Benefits and Challenges in the Implementation of EU HTAR for Medical Devices: Lessons Learned from the Pharmaceutical Industry

HPR35

X. PAN[1], E. BUSINK[1]

[1]Fresenius Medical Care Deutschland GmbH, Bad Homburg, Germany

INTRODUCTION

The EU Health Technology Assessment Regulation (HTAR) introduces new mandatory requirements for medical devices, notably Joint Clinical Assessments (JCAs) to harmonize clinical evaluations across Member States[1]. While the value of conducting JCAs centrally is widely recognized, the absence of a direct link between JCA reports and national reimbursement decisions may raise costs for health technology developers (HTDs) [2].

OBJECTIVE

This study examines cost implications of increased access requirements and advocates for a best practice framework integrating JCA reports into national reimbursement processes.

METHOD

- A targeted literature review was conducted to evaluate the increased costs incurred by the pharmaceutical industry under the implementation of the EU HTAR, as well as the potential benefits gained.
- In addition, stakeholder interviews were carried out to explore the applicability of these findings to the MedTech sector, considering the structural and regulatory differences between medicinal products and medical devices.

RESULTS

Preliminary findings indicate that while the implementation of the EU HTAR introduces additional demands on HTDs, particularly related to data generation, documentation, and stakeholder engagement, it also offers the opportunity to strengthen the overall evidence base and streamline market access processes in the long term.

Experts acknowledge the distinctive nature of the MedTech industry, including limited patent protection, steep learning curves, and the frequent rollout of updated technologies. Furthermore, concerns are raised about the lack of alignment between JCA reports and national reimbursement procedures, which may create uncertainty for HTDs and impact investment decisions. Ultimately, this may delay or limit patient access to technologies addressing unmet medical needs. Experts call for clearer guidance and alignment mechanisms tailored to the MedTech context. Table 1 summarizes challenges and opportunities for the MedTech industry under EU HTAR.

Table 1: Challenges and Opportunities for the MedTech Industry under EU HTAR

	Challenges	Opportunities
Increased Requirements	• Stringent evidence requirements for clinical effectiveness and comparative data • Expanded documentation aligning with JCA templates • Need for standardized methodologies and consistent endpoints across EU markets • Broader stakeholder engagement expectations	• Clearer expectations from HTA bodies, leading to potential long-term savings through centralized evidence generation and database across countries • Reduced duplication of submissions across Member States • Improved predictability of HTA outcomes • Enhanced stakeholder dialogue and early scientific advice
Specificities Implemented for MedTech Industry	• Limited guidance on handling iterative innovation (e.g., software updates, device modifications) • Operator-dependent outcomes and context-specific performance complicate assessment • Lack of established frameworks for real-world evidence integration • Limited patent protection increases pressure for rapid market access	• Potential development of device-tailored HTAR methodologies • Recognition of real-world performance as valid evidence source • Opportunity to co-develop registries and data standards with HTA agencies • Potential for future linkage of JCA outcomes to reimbursement decisions as trust and evidence maturity increase
Business Impact / Strategic Implications	• Longer timelines and higher upfront investment in clinical and HEOR evidence, indicating earlier integration of HEOR and regulatory functions to R&D phases • Increased uncertainty during transition phase before HTAR processes stabilize • Ambiguity in selection criteria creates uncertainty over which devices fall under HTAR, hindering strategic planning and resource allocation • Risk of misalignment between JCA outcomes and national reimbursement • Competitive disadvantage for SMEs with limited resources	• Early movers gain credibility and EU-wide launch advantage • Investment in in-house capability building in evidence generation, EU policy awareness, and stakeholder engagement • Stronger positioning in cross-border tenders and multi-country launches • Trust-building for eventual linkage of JCA and reimbursement decisions • Potential greater investor confidence due to transparent, harmonizing assessments

JCA, Joint Clinical Assessment; EU, European Union; HEOR, Health Economic and Outcome Research; R&D, Research & Development; HTAR, Health Technology Assessment Regulation; SME, Small and Medium-sized Enterprise; HTA, Health Technology Assessment.

CONCLUSIONS

To preserve the benefits of the EU HTAR while limiting its cost burden, Member States should align JCA reports with national reimbursement decisions. This would improve predictability and accelerate patient access.

CONTACT INFORMATION

Xuanqi Pan, xuanqi.pan@freseniusmedicalcare.com

Ellen Busink, ellen.busink@freseniusmedicalcare.com

REFERENCES

1. European Commission. Implementation of the Regulation on health technology assessment [Internet]. Available from: https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment_en
2. European Commission. Health technology assessment: joint clinical assessments of medical devices (draft act) [Internet], 2025 Jun 25. Available from: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13707-Health-technology-assessment-joint-clinical-assessments-of-medical-devices_en