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Jumping Through Hoops: Critical Considerations on Current Draft Reimbursement Guidance for Medical Devices

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Background

- Healthcare decision-making for medical devices (MD) is associated with unique challenges, such as scarce, high-quality trial data and heterogeneous patient populations that limit the comparability of study data.
- Recent changes to regulatory and reimbursement frameworks have increased evidence requirements for MDs with an effort to align them with pharmaceuticals. This includes the European Union's (EU) MD Regulation (MDR), which was initiated in May 2021 and restricted the use of evidence from existing devices in lieu of a formal evaluation of the new device.
- As laws and regulations for regulatory healthcare decision-making of MDs also directly impact the evidence needs supporting MD submissions for market access in many jurisdictions, reimbursement processes are currently being updated to follow suit. One prominent example is the EU's Joint Clinical Assessment Programme, which will cover both pharmaceuticals and MDs. However, many of the currently proposed changes have the potential to add barriers to patient access to MDs during a time when timely access is needed.

Objective

- The objective of this research was to compare reimbursement guidance for MDs with those for pharmaceuticals and provide critical considerations for the decade ahead.

Methods

- Guidance documents from key health technology assessment (HTA) organisations were reviewed to compare requirements for MD submissions with those for pharmaceuticals. Regulations for in-vitro devices were not considered as these tend to be captured by separate frameworks.
- A pragmatic approach was used to select relevant jurisdictions and organisations, focusing on Europe, Canada and the United States. Searches for guidance documents were undertaken using the website of each organisation.
- The findings were analysed thematically to inform critical considerations for reimbursement requirements and pathways for MDs.

Results

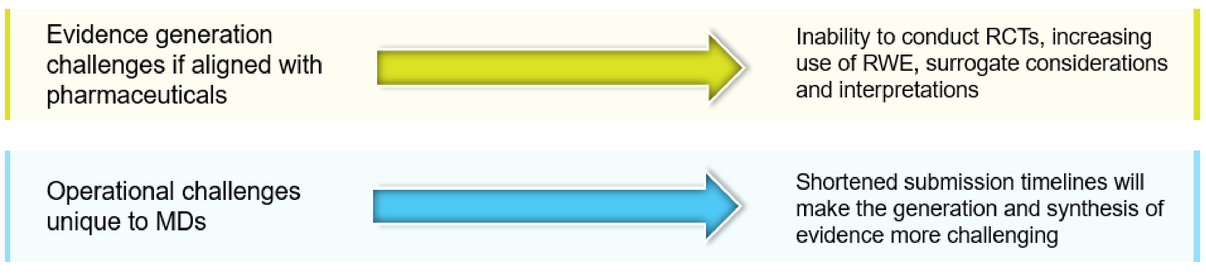
Table 1. List of organisations reviewed

CADTH General guidance *Economic analysis required*	**EUnetHTA** MD specific guidance *Economic analysis not applicable*	**HAS** MD specific guidance *Economic analysis only if significant benefit is claimed by manufacturer*
IQWiG / G-BA General guidance *Economic analysis only if price negotiations fail*	**PNHTADM / AGENAS** MD specific guidance *Economic analysis not applicable*	**AEMPS** MD specific guidance *Economic analysis required*
TLV MD specific guidance *Economic analysis: company chooses appropriate type*	**NICE** MD specific guidance *Economic analysis required*	**ICER** General guidance *Economic analysis required*

Canadian Agency for Drugs and Technologies in Health (CADTH); European Union: European Network for Health Technology Assessment (EUnetHTA); France: Haute Autorité de Santé (HAS); Germany: Federal Joint Committee (G-BA); Institute for Quality and Efficiency in Health Care (IQWiG); Italy: National HTA Program for Medical Devices (PNHTADM; MD assessment framework involves multiple stakeholders and organisations); National Agency for Regional Healthcare Service (AGENAS); Spain: Agency of Medicines and Medical Products (AEMPS), regional bodies; Sweden: Dental and Pharmaceutical Benefits Agency (TLV); United Kingdom (England): National Institute for Health and Care Excellence (NICE); United States: Institute for Clinical and Economic Review (ICER)

- Many HTA bodies have distinct pathways for the evaluation of MDs but only a small number of devices are formally assessed for potential inclusion in reimbursement catalogues.
- There is considerable variation in the level of detail in guidance across the organisations reviewed, with the Canadian Agency for Drugs and Technologies in Health (CADTH), Institute for Quality and Efficiency in Health Care (IQWiG) and the National Institute for Health and Care Excellence (NICE) providing the most detailed documents.
- In general, current guidance rarely distinguishes between MDs and pharmaceuticals in evidence and submission requirements.
- Yet evidence generation activities for MDs face numerous, unique challenges (Figure 1).

Figure 1. Challenges in evidence generation activities for MDs



Abbreviations: MD, medical device; RCT, randomised controlled trial; RWE, real-world evidence

Conclusions

- The recent reimbursement trend for MDs to increasingly align with those for pharmaceuticals ignores the fundamental differences in the way MDs and pharmaceuticals are developed and used.
- This puts manufacturers at the risk of being unable to meet these requirements, potentially barring patient access to effective and safe MDs.
- It is vital that payers consider assessment frameworks that are both feasible and adequate, so manufacturers may optimise evidence strategies outlining the true benefit of an intervention, rather than accommodating methodologies which may be less fit for purpose.

Results (cont.)

Increased methodological quality and scientific validity of clinical data

None of the identified HTA guidance frameworks provide a clear distinction in evidence requirements for MDs and pharmaceuticals. All reviewed HTA bodies require manufacturers to conduct thorough literature reviews for the clinical evidence submission. Although MD-specific guidance documents increasingly include provisions for non-randomised studies to support submissions, there is a push for study designs that are typically used for pharmaceuticals, such as randomised controlled trials (RCT).

Increased scrutiny to demonstrate the relevance of available clinical data

The focus on RCT data in evidence submissions can cause issues for manufacturers as part of the decision problems for MDs. Differences in clinical practice across countries and even between medical centres, are difficult to fully address through a clinical trial. Manufacturers, therefore, face challenges in providing appropriate evidence that sufficiently takes different patient populations and comparators into account, while simultaneously avoiding the introduction of bias and increased uncertainty around the evidence and effect estimates.

Operational challenges related to submission timelines

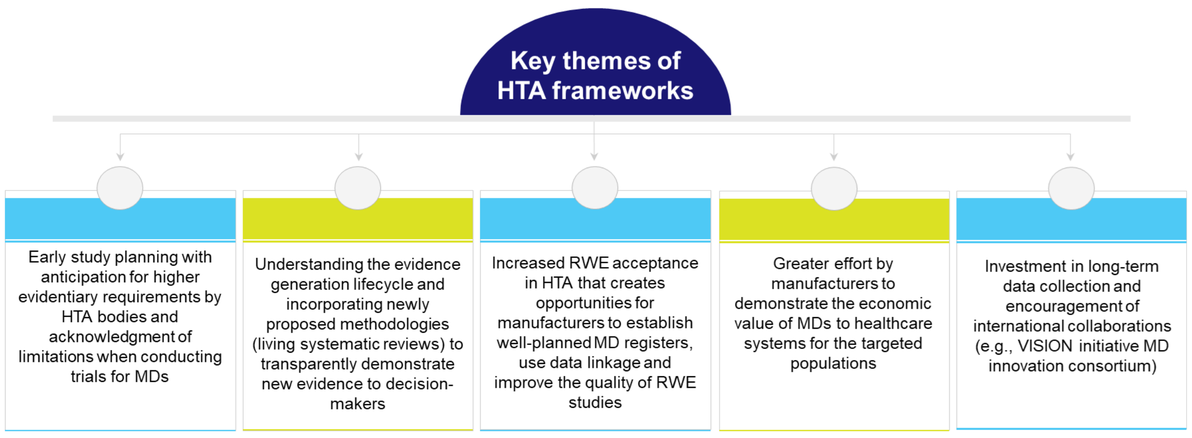
Manufacturers may struggle to provide sufficient, high-quality evidence within a short timeframe and so early in the MD's lifecycle. Submission of the full evidence dossier is often required within two to six weeks following publication of the final scope. In contrast, submission timelines for pharmaceuticals are longer; NICE, for example, requires dossier submission around 60 days after the final scope has been published.

The need for post-marketing, long-term data collection is high for re-assessing the value of MDs to resolve issues of uncertainty as noted in the first assessment. However, current processes do not provide coherent timely sensitive plans for proactive evaluation of new evidence for MDs. The periodicity of re-assessment of new evidence may be triggered with the risk and benefits associated with each device.

Increased transparency in interpretation of the weighted contribution of evidence to decision-making

Given the differences in treatment pathways, heterogeneous patient populations across studies and in clinical practice, and the difficulties in conducting RCTs, submissions for MDs tend to include clinical evidence from multiple sources. As following the hierarchy of evidence is less feasible in the MD space, more clarity is needed around how much weight different types of evidence have in the decision-making process.

Figure 2. Key considerations when establishing new MD guidance



Abbreviations: HTA, health technology assessment; MD, medical device; RWE, real-world evidence

References

[Canada] CADTH (2009): Indirect evidence: indirect treatment comparison in meta-analysis; CADTH (2015): Topic identification and prioritisation process - health technology assessment and optimal use: medical devices; diagnostic tests; medical, surgical, and dental procedures; CADTH (2017): Guidelines for the economic evaluation of health technologies; CADTH (2022): Procedures for CADTH reimbursement reviews; **[EU]** EUnetHTA (2022): Joint clinical assessment of high-risk medical devices; **[France]** HAS (2017): Pathway of medical devices in France - practical pathway; **[Germany]** G-BA (2022): Methods for diagnostic and interventional procedures (§ 135, 137c and 137e SGB V); G-BA (2022): Methods for diagnostic and interventional procedures with medical products (high-risk class) (§ 137h SGB V); IQWiG (2022): General methods v6.0; **[Italy]** PNHTADM (2016): Stability Law (Legge 23 dicembre 2014 Disposizioni per la formazione del bilancio annuale e pluriennale dello stato (legge di stabilita' n 190; 2015. n.d)); **[Spain]** AEMPS (2009): Royal Decree 1591/2009, of 16 October; **[Sweden]** TLV (2022): Handbok för hälsoekonomiska bedömningar av medicintekniska produkter; **[UK]** NICE (2017): Medical technologies evaluation program; NICE (2022): NICE health technology evaluations: the manual; **[US]** ICER (2020): 2020-2023 value assessment framework

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