AliraHealth

New European **Health Technology Assessment** Regulation

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Introduction

WHY is New European Health Technology Assessment Regulation important?

> New European Health Technology Assessment (EU HTA) Regulation is the new European Union legislation that regulates a common EU Health Technology Assessment (HTA). It is now in place, making it mandatory for manufacturers to submit a clinical dossier at European level from 2025

> It's important for pharma, biotech and medtech companies to be aware of this new joint assessment methodology (including type of comparators, evidence requested, and stakeholders involved) to understand the level of effort for the joint work by Member States – and what effect that has on access to new medicine

WHAT will you learn from this white paper?

The purpose of this white paper is to provide an overview on this new regulation, including:

> Key points of the regulation

> Methodology

> Timelines

HOW was this white paper developed?

The information gathered in this white paper has been collected via:

> Secondary research

> Primary research with Alira Health internal experts

WHO should read this white paper?

Key stakeholders in the pharmaceutical industry including:

> Healthcare professionals

> Manufacturers

> National/regional payers

> Patients

> Physicians

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Background

Currently, each country in Europe carries out their own HTA processes, often resulting in duplication of effort among countries. Over the last 15 years, the European Commission (EC) has done substantial work to promote cooperation among HTA bodies on a voluntary basis through its European Network for Health Technology Assessment (EUnetHTA), but participation is low.[1]

> HTA is a multidisciplinary process summarizing information about **medical**, **social**, **economic**, and **ethical issues** related to the use of a **health technology** in a systematic, transparent, unbiased, and robust manner. The aim is to **measure the added value of the new health technology compared to existing alternatives**[2]

> The main objective of HTA is to inform **decision-making on a given health technology**

> In **Europe**, the value of a **health technology** is assessed at **national or regional level** by **country – or region – specific HTA bodies** who consider these cultural, social, economic, and systems issues within the context of its Member State

> The result is that the **organization of HTA-related activities** in European countries **varies widely**

> However, there are some aspects of the HTA that do draw on the same evidence, like determining clinical effectiveness for example, and duplication of effort to collect such evidence persists, despite the EC's substantial work to promote cooperation among Member States

1. About EUnetHTA - EUnetHTA. https://www.eunethta.eu/about-eunethta/

2. O'Rourke, B., Oortwijn, W. & Schuller, T. The new definition of health technology assessment: A milestone in international collaboration. Int. J. Technol. Assess. Health Care 36, 187–190 (2020).

The New EU HTA Regulation

In December 2021, the EC adopted the new EU HTA Regulation, requiring clinical submissions at the European level, nearly four years after it was initially proposed in January 2018. Ultimately aimed at strengthening cooperation among European HTA agencies, the new regulation will have a progressive implementation, from 2025 to 2030.

New EU HTA Regulation Objectives

> **Reduce duplication** of effort for HTA agencies and the industry

> **Increase access equity** between Member States

> Ensure the **long-term sustainability** of EU HTA cooperation

> **Promote alignment** in HTA tools, procedures, and methodologies

> **Provide joint work** on common scientific and clinical aspects of HTA driven by Member State HTA bodies

> **Ensure high quality work**, clear timelines, and greater transparency

> **Assure use of joint work** in national HTA processes

New EU HTA Regulation Key Aspects

> Beginning in 2025, **manufacturers will be required to submit a clinical dossier** for a joint clinical assessment (JCA) at European level. Member States will have to take "due consideration" of these JCA reports when conducting a national HTA, but Member States will determine when in their HTA assessment JCA reports will be considered

> Member States won't be able to ask manufacturers for information that has been already submitted at European level, but they may **complement the JCA with additional clinical and non-clinical analysis**. HTA bodies will also participate in Joint Scientific Consultations (JSC) to advise manufacturers on clinical study designs that generate appropriate evidence

> Member States will **remain responsible for drawing conclusions** on the overall value of a new health technology for their health system, as well as for pricing and reimbursement (P&R) decisions[3]

> This progressive implementation, from 2025 to 2030, will start with **cancer drugs** and **ATMPs** and some **medical devices/IVDs**. It will be extended to **OMPs** in 2028 and to all **centrally authorized medicinal products** by 2030

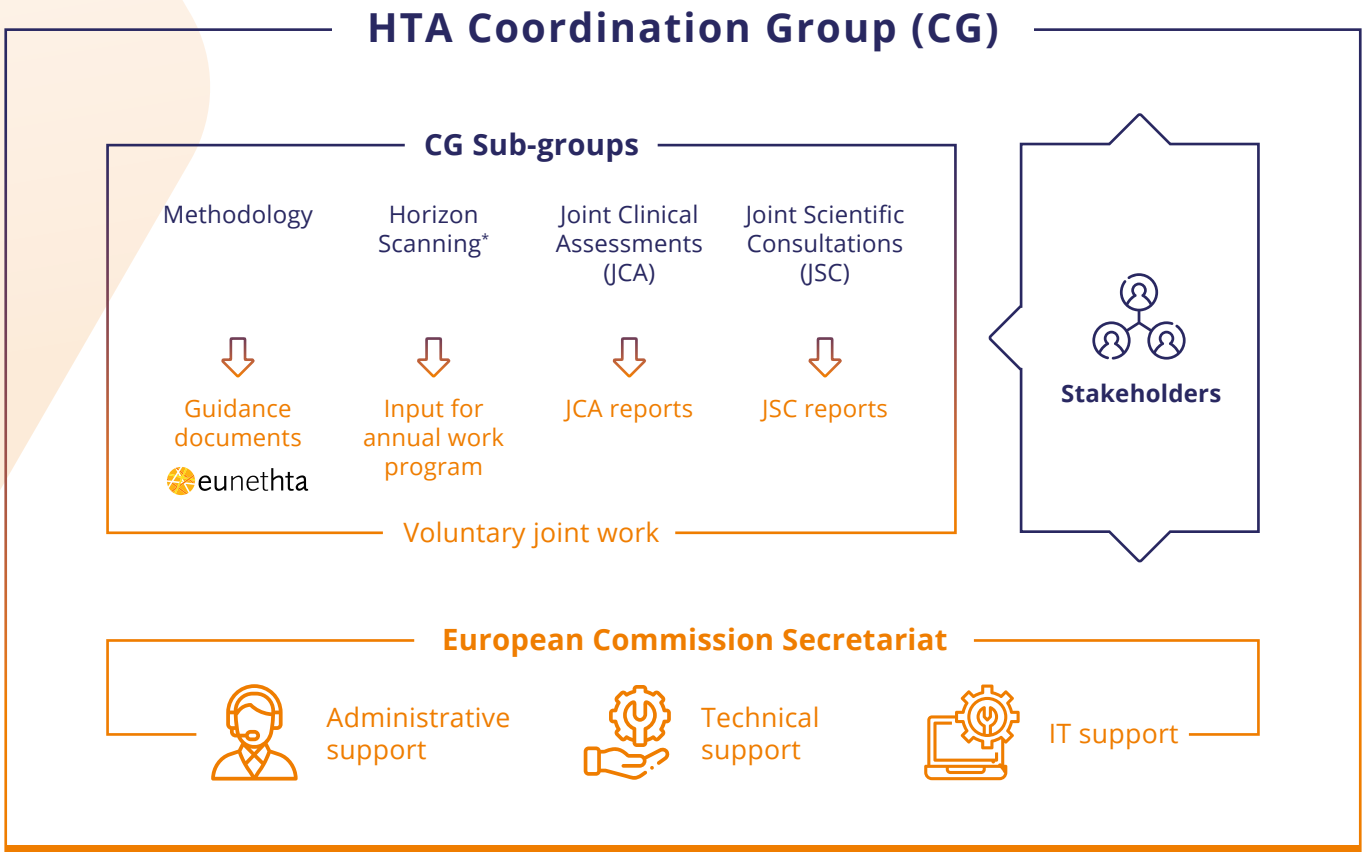
> Between 2022 and 2024, the governance structure (Coordination Group, EC and EUnetHTA 21) will begin implementation activities including **formation of a coordination group and stakeholder network**, **draft implementation** and **delegated acts**, as well as guidance documents including procedural rules and the methodology for the new EU HTA

> Given the current soft-binding nature of JCA reports, more work is needed to **avoid increasing the administrative burden on companies**

3. Instruments, L. acts and other. Regulation of the European Parliament and of the Counci on health technology assessment and amending Directive 2011/24/EU. vol. 2021 (2021).

Governance Structure of the EU HTA Regulation

The governance of EU HTA procedures will be carried out by a Coordination Group made up of all Member States, with the European Commission serving as secretariat.



Key Aspects

> The Coordination Group will oversee the **joint technical work carried out by subgroups** of national and regional representatives for specific types of work, including JCAs, JSCs, methodological guidance documents, and horizon scanning

> EUnetHTA will support the methodology sub-group through **EUnetHTA 21 Service Contract**, for the development of methodological and procedural guidance

> A Stakeholder Network will be set up by the EC to **facilitate regular dialogue between European stakeholder organizations and the Coordination Group**. External experts, including clinicians and patients, will have the opportunity to provide comments on draft joint work

> Finally, the EC will serve as **secretariat to the HTA cooperation**

*Identification of emerging health technologies

The Role of EUnetHTA 21

EUnetHTA 21 is consortium led by the ZIN (the Netherlands) to develop the HTA methodology to be applied when carrying out joint work. EUnetHTA has a two-year service contract from the European Health and Digital Executive Agency (HaDEA) on behalf the EC.

Over the next two years, the role of EUnetHTA will be essential in **laying the groundwork for the new regulation**, including the development of guidance documents that will be adopted by the Coordination Group, and drafting the EC's implementation legislation.

Key Aspects of the EUnetHTA 21 Service Contract

> EUnetHTA21 will build on the **achievements and lessons** learned from previous EUnetHTA joint actions

> EUnetHTA 21 is expected to consult with **stakeholders** – including **industry**, **patients**, and **clinicians**

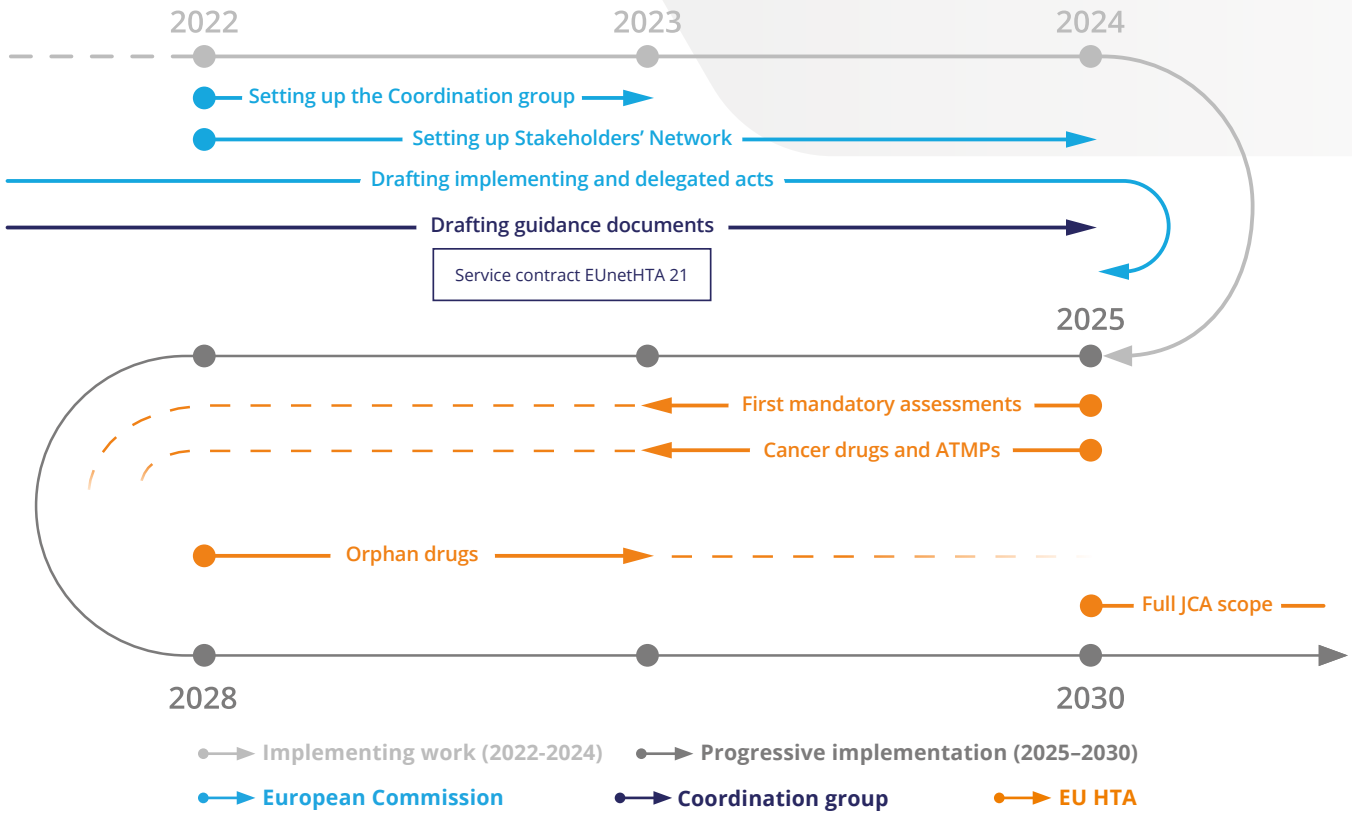
> EUnetHTA 21 will provide **pilot tests** for the following: 8 JSCs (or at least, not less than 6) for medicinal products, 2 JCAs for medicinal products, and 4 JCAs for medical devices

Netherlands **ZIN***	France **HAS**	Portugal **INFARMED**	Belgium **KCE**
Spain **AEMPS**	Austria **AIHTA**	Sweden **TLV**	Italy **AIFA**
Germany **GBA / IQWIG**	Ireland **NCPE***	Norway **NOMA**	Hungary **NIPN**

EUnetHTA 21 joint consortium (13 HTA agencies)

*ZIN is providing leadership to the EUnetHTA 21 joint consortium.

EU HTA Regulation Roadmap



Note: The Coordination Group can designate a specific medicinal product to be subject to JCA at an early date when they have the potential to address unmet medical need or public health emergencies or have a significant impact on health care systems.

Implementation of the EU HTA Regulation

The Heads of Agencies Group (HAG) will support the preparation of national systems for the adoption of the EU HTA Regulation.

The HAG is a European collaborative network focused on new HTA for high-level strategic exchange and discussion. The HAG will complement the work carried out by the EUnetHTA 21 consortium.

Key Aspects of HAG

> **Support development of the basis** for joint work on all HTA activities at the European level

> **Prepare national systems for enforcement** of the new HTA Regulation, including increased capabilities

> **Support the technical and scientific joint work** performed by HTA agencies across Europe

> **Advise** EU and national institution **policymakers** on HTA

The 19 European HTA agencies forming the HAG

Netherlands **ZIN***	France **HAS**	Portugal **INFARMED**	Belgium **KCE** **RIZIV-INAMI**
Spain **AEMPS / REDETS**	Austria **AIHTA**	Sweden **TLV**	Italy **AIFA / RER** **AGENAS**
Germany **GBA / IQWIG**	Ireland **NCPE / HIQA**	Norway **NOMA / NIPH**	Hungary **NIPN**

* ZIN* is providing leadership to the EUnetHTA 21 joint consortium.

Executive Summary

> A new EU HTA Regulation will take e ect in 2025, **requiring manufacturers to submit a clinical dossier for a HTA at the EU level**. This regulation is the culmination of over 15 years promoting voluntary cooperation between HTA agencies

> The new EU HTA Regulation will have a **progressive implementation** from 2025 to 2030, starting with cancer drugs, ATMPS and some medical and IVDs

> From 2022 to 2024, the EC, together with the Coordination Group and sub-groups, will develop **procedural rules and the methodology** for the new EU HTA

> The EUnetHTA 21 consortium will **support the Coordination Group in the development of guidance documents** based on previous joint actions. In parallel, the HAG will support national systems as they prepare for adoption of the EU HTA Regulation

> This new Regulation seeks to **align HTA tools and methodologies**, establish common information criteria, and increase access equity among Member States

EU HTA Regulation represents an opportunity to reduce duplication of efforts for HTA agencies and the industry. However, given the current soft-binding nature of JCA reports, more work is needed to avoid increasing the administrative burden on companiest.

How Alira Health Can Help

Our international team of multidisciplinary experts includes national and regional HTA experts, former payers, physicians, and patient engagement experts. Together, we'll work closely with you to:

> Deepen your understanding of this new Regulation, including its risks and opportunities

> Co-create your HTA strategy and expand your capabilities for increased success with JSCs and JSAs

> Guide your clinical dossier submission according to the new requirements

> Work together to increase your success rate in PMA activities at the national and regional level

Contact us at **info@alirahealth.com**

AliraHealth

Alira Health is an international patient-centric and technology-enabled advisory firm whose mission is to humanize healthcare. We work with healthcare and life sciences organizations looking for support across their entire solutions lifecycle. From development to medical care, we complement our clients' expertise with a full spectrum of services including research and clinical development solutions, technology-powered consulting, and real-world evidence.

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Nerea Blanqué-Catalina has more than 20 years of experience, with recent positions leading global market access and pricing teams at international pharma companies. Her in-depth market access and pricing experience includes strategy, negotiation, global value dossier design, local adaptations, clinical trials, and TPP assessments for a wide range of conditions. Nerea has a BSc and an MSc in Pharmacy from the Universitat de Barcelona, as well as several post-graduate degrees and certificates in business.

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Marta Aguado joined Alira Health in March 2021 with 1 year of experience as a consultant in a Spanish market access and health economics consultancy firm. Marta has been working on value and communication evidence generation projects generating/updating GVDs, SLRs, POH and PVS.
She has been involved in projects of several therapeutic areas like neuromuscular diseases, infectious diseases, metabolic diseases, renal diseases, and rare diseases.
Marta holds a degree in Biotechnology and a master on Pharmaceutical Industry with mention in Project Management and Market Access from Barcelona University.