POSTER
HTA174

National Health Technology Assessment (HTA) guidance for medical devices in Europe

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INTRODUCTION & OBJECTIVES

- The role of HTA in the reimbursement of new health technologies has grown in Europe over the last two decades. In 2025 and every 2 years thereafter, under the Regulation on Health Technology Assessment 2021/2282 (EU HTAR), selected Class IIb/III medical devices (MDs) and Class D in vitro diagnostic MDs will be subjected to Joint Clinical Assessment (JCA).[1] However, evaluation for local access and reimbursement decision-making remain the responsibility of the individual Member States (MS)
- Some MS have published local guidelines to support health technology developers (HTDs) meet local requirements for reimbursement. General features of local HTA guidelines include the specification of the HTA body purpose and remit, evidence requirements and evidence review process, and procedural and/or decision-making transparency[2, 3]
- Against this context, we examined existing national HTA guidance for MDs across the 27 MS, with a focus on methodological guidance. The aim was to identify commonalties and differences in methodological guidance availability and local requirements on MDs that may impact HTD preparedness from an international and national perspective

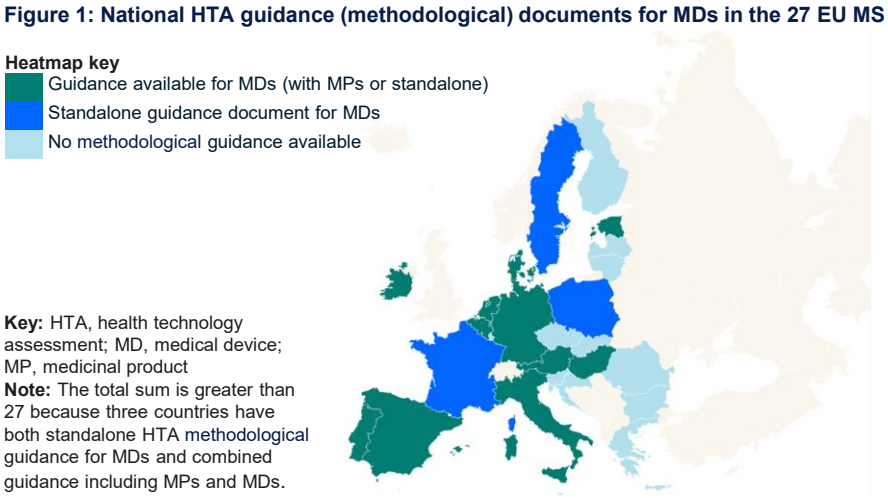
METHODS

- In June 2025, HTA websites of the 27 MS were hand-searched to identify HTA guidance for MDs, using English-language keywords and local language translation
- The review included methodological guidance relevant to the assessment of MDs, which may have been combined for medicinal products (MPs) and MDs, and/or process and methodologies, within a single document. HTA guidance without reference to methodological recommendations or their applicability to MDs was not included
- Features of interest for extraction and summarization included the assessment remit, type of guidance and level of detail, and methodological recommendations for MD evaluation

RESULTS

- Fourteen MS have explicit and established HTA methodological guidance for MDs, either combined with MPs or as standalone MD chapters/documents (Figure 1 and Table 1)
  - All countries with HTA guidance for MDs included an assessment of efficacy/safety; 11 also involved economic considerations. However, the level of detail within the guidance documents varies substantially across countries
- No specific HTA methodological guidance for MDs were identified for the remaining MS
- Standalone HTA methodological guidance for MDs is available in France, Poland and Sweden. Italy has a comprehensive National HTA Program for Medical Devices (PNHTA), which references recommendations from the EUnetHTA 2021 program and the EU HTAR, but no methodological guidance for MDs was otherwise identified[4, 5]

Figure 1: National HTA guidance (methodological) documents for MDs in the 27 EU MS



CONCLUSIONS

- This review highlights the substantial heterogeneity in national HTA guidance for MD across the 27 EU MS. We identified published HTA guidance for MDs in around half of the EU MS
- Although HTA systems and guidance for MPs are well-established across EU, equivalent frameworks for MDs remain considerably less developed, with inconsistent review processes and methodological approaches [9, 25, 26]
- Although there are many commonalities in the clinical and economic elements considered within HTA processes, the depth and clarity of methodological expectations vary widely [9, 25, 26]
- HTA bodies should aim to provide clearer, and more accessible guidance on evidence requirements while considering the evidence standards for MDs
- HTDs seeking local reimbursement for MDs need to understand country-level differences in access requirements. Lower predictability and efficiency related to reimbursement planning may be expected for countries lacking detailed HTA guidance
- In the context of the implementation of the HTAR and JCAs for selected MDs, MS have an important role in supporting harmonization and local HTA efficiencies. For MDs selected for JCA, this includes clarifying how the JCA reports will be used during national evaluation and decision-making processes, and which (if any) methodological guidance will be applicable [27, 28]

RESULTS

Clinical evaluation

- For the clinical assessment of MDs, each HTA typically provided guidance regarding the following requirements:
  - Description of the health problem and current use of technology
  - Overview of the product characteristics
  - Analysis of clinical effectiveness, comparative efficacy and benefits
  - Safety data and analysis
- In general, randomized controlled trials (RCTs) were referenced as the robust standard for clinical evidence. Many countries also require systematic literature reviews (SLRs) with explicit inclusion and exclusion criteria following the PICO (population, intervention, comparator[s], outcome[s]) framework, and/or a meta-analysis (Table 1)
- Comparators may include pharmaceuticals, MDs, surgical and medical procedures and other therapeutic technologies. Most guidance documents detail that the comparator should reflect the standard of care used in routine clinical practice, and supported by evidence on efficacy and safety within the relevant indicated population

Table 1: Detail provided in HTA guidance across 14 MS: clinical evaluation and evidence synthesis

Country	Date	Evidence from SLR	Evidence from M-A	RCT is the gold standard	ITCs	Choice of comparator	Effectiveness & safety of MD evaluated
Austria[6]	2020						
Belgium[10]	2025						
Denmark[11]	2023						
Estonia[12]	2024				*		
France[13]	2025						
Germany[8]	2023				**		
Hungary[14]	2023						
Ireland[15]	2018						
Italy[16, 28]	2020						
The Netherlands[17]	2024						
Poland[18]	2021						
Portugal[19]	2023						
Spain[20]	2023						
Sweden[21]	2022						

Key: HTA, health technology assessment; ITCs, indirect treatment comparisons; M-A, meta-analyses; MDs, medical devices; MS, member state(s); RCT, randomized controlled trial; SLR, systematic literature review
Note: *Inclusion of indirect comparison must be justified; **Rarely conducted, Bucher ITC is preferred by IQWIG

Heatmap	Category description
High	Evidence/methodology is highly detailed with dedicated chapter
Medium	Evidence/methodology is reported in a paragraph with general description
Low	Evidence/methodology is mentioned in a sentence with short description
Not reported	No evidence/methodology reported at all

Table 2: Detail provided in HTA guidance across 14 MS: economic evaluation

Country	Date	Level of detail
Austria[6]	2020	*
Belgium[10]	2025	
Denmark[11]	2023	
Estonia[12]	2024	
France[7]	2020	**
Germany[8]	2023	*
Hungary[14]	2023	
Ireland[22]	2025	
Italy[16, 23]	2020	
The Netherlands[17]	2024	
Poland[18]	2021	
Portugal[24]	2019	
Spain[20]	2023	
Sweden[21]	2022	

Key: HTA, health technology assessment; MS, member state(s)
Note: *Rarely conducted; **Conducted conditionally

Heatmap	Category description
High	Evidence/methodology is highly detailed with dedicated chapter on economic model
Medium	Evidence/methodology is reported with general description with economic model
Low	Evidence/methodology is mentioned in a sentence with or without economic model

Economic evaluation

- All 14 countries mentioned an economic evaluation component in their HTA processes (Table 2), although it was not always a requirement
- However, 3 out of the 14 countries where methodological guidance was available for MDs explicitly note that economic evaluations are not always warranted:
  - Austria: economic evaluations / budget impact analyses are “rarely conducted” and not systematically applied [6]
  - France: economic evaluation is only required when the HTD claims a high clinical added value score (ASA I to III) and either: (1) forecasted pre-tax sales in the second year of marketing for the relevant indication are equal to or exceed €20 million per year (in the case of initial registration), or (2) pre-tax sales recorded during the 12 months prior to the renewal application exceed €20 million per year (in the case of renewal)[7]
  - Germany: no formal economic evaluation within the HTA assessment, though a cost-benefit analysis may be conducted by IQWiG if there is no agreement on price

Gaps in public HTA methodological guidance

- Gaps in the availability of HTA guidance may be attributable to variations in national healthcare systems, policy environments and historical development in each country.[9] From an international perspective, this may be compounded by language barriers, non-user-friendly website design and other navigation difficulties, which further complicate ease of access to information.
- The lack of easily identifiable and publicly available guidance poses challenges to transparency, leading to uncertainty and inefficiencies for HTDs of MDs who are planning for local reimbursement
- Beyond the HTA guidance documents themselves, wider differences in the assessment of MDs were identified as part of this review. Examples include:
  - Different assessment authorities for the clinical review compared with the economic or efficiency review
  - Development of a specific national HTA program for MDs
  - Level of transparency and/or explicit influence on the procurement and dissemination of MDs
  - Degree of explicit alignment with the Regulation (EU) 2017/745 (Medical Device Regulation)

Poster presented at ISPOR Europe; 9-12 November 2025; Glasgow, Scotland

An electronic version of the poster can be viewed by scanning the QR code.

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