these inequalities by harmonising HTA processes across Member States, allowing for faster, fairer and more collaborative assessments.

To achieve this, Regulation (EU) 2021/2282 has opted for a separate set-up for medicines and medical devices on the one hand and other technologies on the other. This is because traditionally the requirements for the marketing authorisation of medicinal products and/or medical devices have been different and the industries of the two types of technology are also different. To point out a difference, the use of medicinal products does not depend on the skill of the professional whereas the use of a medical device often requires the skill of the professional using it and sometimes also the characteristics and conditions of the healthcare facility in which it is to be used.

This dual configuration is what Spain has maintained with the Spanish Agency for Medicines and Health Products (AEMPS) on the one hand, and the Network of Agencies for the Evaluation of Health Technologies and Services of the National Health System (RedHTA) on the other. Although these two institutions are independent and use different methodologies, they have shared the same objective, which is to inform the decision-making process for incorporation into the portfolio of benefits and public funding.

Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021

In Europe, the HTA is regulated by Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

Regulation (EU) 2021/2282 entered into force on 11 January 2022 and has been applied since 12 January 2025.

This Regulation aims to help member states make informed decisions, both on scientific clinical and non-clinical aspects, when deciding whether or not to incorporate a health technology. To this end, it proposes standards and a common methodology to avoid new evaluations in each country, with the ultimate aim of advancing patient access to these innovations.

To this end, the Regulation establishes a supporting framework and procedures for cooperation between Member States on health technologies at EU level, the so-called Joint clinical assessments (JCAs), and a mechanism whereby all information, analyses and evidence necessary for the Joint Clinical Assessment of health technologies are submitted by the health technology developer only once at EU level.

> "Health technologies are a key driver of economic growth and innovation."

Joint Clinical Assessments

The introduction of Joint clinical assessments (JCAs) in the new HTA Regulation (EU) 2021/2282 aims to streamline the HTA process across the European Union, although some competences (such as the decision whether or not to reimburse a new technology) will remain a national prerogative. We can therefore say that CCPs are EU-wide assessments of the clinical value of new technologies.

The health technologies subject to joint clinical assessments are:

(a) Medicinal products for human use, for which an application for marketing authorisation has been submitted in accordance with Regulation (EC) No. 726/2004.

(b) Medicinal products authorised in the Union for which a joint clinical assessment report has been published, in order to vary a marketing authorisation for a new therapeutic indication.

(c) Medical devices classified in classes IIb or III in accordance with Article 51 of Regulation (EU) 2017/745.

(d) *In vitro* diagnostic medical devices classified in class D in accordance with Article 47 of Regulation (EU) 2017/746.

In relation to the joint assessment model, Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 establishes four clinical and five non-clinical domains for medicinal products and medical devices, identified by the European HTA Network (EUnetHTA).

The clinical domains are:

- Identification of a health problem and current health technology
- Analysis of the technical characteristics of the new technology
- The relative safety of the new technology
- The relative clinical efficacy

In Spain, the Ministry of Health has published a draft Royal Decree regulating health technology assessment ("PRDHTA"). While Spanish regulations cannot deviate from or oppose the provisions of EU legislation, the PRDHTA seems likely to establish a number of additional requirements and local specifications that would be mandatory at the national level. The five non-clinical domains for medicines and medical devices identified are:

- Cost and economic evaluation
- Ethical aspects
- Organisational aspects
- Social aspects
- Legal aspects

The resulting joint clinical assessment report should be taken into account by the Member States, without prejudice to each State conducting further clinical analyses as necessary, nor does it restrict the ability of each State to conduct non-clinical evaluations. In addition to annexing the joint clinical assessment report to the national STD report, the Member State must report on how each joint clinical assessment report was duly taken into account in the assessment at national level.

Ultimately, Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 aims to make the HTA an evidence-based scientific process that enables competent authorities to determine the relative effectiveness of existing or new health technologies, and focuses specifically on the added value of a health technology compared to other existing or new technologies.

Any development at national level in European Union (EU) member states has to be aligned with the above-mentioned Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021.

In this regard, work is underway in Spain on the draft Royal Decree regulating technology assessment in Spain, which is expected to be published in the coming weeks.

Coordination Group

Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 establishes a Coordination Group that adheres to the following criteria:

- It is made up of members appointed by each Member State.
- Its role is to oversee, review and approve the joint technical work carried out by the sub-groups of national representatives for joint clinical assessments and joint scientific consultations.
- It aims to ensure that the joint work performed is of the highest quality, HTA international standards of evidence-based medicine and is timely.
- It must conduct its activities in an independent, impartial and transparent manner.

> "The HTA is not an end in itself but a means to make the best decisions."

With regard to independence, impartiality and transparency, the first thing to remember is that the HTA is not an end in itself but a means to make the best decisions. Its outcomes are used to inform decisions regarding the allocation of budgetary resources in healthcare, such as the setting of price levels or reimbursement for health technologies.

In order to ensure inclusiveness and transparency of joint work, the Coordination Group should collaborate and consult widely with stakeholder organisations that have a willingness and vocation for Union cooperation on STD. These include patient organisations, health professional organisations, clinical and academic societies, health technology developers' associations, consumer organisations and other non-governmental organisations in the field of healthcare. A network of stakeholders should be established to facilitate dialogue between these organisations and the Coordination

Group, and this dialogue should be transparent. In this regard, the regulation indicates that patients, clinical experts and other relevant experts involved in any joint work shall not have any financial or other interest in the health technology developers' industry that could affect their independence or impartiality. We cannot forget that these groups are affected by the HTA and are also covered by Regulation (EU) 2021/2282.

and training materials to improve the training and empowerment of patients, caregivers and users.

The second group of stakeholders consists of health technology developers. It is an advantage for this group that they can submit all the information, data, analyses and other evidence needed for the joint clinical assessment in one go at Union level. However, the Regulation does not restrict Member States' ability to perform non-clinical assessments on the same health technology neither before nor after the publication of a joint clinical assessment report. That is why Member States can request additional information needed for complementary clinical analyses from the developers. Another important advantage is that developers can use real-life data which can improve their market positioning. What health technology developers must respect are the deadlines for submitting the requested information.

> "Patients have knowledge, perspectives and experiences that are unique and can make an essential contribution to HTA."

To ensure appropriate participation, the Coordination Group will set up sub-groups, in particular for joint clinical assessments, joint scientific consultations, identification of emerging health technologies and the development of methodological and procedural guidance.

Stakeholders

The first category of stakeholders is represented by patients and patient organisations as beneficiaries of new technologies that contribute to improving their level of health. In this respect, CCPs can effectively facilitate market access and contribute to the timely availability of innovative health technologies for patients.

In this respect, it should be noted that the Spanish Network of Health Technology Assessment and Benefit Agencies of the National Health System (RedHTA) issued a public statement on the progressive strategy of involving patients in the health technology assessment process. This statement, signed jointly with the Ministry of Health, Social Services and Equality (MSSSI), recognises *"the need and value of the active participation and collaboration of patients, caregivers and users to improve decisions related to health technologies in the National Health System. Patients have knowledge, perspectives and experiences that are unique and can make an essential contribution to HTA. Knowing, understanding and harnessing this knowledge allows patients' needs to be met more accurately, while improving the sustainability, transparency, accountability and democratisation of the decision-making process"*. This engagement strategy, initiated in 2017, takes the form of directly inviting technology-related patient organisations to evaluate and develop information

Healthcare professionals and their organisations such as scientific and academic societies also cooperate with the Coordination Group. Regulation (EU) 2021/2282 states that these experts should advise administrations on the potential value of a new medicine or medical device but should not have a relationship with the developers of that innovation. The point is that, normally, the most clinical research is conducted by doctors who have extensive knowledge of a pathology and understand the potential contributions of new medicine or medical devices, and this requires participating in trials and collaborating with the industry.

Joint Scientific Consultations

The Coordination Group will conduct joint scientific consultations to exchange information with health technology developers on their development plans for a particular health technology. These consultations will generate evidence to meet the likely evidence requirements of a subsequent joint clinical assessment on that health technology. The scientific consultation will result in a final document indicating the scientific recommendation being made and will address, in particular, all relevant design aspects of the clinical studies or clinical research design, including

comparators, interventions, health outcomes and patient populations.

Some Impacts

European health technology assessment agencies, including the Spanish Agency for Medicines and Health Products (AEMPS), together with the European Medicines Agency (EMA), have published a Report setting out a framework for collaboration between medicines regulators and health technology assessment agencies in Europe, aiming to create synergies between regulatory assessment and health technology assessment, as set out in Regulation (EU) 2021/2282.

Some of the key points on medicines assessment jointly identified are the following:

Scientific evidence in the form of randomised studies is preferred, both for benefit/risk assessment and for the evaluation of comparative effectiveness of medicines.

- Improved collection, analysis and reporting of outcomes other than clinical trial endpoints can substantially reduce uncertainty in decision-making.
- The availability of individual patient data from clinical trials could improve the quality of evidence, indirect comparisons and other analyses across studies.
- Better sharing of data, both from clinical trials and from registries and observational studies with real-world data, could help to interpret scientific evidence.
- They share a common interest in developing frameworks that support structured and informed decision-making, even under conditions of uncertainty.

Ultimately, this collaboration aims to create synergies between regulatory assessment and health technology assessment.

Next Steps

The scope of Regulation (EU) 2021/2282 will be extended to include orphan medicines from 2028, and all new medicines authorised by the European Medicines Agency (EMA) from 2030. These assessments will provide a single, harmonised assessment that Member States can use for national pricing and reimbursement decisions.

Conclusion

Health technologies are a key driver of economic growth and innovation and are part of an overall market for healthcare spending that represents 10% of the European Union's gross domestic product. The HTA aims to help Member States build and maintain sustainable health systems and encourage innovation that delivers better outcomes for patients.

The EU HTA Regulation (EU) 2021/2282 aims to raise the level of health protection for patients and users and to ensure the proper functioning of the European internal market for medicinal products, medical devices and *in vitro* diagnostic medical devices. To achieve this, it establishes a framework for the cooperation of Member States and the necessary measures for joint clinical assessment of health technologies.

The Regulation introduces significant updates, including the following:

1. Faster and more coordinated assessments

Member States will have to include the European findings in their own national report, although these European findings will not be binding in relation to national reimbursement procedures.

2. Greater transparency

The process is more open, with clear summaries that should include stakeholder input from the CCP reports for patients and stakeholders.

3. More input from patients and experts

Patients and healthcare professionals play a greater role in contributing to the CCP and Joint Scientific Consultations (JSC).

4. Consistent methods across Europe

Harmonised procedures make assessments consistent and comparable across Member States, promoting equity in decision-making.

5. Reducing duplication of effort

Centralising assessments at EU level reduces duplication of work and will allow Member States to tailor the results to their local health systems.

Conflict of Interest

None.

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