FROM CHALLENGE TO OPPORTUNITY:

MASTERING THE **NEW EU HTA** LANDSCAPE

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Understanding the EU HTA regulation: a new era in HTA

In December 2021, the European Parliament and the Council of the EU adopted the European Regulation on Health Technology Assessment (EU HTA R (EU)2021/2282), which came into effect in January 2022 [1]. The EU HTA regulation will focus on the 'clinical domain' of HTA, which includes the estimation of relative clinical effectiveness and relative clinical safety, of health technologies as compared with existing ones, since this is the component that is more generalizable from setting to setting [2]. Once Joint Clinical Assessments (JCAs) are conducted, individual countries must take them into consideration but may supplement them with additional clinical analyses that are needed in their national HTA process and/or in their own context. The 'non-clinical domain' of HTA, which includes the assessment of cost-effectiveness or value for money, will remain the responsibility of individual countries. Starting from January 2025, JCAs will be carried out for all cancer medicines and advanced therapy medicinal products (ATMPs), followed by orphan drugs from January 2028 and, finally, all other centrally approved medications and a selection of medical devices from 2030 onwards [1].

Benefits associated with EU HTA regulation

1) Efficiency: ***The EU HTA regulation could improve the efficiency of HTA within the EU, as countries will be able to pool their HTA resources and expertise and avoid duplication of efforts*** [3]. This gain in efficiency is considered the main benefit due to a reduction in administrative burden as pharmaceutical companies will have to submit the clinical file only at the European level instead of to 27 different countries.

2) Quality: ***By bringing together experts from different countries, the regulation enables the pooling of resources and expertise****, which is likely to result in higher quality assessments than what individual countries could achieve independently.*

3) Consistency: ***The regulation promotes consistency by establishing standardized methodologies and procedures for HTAs across member states.*** This harmonization reduces differences in assessment practices, ensuring that all countries evaluate health technologies based on the same criteria.

4) Faster access: ***The clearer and more harmonized procedures, could in turn lead to faster access across Europe*** [3]. Once the JCA is published, member states could immediately adopt it in their national dossier requirements and add cost-effectiveness analysis if desired.

5) Equity: ***The coordination of efforts will be especially beneficial for smaller and less prosperous EU countries with less established HTA bodies*** considering they have less capacity to conduct thorough HTAs.

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Challenges associated with EU HTA regulation

1) Time-consuming and resource intensive systematic literature reviews (SLRs) [2]: Assessing relative clinical effectiveness usually involves an SLR to synthesize evidence from diverse comparators and healthcare systems across EU countries. The JCA requirement to address variations in standard of care across markets can make the SLR more complex and time-consuming. **In addition, health technology developers must submit the dossier in digital format 100 days after they have received the final scope, and the assessors may ask for additional data analyses or other evidence, with a deadline of between 7- 30 days.** Thorough and comprehensive SLRs within these timeframes can be difficult, especially for complex treatments or disease areas.

2) Differences in current standard of care [2]: For the purposes of HTA, the relative clinical effectiveness of the new treatment or technology is assessed in comparison with the current standard of care. **Although some similarities across the EU in the current standard of care are expected, there may be some differences, particularly if the central and eastern European countries are considered.** Therefore, the new EU HTA system will need to ensure that all member states' needs will be accounted for; relevant comparators will be based on the local standards of care.

3) Lack of relevant head-to-head clinical trials [2]: As the range of possible alternatives to the new technology of interest increases, the likelihood of head-to-head clinical trials decreases. Therefore, it seems inevitable that the JCA will have to rely on indirect treatment comparisons. **Network meta-analyses (NMAs) are well-established in HTA submissions, but the new EU HTA regulation may require matching-adjusted indirect comparisons (MAICs). This is because MAICs can adjust for population differences using individual patient data, particularly in cases where NMAs are not feasible or sufficient due to heterogeneity among trials.**

4) Insufficient clinical data for the initial HTA submission [2]: **While JCAs are based on existing clinical data, making informed reimbursement decisions often requires real world experience, which may require months or years.** Although the regulation permits voluntary joint post-launch data collection, the lack of a structured framework for incorporating real-world data represents a missed opportunity for standards and consistency in the regulation's implementation. To fully realize the potential of the new EU HTA system, a more comprehensive, lifecycle approach to data generation and assessment could ensure that HTAs evolve with the accumulation of real-world evidence over time.

5) Economic modelling for local HTA bodies: With economic evaluations remaining at the national level, there may be continued heterogeneity in coverage recommendations and decision-making across Europe due to differences in how value is defined and quantified in different healthcare systems. While the regulation aims to improve efficiency by pooling resources for clinical assessments, individual member states may still need to allocate significant resources for country-specific economic evaluations. Given the local nature of healthcare economics, there may be additional challenges in transferring or adapting JCAs to inform country-specific economic evaluations.

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Navigating the future of EU HTA

To conclude, the EU HTA regulation represents a significant step towards harmonizing and streamlining HTAs across Europe. The new regulation offers several benefits, including improved efficiency through resource pooling, enhanced quality of assessments, potential for faster access to innovative treatments, and increased equity among EU member states. However, some challenges remain, such as the need for more comprehensive and time-constrained SLRs, addressing differences in standard of care across countries, managing the lack of head-to-head clinical trials, and bridging the gap between available clinical data and comprehensive HTA requirements.

As this new era in EU HTA unfolds, it is important to recognize that the implementation of the EU HTA regulation is an evolving process. The field is dynamic, and new opportunities are likely to emerge as the first JCAs are conducted in 2025. We can expect ongoing refinements and adjustments to the EU HTA regulation and its implementation as stakeholders gain practical experience and identify areas for improvement.

This adaptive approach will be crucial in ensuring that the EU HTA system can effectively meet its goals of improving efficiency, quality, and access to innovative health technologies across Europe.

References

1. European Commission. Health Technology Assessment: Commission welcomes the adoption of new rules to improve access to innovative technologies. 2021; https://ec.europa.eu/commission/presscorner/detail/en/ip_21_6771. Accessed 2024-11-25, 2021.
2. Desmet T, Brijs M, Vanderdonck F, Tops S, Simoens S, Huys I. Implementing the EU HTA regulation: Insights from semi-structured interviews on patient expectations, Belgian and European institutional perspectives, and industry outlooks. Front Pharmacol. 2024;15:1369508.
3. Drummond M, Tarricone R, Torbica A. European union regulation of health technology assessment: what is required for it to succeed? Eur J Health Econ. 2022;23(6):913-915.

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