GRHTA
Glob Reg Health Technol Assess 2025; 12: 194-197
ISSN 2283-5733 | DOI: 10.33393/grhta.2025.3502
POINT OF VIEW

Paving the road for a successful EU HTA Reform implementation

Hans Severens[1], Andrew Dillon[2], Francois Meyer[3], Claudio Jommi[4,5], Lipska Iga[6], Pier Luigi Canonico[7], Oriol Solà-Morales[8,9], Herbert Altman[10]

[1]Independent scientific and strategic Advisor HTA /HEOR, Venray - Netherlands
[2]Independent Advisor, London - UK
[3]Independent Advisor, Paris - France
[4]Professor of Management at the Department of Pharmaceutical Sciences, Università del Piemonte Orientale, Novara - Italy
[5]Member of the Programme Board and Scientific Committee of the Master of Discipline Regolatorie e Market Access in Ambito Farmaceutico e Biotecnologico
[6]Chairwoman of the Board, Health Policy Institute Poland, Warsow - Poland
[7]Department of Pharmaceutical Sciences, Università Piemonte Orientale, Novara - Italy
[8]Chairman of the Board and CEO, Fundació HiTT, Barcelona - Spain
[9]Department of Basic Sciences, Universitat Internacional de Catalunya, Barcelona - Spain
[10]VP Market Access & Healthcare Consulting Europe, Cencora, Munich - Germany

ABSTRACT

The article explores the challenges and opportunities presented by the implementation of the EU Health Technology Assessment Regulation (EU HTAR). It highlights the varying degrees of readiness among Member States (MSs) and the perceived concerns regarding loss of sovereignty. The discussion emphasizes the importance of national preparedness, reducing bureaucratic inefficiencies, and fostering transparent communication among stakeholders. The article also underlines the critical role of Joint Scientific Consultation (JSC) in optimizing regulatory and HTA processes, advocating for an expansion of JSC slots and selection criteria. Moreover, it calls for greater involvement of clinicians and patient advocacy organizations to enhance trust and facilitate effective implementation. Ultimately, the article argues that strengthening collaboration, optimizing regulatory pathways, and ensuring comprehensive stakeholder engagement are key to realizing the full potential of the EU HTAR and improving patient access to innovative medicines across Europe.

Keywords: HTA, EU HTA Regulation, Implementation Policy

Introduction

In May 2024 the ETTHICS think thank (European Think Tank on Health Innovation and Competitiveness for Sustainability) was put in place to discuss equitable access to new medicines by reflecting on the EU's common problems and proposing some ways forward. The initial objective of ETTHICS was steering, facilitating, and coordinating a think tank for selected healthcare systems topics to contribute to a better understanding of the dynamics and their impact in Europe, and initially focused on the EU HTA Regulation that came into effect in January 2025 as a way to improve access to medicines in Europe (1). This regulation is different in many aspects from other EU regulations, mainly because it's a federated process coordinated and not led by the European Commission. In the current context, we believe it is an opportunity for the progress of the healthcare industry and the EU overall.

Continuing their series of meetings, ETTHIC members convened in Barcelona in November 2024 to review developments that had occurred since their previous meeting in May 2024 and to discuss the approaches being taken by member states to the implementation of the EU HTA regulation. Former HTA (Health Technology Assessment) people with extensive policy exposure in their home countries were asked to join the group bi-annually to provide reflection and opinion on the latest developments in healthcare and drug policies.

In the past ETTHIC has advocated that the implementation of the EU HTA reform legislation (1,2) will require significant effort at different levels: pan-EU legislation and the national policy level, the development of methodologies, transparent communication, trust-building and effective support between member states, to mention but a few.

Received: February 19, 2025
Accepted: June 5, 2025
Published online: August 29, 2025

Corresponding author:
Oriol Solà-Morales
email: osola@fhitt.org

Well aware that the EU HTAR has a learning curve, we focussed the discussion on two elements: (a) progress at the national level and (b) addressing implementation success.

(a) *Member States (MS) national preparedness*

When looking at the recent national developments we focused on countries represented by the think tank members.

Italy is still in a transition phase currently implementing a redesigned AIFA (Agenzia Italiana del Farmaco – Italian Medicines Agency) organization and procedures, where the JCA (Joint Clinical Assessment) process needs to be integrated. As per the public declarations prior to the meeting, there is a strong intention of the new AIFA to support the pan-EU processes and to include the resulting JCA report in the local HTA assessment. A non-binding opinion on the JCA has been listed among the activities of the new Scientific and Economic Committee (CSE) by the relevant regulation. The CSE (3) is the new committee supporting AIFA in the scientific and economic assessment of new medicines. After the meeting (on the 28th of April 2025) a Working Group was established in AIFA to manage the EU HTA Regulation. The group is made up of 8 members and a coordinator coming from AIFA's staff; The group will mainly participate in the JCA process (supporting the PICO scoping phase, the JCA Subgroup -or direclty joining the JCA Subgroup), acting as assessor and co-assessor for the procedures assigned to AIFA and supporting the CSE (the JSC -Joint Scientific Consultation-, acting as assessor / co-assessor or as ad hoc representative in the JSC Subgroup) (4). However, the Innovativeness and Price and Reimbursement (P&R) Dossier has not been updated so far to incorporate the JCA. Also, it will be necessary to increase resources on a country level to support EU HTAR requirements, as it was stated by the new AIFA's President (5), who expressed concern that new resources have not been foreseen by Italy's 2025 Financial Law.

Poland, one of the biggest CEE countries could benefit from the JCA implementation in terms of faster and broader approval, although there is still some internal resistance; a few key positions have been onboarded to the JCA process but there is still some perception that not enough capacity may be in the system overall to support the pan-EU processes. AOTMiT (Agencja Oceny Technologii Medycznych i Taryfikacj or Agency for Health Technology Assessment and Tariff System), the Polish HTA body and relevant stakeholder, has joined the Heads of HTA Agencies Group (HAG) in what seems an approach to EU.

Spain is an example of a country that has done major legal reforms locally and is committed to being strongly involved in the process even if the details of how the reform is going to be grounded are still missing. While there is less concern about leveraging the JCA report within the local HTA assessment process, it will be necessary to allocate the resources required to support the JCA and JSC processes on a European level. As the national scaffolding has been reinforced, the details of the methodologies and processes that will be used are still to be defined, so although in principle it is a good opportunity, there are a lot of expectations on how the details will pan out (and there is where the interpretation and implementation difficulties may reside).

On a more proactive side, **The Netherlands** has been already very concrete, and appointed ZIN (Zorginstituut Nederland –The National Health Care Institute) to oversee the evaluation process at least till 2030. The government has provided some extra funds and with that secured, has stayed deeply involved in the JCA production and the EU discussions. As a consequence of its new role, ZIN should become a relevant stakeholder not only in developing the methods but also in driving the design and governance of the new EU HTAR; we anticipate ZIN taking an important role in monitoring the implementation of the EU HTAR and evaluating potential improvement areas already in the early phase for Advanced Therapies and Medicinal Products (ATMPs) and Oncology Medicinal Products (OMPs).

Both **France** and **Germany**, who led the development of the EU HTAR and have made most of the necessary reforms to adapt their internal process while preserving their building blocks, seem well-prepared. G-BA (Gemeinsamen Bundes-Ausschuss or Federal Joint Committee) and HAS (Haute Autorité de la Santé or High Health Authority) both acknowledged that a major challenge of the reform will be to keep PICO (6) requirements for the JCA assessment manageable. This is something which was underlined by industry associations, including EFPIA (European Federation of Pharmaceutical Industries and Associations), EUCOPE (European Confederation of Pharmaceutical Entrepreneurs), and ARM (Alliance for Regenerative Medicine) and is seen as one of the biggest uncertainties for HTDs (Health Technology Developers) in their effort to prove the HTA value of their innovative medicinal solutions. The resources committed by these two countries have not significantly changed.

We want to refer to and learn from the UK as an example of a country that was recently a member of the EU regulatory system but which now has to engage with the global life sciences industry on its own. Its experience in this regard may offer important lessons on how to remain attractive to HTDs. The decision by the UK to leave the European Union in 2016 and the subsequent departure from most EU institutions in 2020 has led to changes in the approach to the regulation and adoption of new health technologies. The immediate concern was to ensure that the UK maintained access to new treatments given the small size of its market relative to the purchasing power of the EU, by creating a nimble and flexible regulatory environment.

The UK's medicines and devices regulator (MHRA – Medicines and Healthcare products Regulatory Agency) introduced new routes for fast-tracking the approval of medicines, such as the Innovative Licensing and Access Pathway (ILAP) (7) to support innovation and accelerate patient access to breakthrough treatments. It also established mutual recognition agreements and collaborations with international regulators.

In 2021 MHRA revised its regulatory framework for clinical trials to align with UK-specific requirements and updated its guidance for medical device manufacturers to reflect the new UK Conformity Assessed (UKCA) mark, replacing the EU's CE mark. NICE (National Institute for Health and Care Excellence) has also leaned into the effort to present the UK as an attractive place to introduce new health technologies.

Its ambition is to increase the number and speed of its technology appraisals and to expand its capacity for evaluating MedTech and digital products. As well as collaborating with the MHRA on accelerating the evaluation of new technologies with innovative potential, NICE introduced what it calls a proportionate approach to technology appraisal in 2022 and revised its methods to support rapid access to new treatments, particularly in areas of unmet medical need. Additionally, NICE has increased its focus on engaging with global HTA bodies, to exchange ideas and experience in a bid to remain a leader in HTA.

Overall, some countries have positively incorporated as much as possible of the new legislation into their local procedures whilst others are not yet fully prepared and still engaged in some internal debates about how to best comply with the requirements of the new EU HTAR. The UK's experience of implementing significant local reforms in the UK will be worth watching both as a potential 'competitor' for the first market launch and to stay alert for any industry-friendly approaches that might be transferable to the EU.

As a think tank, we are aware that the slow and sometimes uncertain preparation for the implementation of the reform was also a consequence of the 'loss-of-control' perception from some MSs and the lack of European resources to implement the new regulation. In terms of policy, this is not a minor issue. It reinforces the need to build trust between MSs and the need for effective support between them (i.e., resourcing, best practice sharing, identification of improvement areas, etc.). At the same time, it will be necessary to build a strong bottom-up support mechanism locally (albeit informal) in parallel to the HTACG (HTA Coordinating Group) managed top-down implementation of JCA and JSC.

Sovereignty is frequently flagged as a policy and political problem in several MSs, although the legislation was carefully crafted to protect national authorities with the reimbursement decision and leaving the more technical part where economies of scale could be sought at an EU level.

However, from our point of view, the fear of disempowerment may be misplaced, as local processes appraising the relative clinical value as well as assessing non-clinical domains and managing pricing are retained MS level. Still, existing concerns could be eliminated by the fruitful participation of MSs in the PICO assessment scoping phase, where MS have a 'one shot' opportunity to intervene. Alternatively, we would advocate for the establishment of formal and informal collaboration networks within the HTA and evaluation teams, steered by the Coordinating Group and the HTA Secretariat, creating transparency and a robust local infrastructure that could both support the evaluations (JCA & JSC) and efficiently implement the reforms locally. In fact, HTA evaluation teams will have to work together and constitute a network while producing JCA and conducting JSC. So existing concerns may be tempered while gaining experience in the production and use of JCAs and the conduct of JSC.

(b) ***EU HTAR implementation (and its success):***

What will success look like? Our second think tank topic was about the definition of "implementation success". Many (8) have advocated the need to define easy-to-measure KPIs (Key Performance Indicators) to follow up with the implementation of the reform and learn quickly about areas for improvements and prepare for corrective actions; the EU HTA Secretariat has defined some landmarks at which the implementation should be revisited (9). The first official feedback collection has been announced for 2028, broadening the EU HTAR for Orphan Drugs in addition to ATMPs and OMPs, before extending to all medicinal products in 2030. We acknowledge these EC efforts constantly collecting feedback from healthcare system stakeholders, monitoring the efficiency of the reform, and the achievement of reform objectives. However, we are convinced that there are at least two major topics that should be addressed immediately from a policy and implementation perspective.

First, the fast, traceable, and visible reduction of bureaucracy will generate meaningful benefits for the wider community. From the beginning, MSs should very much leverage the efficiencies available as a result of the pan-EU processes, in their local procedures – most importantly the JCA report. Local HTA authorities will play an important role in identifying and eliminating non-value-generating process steps while accelerating the local processes for bringing innovative medicines to their patients.

The second important topic is fast and transparent communication among all healthcare system stakeholders, especially between MSs but also fostering better communication within the Stakeholder Network. Participants should actively share learnings and best practices, but also improvement opportunities by proposing changes leading to removing inefficiencies embedded in the new reforms. Such efforts will harmonize and increase the quality of results across Europe. We are convinced, that this will create a positive narrative of success built on individual and shared positive experiences.

In our opinion, clinical societies will be an important partners in this endeavor. We have advocated in the past that they may not perceive themselves as part of this process, which detaches them from the successful implementation of the reforms potentially frustrating the faster introduction of new medical solutions for patients. This is inconsistent with the important role clinicians play in the development phase of new drugs and devices. Their experiences and insights, complemented by patient insights on health-related quality of life are currently leveraged by many HTDs R&D departments but also by authorities and payers. Importantly they will be needed as clinical experts during the JSC and JCA process. Therefore, their direct (following ZIN's approach) or indirect (better awareness) participation in the implementation of the new EU HTA processes is a requirement, and not enough effort has been put into engaging with them.

We should not underestimate the increasing power of patients and patient associations who increasingly participate in the trial design process and in the valuation of the appraisal and implementation of new technologies. The involvement of pan-EU associations will become critical as their advice is increasingly sought, and they are likely to be a key partner by MS in evaluating the new approvals in the national phases.

Finally, success will be achieved when at the end of the JCA process a high-quality, decision-relevant JCA dossier is

produced and effectively incorporated into the national HTA assessments. It is our expectation, that EMA and the HTACG will collaborate closely to ensure the efficiency of the new process and support HTDs in their effort to generate the requested evidence for innovative medicinal products.

In this context, the think tank strongly agreed that there is a major role for JSC (Joint Scientific Consultation) as a cornerstone of the EU HTAR. The more that HTDs are able to collect high-quality and decision context relevant advice from a JSC, the closer the development of evidence will align with the needs of EMA and HTA. Such input will result in appropriate clinical trial designs generating meaningful evidence for regulatory and HTA requirements, and help build trust among MS.

Unfortunately, the EU Secretariat has provided only a very limited number of JSC slots and the announced qualification criteria seem quite restrictive as well. We very much recommend increasing the number of JSC slots as well as opening wider selection criteria and with that allowing a larger number of HTDs to collect joint feedback at an earlier development stage of their innovative medicine. A potential solution for such expansion could be applying fee-for-service contracts (as for EMA or FDA) -with the appropriate waivers- so that more capacity is built within the HTA system.

Conclusion

After an intense discussion about (a) Member States national preparedness and (b) EU HTAR implementation success, based on experiences of think tank members of a small number of EU countries, we concluded that there is still a considerable difference between the 27 MSs about how they are embracing the new EU HTA regulation, and we foresee the risk of not achieving the initial EC objectives: to reduce bureaucracy, improve efficiency, increase the quality of HTA assessments and generate equal access to innovative medicines across EU faster.

Netherlands and Poland give a clear picture of the global situation at the EU level: the readiness for the EU-HTA regulations varies to a great extent.

For the successful implementation of the reform, all the different stakeholders need to be better empowered, preferably on a pan-EU level to pursue the implementation of the EU HTAR, and at the same time they need to confirm their commitment to take such responsibility.

We should not neglect the important role that patient advocacy and clinician organizations/scientific societies will play in this new reform. Although PICOs and the JCA process seem to be the main focus, the development of a strong JSC also needs full support, making it an insightful feedback platform widely accepted and leveraged. In our opinion, this will help reduce (improve) the failure rate of HTDs pipeline products, which is a burden on health systems and companies.

Disclosures

Conflict of interest: None of the participants declares any conflict of interest. CJ, FM, HS, IL, PL-C received participation fees for attending the meeting.

Financial support: The meeting was organized and sponsored by CENCORA and Fundació HiTT.

Authors contributions: All authors contributed equally and made contributions to the initial version of the manuscript and the final version.

Data availability statement: No data were used in this manuscript.

References

1. European Commission. Implementation of the Regulation on health technology assessment. 2025. Online (Accessed February 2025)
2. Lipska I, Meyer F, Canonico PL, Altman H, Solà-Morales O. What is needed to successfully implement the EU HTA Regulation enabling broad patient access in Europe. Glob Reg Health Technol Assess. 2025;12(1):7-8. CrossRef PubMed
3. AIFA. CSE Rules of procedure. Online (Accessed February 2025)
4. AIFA. Determina del Direttore Tecnico Scientifico 38/2025, Online (Accessed July 2025)
5. AIFA. Nisticò (AIFA). "Per velocizzare l'accesso ai farmaci potenziare e qualificare gli organici dell'Agenzia". Online (Accessed February 2025)
6. Lichtenstein AH, Yetley EA, Lau J. Table 3, Example of the PICO method of formulating a systematic review question1. Agency for Healthcare Research and Quality (US); 2009. Online (Accessed February 2025)
7. GOV.UK. 2025. Innovative Licensing and Access Pathway (ILAP). Online (Accessed February 2025)
8. Van Haesendonck L, Ruof J, Desmet T, et al. The role of stakeholder involvement in the evolving EU HTA process: insights generated through the European Access Academy's multi-stakeholder pre-convention questionnaire. J Mark Access Health Policy. 2023;11(1):2217543. CrossRef PubMed
9. European Union. 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 (Text with EEA relevance). 2021. Online (Accessed February 2025)