EUnetHTA21's Joint Committee Assessment is coming: What will the way forward be for MedTech?

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MT26

ISPOR EU 2023
COPENHAGEN, DK

INTRODUCTION

Historically, European reimbursement decision-making has been decentralized, creating inefficiencies and inconsistencies in review across markets and delaying patient access.

In the case of medical devices, this has been increasingly complex, as reimbursement decision-making may be conducted at a regional, local, or hospital level.[1-4]

In response, the European Parliament has introduced a regulation that is set to facilitate the health technology assessments (HTA) process through a centralized evaluation process.[1-5]

The EUnetHTA21 Consortium has developed a framework enabling a Joint Clinical Assessment (JCA) for medicinal products, including medical devices. The rollout of this framework is ongoing and will apply since January 2025.[1-5]

OBJECTIVES

This study sought to understand the impact of the JCA across Europe and analyze the impact on manufacturers' evidence development strategies.

METHODS

A targeted literature review evaluated how the JCA will impact country-level decision-making. Sources included PubMed, the ISPOR database, and gray literature (e.g., EUnetHTA publications).

We identified 26 relevant sources: 5 manuscripts, 9 posters or presentations, 9 grey literature articles, and 3 EUnetHTA publications (Tables 1 and 2).

Table 1 – PubMed Search Results

Different Search Strings (Pubmed)	Hits	Relevant Sources
(((EUnetHTA[Title/Abstract]) AND (Joint Committee Assessment[Title/Abstract])) OR (JCA[Title/Abstract])) OR (Joint Clinical Assessment[Title/Abstract]) Limit- Last 3 Years, English, Humans	17	3
(Joint Committee Assessment[Title]) OR (Joint Clinical Assessment[Title]) Limit- Last 3 Years, English, Humans	19	2

Table 2 – Grey Literature and ISPOR Database Search Results

Source	Search Terms	Hits	Relevant Sources
ISPOR Presentations Database	EUnetHTA, Limit – Last 3 Years	68	9
Grey Literature	EUnetHTA JCA	24	9
EUnetHTA Website	N/A	12	3

RESULTS

HTA Roles and Responsibilities[5,6]

The EUnetHTA21 framework provides a detailed framework on how responsibilities will be distributed across the centralized evaluation committee and the national reimbursement authorities (Figure 1 – Comprehensive HTA Elements)

Figure 1 – Comprehensive HTA Elements

eunethta HTA Core Model® Domains

Rapid Relative Effectiveness Assessment (IREA)

REA

CUR	Health problem and current use of technology
TEC	Description and Technical Characteristics
SAF	Safety
EFF	Clinical Effectiveness

National Assessments/Appraisal Domains

For Member States and National Appraisal

National Appraisal

ECO	Cost and Economic Effectiveness
ETH	Ethical Analysis
ORG	Organisational Aspects
SOC	Patient and Social Aspects
LEG	Legal Aspects

Experience from the MedTech Assessments Published[7,8]

For medical devices and in vitro diagnostics, various filters restrict the application of the HTA regulation, as only high-risk, novel, and/or likely high-impact class III implantable devices and class IIb active devices will be clinically assessed

The JCAMD001 (Optilume urethral drug-coated balloon) and JCAMD002 (Evoke Spinal Cord Stimulation System) were the first published JCAs by EUnetHTA; several opinion pieces hypothesize on the implications that a JCA will have on reimbursement decisions (Figure 2 – Drivers, Challenges, and Unknowns from the first MedTech Assessments)

Figure 2 – Drivers, Challenges, and Unknowns from the first MedTech Assessments[1-4,9-26]

Drivers

EU HTA promises to provide methodological clarity for indirect comparisons (ICs), and therefore, the hopes for increased acceptance of ICs are high

Unknowns

- It is unclear if single-arm studies and real-world evidence (RWE), common in MedTech, are acceptable
- The use of ICs may still not be accepted at a national level
- JCA may not accelerate reimbursement

Challenges

- Each country's health technology assessment prioritizes unique types of evidence; this lack of conformity is a potential early barrier to implementing JCA effectively
- Positive JCAs do not necessarily translate to positive reimbursement decisions at the national level, where the country-level HTA framework, budget impact, and/or cost-effectiveness become key
- Most frequent misalignment occurred in areas with limited consensus across the member states (comparator selection, endpoint relevance). A negative impact on national benefit ratings usually originated from those areas
- The assessments have inconsistently represented the unmet needs and the standard of care in the therapeutic areas as a result of differences in experiences of patient and healthcare professional inputs on SoC across countries

DISCUSSION

The application of the JCA will take place in January 2025; while there is still time for medical device manufacturers to prepare for their future launches, some early planning considerations should be assessed moving forward (Figure 3 – Implications and Actions for Medical Device Manufacturers). Ensuring that all critical evidence has been developed ahead of JCA submission, including RWE that demonstrates the burden of disease, will be a crucial component of future product launches and play a key role in downstream product success

Implications and Actions For Medical Device Manufacturers

Target Medical Devices	Only for high-impact class III implantable devices and class IIb active devices
Launch Timing	Prepare for MDR and HTAR simultaneously ahead of national decision; expect for national timelines to not be impacted by JCAs
Stakeholder Involvement	Early conversations between global/regional market access and local affiliates to align on submissions across both processes will be key to avoid duplication of efforts. The role of HEOR teams will remain important given role of national authorities in economic evaluations Higher importance of regional experts in HEOR and RWD/RWE to successfully negotiate evidence generation and access in Europe, within the JCA and the EU-wide medical device regulation (MDR)
Evidence Required	Limited/no updates in this area; the clinical standards will remain unchanged but as the HTAR implementation rolls out there may be higher willingness to accept ITCs at a national level. Individual country authorities will continue to be responsible for the evaluation of cost and economic effectiveness, highlighting the importance of collaborating with HEOR experts with regional knowledge

LIMITATIONS AND CONCLUSION

Limitations

This research was conducted in October 2023, as only two JCAs have been conducted to date (MD001 and MD002). The authors reviewed articles written in English over the last 3 years. The industry implementation component of this poster did not include research with industry experts, a potential next step for this research.

Conclusion

The JCA mandate is to streamline the clinical evaluation of medical technologies; however, our findings indicate it currently does not address critical components of product value, including humanistic and societal impact, which play an essential role in reimbursement evaluations for medical devices.

Additionally, the development of broadly accepted criteria that define accepted evidence types and clear frameworks for the use of indirect comparisons are paramount.

As JCA is rolled out, medical device manufacturers must be vigilant of changing requirements and evolving evidence needs, maintaining in mind the key role that national authorities will continue to play in the cost and economic effectiveness evaluation of medical devices and the importance that having regional HEOR expertise will have for a successful launch

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