Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Review of the European landscape for assessment of high-risk medical devices in the context of the EU Health Technology Assessment Regulation

Publication date: 29 October 2026

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory body established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

Reporting to the Minister for Health and engaging with relevant government Ministers and departments, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector of Social Services within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of permanent international protection accommodation service centres, health services and children's social services against the national standards. Where necessary, HIQA investigates serious concerns about the health and welfare of people who use health services and children's social services.
- **Health technology assessment** — Evaluating the clinical and cost effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health and social care services, with the Department of Health and the HSE.

Visit www.hiqa.ie for more information.

Table of contents

About the Health Information and Quality Authority **1**
Table of contents **2**
List of Tables 4
List of Figures 5
Foreword **6**
Acknowledgements **7**
Key Findings **8**
Executive Summary **10**
Plain language summary **16**
List of abbreviations used in this report **18**
1 Background **22**
1.1 Evolution of the European regulatory framework 22
1.2 The Health Technology Assessment Regulation (HTAR) 23
1.3 The role of HTA in reimbursement decision-making and the HTAR-driven change 24
1.4 Rationale for this report and its structure 24
1.5 Relevance of the findings and expected contribution 25
2 Mapping current decision-making pathways and reimbursement processes for high-risk medical devices in EU/EEA Member States and the UK: A scoping review **26**
Key Points 26
2.1 Background 28
2.2 Methods 30
2.3 Research questions and objectives 30
2.4 Criteria for considering publications for this review 30
2.5 Search methods for identification of studies 33
2.6 Screening, data extraction and data analysis process 34
2.7 Results 36
2.8 Discussion 92
2.9 Conclusion 98
3 The early experiences of health technology assessment bodies in the implementation of the EU HTA Regulation (HTAR) for high-risk medical devices: A qualitative study **99**
Key Points 99

3.1 Introduction 102
3.2 Methods 103
3.3 Results 106
3.4 Discussion 126
3.5 Conclusion 128
4 Discussion 129
4.1 Diversity and fragmentation across Europe 129
4.2 Preparedness and capacity for HTAR adaptation 130
4.3 Implications for policy and practice 131
4.4 Relevance for Ireland 131
4.5 The path forward 132
4.6 Strengths and limitations 132
5 Conclusion 134
References 135
Appendix 151
List of supplementary Tables 151

List of Tables

Table 2.1 Population, Concept and Context for the research questions 31

Table 2.2 Reported HTA processes for reimbursement decisions of medical devices across EU/EEA/UK as of November 2024 40

Table 2.3 Overview of the oversight structures involved in the assessment and reimbursement of high-risk MDs and IVDs across the EU/EEA/UK, as of November 2024 42

Table 2.4 Role of HTA in high-risk MDs/IVDs reimbursement pathways across countries with any form of HTA (as of November 2024) 57

Table 2.5 Overview of key national reimbursement mechanisms of MDs/IVDs that involve HTA, the role of HTA in the process and utilisation of safety and effectiveness evidence for recommendation and reimbursement decisions for selected countries across the EU/EEA/UK as of November 2024 59

Table 2.6 Regional variations in the reimbursement frameworks for high-risk MDs in the EU/EEA/UK as of November 2024 78

Table 2.7 Mechanisms to address the uncertainty of comparative safety and effectiveness evidence for MDs/IVDs in selected countries 87

Table 3.1 Characteristics of the HTA bodies represented (n =11) and interview participants (n = 15) 107

Table 3.2 Key quotes from participants across the four overarching domains 109

List of Figures

Figure 2.1 PRISMA-ScR flow diagram of the records identification and screening process for the scoping review..... 37

Figure 2.2 HTA Processes for Reimbursement of High-Risk MDs/IVDs Across EU/EEA and UK (as of November 2024)..... 39

Figure 2.3 Centralisation levels of reimbursement frameworks for MDs/IVDs across countries with any form of HTA for medical devices (as of November 2024). 77

Figure 2.4 Formal mechanisms to address evidence uncertainty in the reimbursement of high-risk MDs/IVDs across the EU/EEA/UK (as of November 2024) 86

Figure 3.1 Geographic distribution of the 11 EU/EEA Member States that participated in the semi-structured interviews (in blue)..... 105

Figure 3.2 The thematic framework of findings from stakeholder interviews on the implementation of HTAR..... 115

Figure 3.3 Expanded visualisation of Domains 3 and 4 from Figure 3.2, highlighting participants' reported opportunities in adapting to the HTAR 121

Foreword

High-risk medical devices (MDs) and in vitro diagnostics (IVDs) play a critical role in modern healthcare, supporting the diagnosis, monitoring and treatment of a wide range of conditions. Ensuring timely patient access to these technologies while maintaining robust standards of clinical effectiveness and safety is important. The implementation of the European Union (EU) Health Technology Assessment Regulation (HTAR; Regulation (EU) 2021/2282) represents a significant step towards strengthening the assessment of health technologies through Joint Clinical Assessments (JCAs), with high-risk MDs and IVDs entering the scope of the Regulation from 2026. While the HTAR establishes a common European framework for the clinical assessment of selected technologies, responsibility for reimbursement and funding decisions remains with individual Member States. As countries continue their preparations for JCAs of high-risk MDs/IVDs, there is a need to understand how these devices are currently assessed and reimbursed across Europe, and how national health technology assessment (HTA) systems are adapting to the introduction of JCAs.

The Health Information and Quality Authority (HIQA) undertook this project in collaboration with University College Cork (UCC) to examine the current reimbursement pathways for high-risk MDs/IVDs across the EU/EEA and the UK, and to explore how national HTA bodies are preparing for implementation of the HTAR. The project comprised a comprehensive scoping review of national reimbursement pathways alongside qualitative interviews with representatives from European HTA organisations to capture early experiences and anticipated challenges associated with the implementation of the HTAR. Together, these complementary studies provide an overview of the diversity of current national approaches, identify opportunities and challenges associated with the introduction of JCAs, and establish an important baseline against which future implementation of the HTAR can be evaluated.

We would like to sincerely thank the UCC researchers, the members of the HIQA team, and the representatives from HTA bodies across Europe who generously contributed their time, expertise and feedback throughout this project.



Dr Máirín Ryan

Deputy Chief Executive & Director of Health Technology Assessment

Acknowledgements

HIQA would like to thank the HTA bodies and their representatives who supported the data verification process of the scoping review and who participated in the interviews.

Organisations that assisted HIQA in providing information, in writing or through meetings, included:

HIQA would like to thank the School of Pharmacy, University College Cork, CÚRAM (the Research Ireland Centre for Medical Devices) and Research Ireland for providing scientific support to this study.

Funding

This publication originated from research conducted with the financial support of Research Ireland under grant number 13/RC/2073_P2.

Members of the Evaluation Team:

This report was led by staff in HIQA's HTA Directorate in conjunction with staff from the School of Pharmacy, University College Cork. The following individuals contributed to the management, technical writing or dissemination of this report: Rasha A. Alshaikh (project lead), Caitriona M. O'Driscoll, Conor Teljeur, Fatma El-Komy, Kieran A. Walsh, Louise Larkin, Lydia O'Sullivan, Máirín Ryan, Marie Carrigan, Michelle O'Neill, Patricia Harrington, Susan Spillane.

Conflicts of Interest

None reported.

Key Findings

- Across Europe, reimbursement of medical devices (MDs) and in vitro diagnostics (IVDs) varies significantly in terms of structure, centralisation, and integration of health technology assessment (HTA) into reimbursement frameworks.
- Ireland currently lacks a centralised comprehensive system for HTA and reimbursement of high-risk MDs/IVDs. There is uncertainty regarding how decisions on adoption and procurement are being made, leading to variable evidence standards and limited national oversight.
- The EU Regulation on HTA (HTAR), which has applied since January 2025, establishes a framework for Joint Clinical Assessment (JCA), aiming to provide a single assessment of the comparative clinical effectiveness and safety of selected health technologies, promote consistent methodology, and reduce duplication. Harmonised clinical evaluations may facilitate more timely reimbursement decisions, accelerate patient access to innovative technologies, reduce inequalities in access across and within Member States, and support national and regional decision-making. Since 2026, HTAR has applied to a selection of high-risk MDs/IVDs, which represents a critical shift in how clinical evidence of these devices is assessed in Europe. The first JCAs of high-risk MDs/IVDs are due to be published in 2027.
- This report summarises the findings of two 2025 studies which examined the European landscape for assessment of high-risk MDs/IVDs in the context of HTAR.
    - The first study was a scoping review which aimed to map existing reimbursement frameworks for high-risk MDs/IVDs, identify key oversight structures, and evaluate the use of comparative effectiveness and safety evidence in reimbursement decisions across the European Union (EU)/ European Economic Area (EEA)/United Kingdom (UK) before the implementation of HTAR.
    - The second study – a qualitative semi-structured interview study – aimed to explore how selected EU/EEA HTA bodies were planning for JCA integration and HTAR implementation for high-risk MDs/IVDs.
- The scoping review comprehensively mapped reimbursement pathways and HTA integration for high-risk MDs/IVDs across 34 EU/EEA/UK countries.
    - Of the 34 countries reviewed, 23 incorporated HTA for MDs/IVDs reimbursement decisions; of these, only 11 countries had a formal HTA process as part of reimbursement pathways.

  - Eight countries had structured mechanisms to address uncertainty in effectiveness and safety evidence.
  - Twelve countries had primarily centralised processes, while six relied on regional or local decision-making.
  - Some countries were found to have a well-established reimbursement framework with formal HTA components, whereas others relied on ad hoc HTA processes.
  - The review highlighted the variability in how countries integrated HTA into reimbursement frameworks for MDs/IVDs, how the national decisions were implemented, and how the evidence uncertainty was assessed.

- The qualitative interview study was undertaken with representatives from 11 national HTA bodies across EU/EEA Member States.
  - The stakeholders interviewed expressed broad support for JCAs. Key opportunities identified included work sharing, improved evidence standards, and capacity building, particularly in smaller HTA systems that might not have access to high-quality assessments without JCAs.
  - However, substantial challenges were reported including regulatory uncertainty, resource constraints, potential timing and selection misalignment, and issues with the contextualisation of JCAs within national reimbursement frameworks.
  - Some representatives reported that their HTA body had initiated procedural or legislative adaptations to enable HTAR implementation at a national level; however, many HTA bodies remained in an observational phase, waiting for further implementation documents.
- For Ireland, the findings provide an important international benchmark. Ireland currently lacks a formal national HTA and reimbursement pathway for high-risk MDs/IVDs. The evidence presented in this report can inform future discussions regarding how Ireland may best integrate JCAs for high-risk MDs/IVDs into its own decision-making processes while reflecting national healthcare priorities.

Executive Summary

Background and Purpose

Medical devices (MDs) and in vitro diagnostics (IVDs) play an increasingly important role in modern healthcare. They support the prevention, diagnosis, monitoring and treatment of disease across almost every clinical specialty and are essential for delivering safe and effective healthcare. Compared with medicines, however, the assessment of MDs presents unique challenges. Devices often evolve rapidly throughout their lifecycle, evidence may continue to develop after market introduction, and comparative clinical studies are frequently more limited than those available for medicinal products. These characteristics have contributed to considerable variation in how European countries assess the clinical effectiveness and cost effectiveness of high-risk MDs before making reimbursement decisions.

The introduction of the European Union (EU) Health Technology Assessment Regulation (HTAR) (Regulation (EU) 2021/2282) represents a significant change in the assessment of health technologies across Europe. Since 2026, Joint Clinical Assessments (JCAs) at European level have commenced for selected high-risk MDs and IVDs. The first JCAs of high-risk MDs/IVDs are due to publish in 2027.

These assessments aim to provide a single evaluation of comparative clinical effectiveness and safety that can be used by all participating Member States, while national authorities retain responsibility for reimbursement and funding decisions. JCAs aim to promote consistent methodology and reduce duplication. Harmonised clinical evaluations may facilitate more timely reimbursement decisions, accelerate patient access to innovative technologies, reduce inequalities in access across and within Member States, and support national and regional decision-making.

One key factor which will likely determine the success of HTAR implementation for high-risk MDs is how effectively Member States can integrate JCA outputs into their existing national assessment and reimbursement processes. However, relatively little was previously known about how reimbursement decisions for high-risk medical devices are currently made across Europe or how national health technology assessment (HTA) bodies are preparing for implementation of the Regulation.

This report was undertaken to address these knowledge gaps and to support Ireland in preparing for implementation of HTAR for high-risk MDs/IVDs. The objectives were to:

- map current reimbursement pathways and decision-making structures for high-risk MDs/IVDs across EU/European Economic Area (EEA) Member States and the UK

- examine how comparative effectiveness and safety evidence is currently used within national reimbursement processes
- explore how national HTA bodies are preparing for implementation of HTAR
- identify opportunities and challenges associated with integrating JCAs into national decision-making.

The work consisted of two complementary studies. The first mapped existing reimbursement pathways and decision-making structures for high-risk MDs/IVDs across EU/EEA Member States and the UK through a comprehensive scoping review (presented in Chapter 2). The second explored how national HTA organisations are preparing for implementation of HTAR through semi-structured interviews with representatives from European HTA bodies (presented in Chapter 3).

Methods

The first study comprised a scoping review undertaken in accordance with established methodological guidance and reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) recommendations. Searches included official organisational websites, peer-reviewed literature, grey literature and HTA-specific resources. No language restrictions were applied. Information describing national reimbursement pathways was identified for 31 of the 34 EU/EEA Member States and the UK. To improve the accuracy and completeness of the findings, country summaries were externally validated by national organisations, with responses received from 30 of the 34 countries contacted.

The second study consisted of semi-structured interviews with representatives from national HTA organisations in Austria, Belgium, Estonia, Finland, France, Germany, Ireland, Italy, Norway, Slovakia and Sweden. Interviews were conducted between January and April 2025 and analysed using reflexive thematic analysis. The interviews explored current national HTA structures, anticipated adaptations in response to HTAR, perceived opportunities associated with JCAs, and anticipated implementation challenges. The study received ethical approval from the Social Research Ethics Committee at University College Cork, Cork, Ireland (approval number: SREC 2024-206) and was conducted accordingly. The consent procedures aligned with the General Data Protection Regulation and the University's research ethics policies.

Key Findings

The scoping review identified considerable variation in reimbursement pathways for high-risk MDs/IVDs across Europe. Of the 31 countries for which publicly available information was identified, 23 had some form of HTA process that contributed to reimbursement decision-making, while eight countries had no identified HTA process

for high-risk MDs/IVDs. Among countries using HTA, its role differed substantially. In some jurisdictions, HTA formed a formal component of reimbursement decision-making, whereas in others it was advisory, conditional or undertaken only on an ad hoc basis.

Although most countries followed a broadly similar sequence of technology identification, assessment, recommendation and reimbursement decision-making, the organisations responsible for each stage differed considerably. Some countries operated highly centralised national systems, whereas others relied heavily on regional or hospital-level procurement and assessment processes. Twelve countries were classified as having generally centralised reimbursement frameworks, while six operated decentralised or mixed systems where regional authorities retained substantial responsibility for implementation.

Approaches to evidence assessment also varied considerably. While comparative clinical effectiveness and safety formed the basis of assessment in most countries, some systems focused primarily on demonstrating added clinical benefit compared with current care, whereas others additionally considered cost effectiveness, budget impact, organisational implications, ethical considerations and wider societal effects.

Variation was also evident in how countries addressed uncertainty surrounding evidence for innovative technologies. Only eight countries had established formal mechanisms to support reimbursement where clinical evidence remained uncertain, such as conditional reimbursement schemes or managed access arrangements linked to further evidence generation. Most countries lacked clearly defined processes for managing evidence uncertainty.

The second study explored how national HTA bodies were preparing for implementation of HTAR for high-risk MDs/IVDs. The interviews with 11 HTA bodies were analysed using reflexive thematic analysis, resulting in four overarching themes relating to current national systems, anticipated adaptations, opportunities created by HTAR, and perceived implementation challenges.

The participating countries represented a wide spectrum of HTA maturity. Some countries operated well-established HTA systems where MDs/IVDs assessment forms an integral component of reimbursement decision-making, while others were continuing to develop more structured approaches to assessing high-risk MDs/IVDs.

Despite these differences, interviewees consistently expressed strong support for the overall objectives of HTAR. Participants viewed JCAs as an important opportunity to improve the quality and consistency of clinical evidence, reduce duplication of assessment across Europe, encourage manufacturers to generate stronger evidence

earlier during technology development, and strengthen evidence-based decision-making.

However, interviewees also emphasised that national HTA processes would continue to play an important role after implementation of HTAR. While JCA reports were expected to inform the assessment of comparative clinical effectiveness and safety, national authorities would continue to evaluate broader considerations including economic value, organisational implications, ethical issues, legal requirements and country-specific healthcare priorities.

Preparedness for implementation varied considerably between countries. Some organisations had already established internal governance structures and implementation plans, while others remained in an early observational phase because important operational details of HTAR had not yet been finalised.

Participants identified several challenges that may influence successful implementation. These included uncertainty surrounding governance arrangements, methodological complexity, alignment of European assessment timelines with national reimbursement processes, development of consolidated PICO (Population, Intervention, Comparator, Outcomes) questions that remain relevant across diverse healthcare systems, and ensuring that JCA reports can be effectively integrated into existing national decision-making frameworks. Smaller HTA organisations particularly highlighted the importance of continued European collaboration, technical guidance, training and capacity building to support implementation.

Discussion

Taken together, the findings from these two studies demonstrate that Europe enters implementation of HTAR with substantial diversity in existing assessment and reimbursement systems for high-risk MDs/IVDs. National differences extend beyond organisational structures to include methodological approaches, governance arrangements, evidence requirements and decision-making responsibilities. The findings suggest that successful implementation of HTAR will depend not only on the quality of JCAs themselves, but also on the ability of Member States to integrate European clinical evidence into diverse national reimbursement frameworks. While HTAR provides an opportunity to improve consistency in clinical assessment across Europe, considerable national variation in reimbursement processes is likely to remain.

This divergence in practice has several important implications. For manufacturers, it increases the complexity of market access and results in multiple, sometimes duplicative, submissions. For patients, it may lead to delayed or unequal access to innovative devices depending on national capacity, policy priorities, or evidence

expectations. For HTA bodies and other reimbursement authorities, they may face unique challenges in terms of implementing HTAR for high-risk MDs/IVDs at a national level, which may be both individual to the Member State and distinct from issues relating to HTAR for medicinal products. These findings reinforce long-standing observations about the need for greater coordination and standardisation of evidence requirements for high-risk MDs/IVDs across Europe.

This review also demonstrates that many implementation challenges identified in the emerging HTAR literature for medicines (including variable national readiness, limited capacity, methodological complexity, alignment of European and national processes and stakeholder engagement) are equally relevant for high-risk MDs/IVDs. However, these challenges may be amplified for MDs/IVDs because HTA and reimbursement systems remain substantially more heterogeneous than those for medicinal products.

The findings also reinforce the potential for HTAR to strengthen national HTA capacity over time. For countries with less developed HTA systems, participation in the European process may provide access to shared expertise, common methodologies, and high-quality clinical assessments that would otherwise require substantial national resources. Conversely, countries with established HTA programmes may benefit from reduced duplication of clinical assessment activities while contributing methodological expertise to the European system. However, as highlighted by participants in the qualitative study, these potential benefits will only be realised if sufficient implementation support accompanies the early phases of HTAR and if national processes evolve to effectively operationalise JCA outputs within existing reimbursement pathways.

For Ireland, the findings provide an important international benchmark. Ireland currently lacks a formal national health technology assessment and reimbursement pathway for high-risk MDs/IVDs. The evidence presented in this report can inform future discussions regarding how Ireland may best integrate JCAs for high-risk MDs/IVDs into its own decision-making processes while reflecting national healthcare priorities.

Conclusion

This report provides one of the first comprehensive assessments of reimbursement pathways for high-risk MDs/IVDs across Europe in the context of the ongoing implementation of JCAs under the EU HTAR.

The findings demonstrate substantial diversity in national reimbursement systems, the integration of HTA into decision-making, governance arrangements and approaches to evidence uncertainty. At the same time, representatives from national

HTA organisations expressed broad support for the objectives of HTAR and recognised its potential to improve the quality and consistency of evidence available for reimbursement decisions. The successful implementation of HTAR will require continued collaboration between Member States, methodological development, capacity building and clear governance arrangements to ensure that JCAs for high-risk MDs/IVDs can be effectively incorporated into national decision-making.

Plain language summary

Medical devices and in vitro diagnostics (IVDs) are important tools that help diagnose, monitor, and treat many health conditions. Examples include pacemakers, artificial joints such as those for hips and knees, and diagnostic tests. In Europe, every country has its own system for deciding which devices can be paid for by the public health system. These decisions often depend on whether there is enough evidence to show that a device is safe, effective, and provides good value for money.

A new European law called the Health Technology Assessment Regulation (HTAR) aims to improve how research about new health technologies (for example, medicines and medical devices) is assessed across the EU. One of the ways that new health technologies will be assessed under the HTAR is by using a Joint Clinical Assessment (JCA). A JCA is a way for countries to work together to see how well a new medicine or medical device works and whether they are safe, instead of each country doing the same assessment separately. Since 2026, EU Member States have started evaluating high-risk medical devices and diagnostics through JCAs. JCAs are shared publicly to help countries decide whether and how technologies should be used and funded.

This report presents findings from two studies. First, a scoping review that looked at how 34 countries in the EU, European Economic Area, and the UK assess and pay for high-risk medical devices and diagnostics. Second, interviews were carried out with representatives from national health technology assessment (HTA) bodies across Europe to understand how different countries are preparing to implement HTAR and start using JCAs.

The scoping review found that there were large differences across countries in how these decisions are made. Some countries used formal HTA processes to look at the safety and effectiveness of medical devices before they are funded. Others had less structured systems, meaning that decisions may be different between hospitals or regions. Some countries carried out national HTA processes to evaluate evidence before making any funding decisions. Other countries made decisions at regional or hospital level with limited national oversight. Because of these differences, it is not yet clear how the new European assessments will be used in national decision-making for medical devices in some countries.

Interviews with experts from 11 countries showed that the new EU HTAR was seen as an important opportunity to make the assessment of medical devices more consistent across Europe. However, countries were at different stages of readiness. Some were actively preparing for the new regulation, while others were waiting for

more details about how the JCA process will work in practice. Smaller countries in particular said they will need extra support and resources to take part effectively.

For Ireland, the findings are especially relevant. At the moment, there is no central national system for assessing or reimbursing high-risk medical devices and diagnostics. This makes it difficult to know how best to use JCAs to ensure patients can access medical devices and diagnostics which are shown to be beneficial. These findings highlight the importance of understanding how Ireland can best use this new European framework.

List of abbreviations used in this report

AIHTA	Austrian Institute for Health Technology Assessment
AOTMiT	Agency for Health Technology Assessment and Tariff System (Agencja Oceny Technologii Medycznych i Taryfikacji in Polish)
CATS	Portuguese Commission for Health Technology Assessment (Comissão de Avaliação de Tecnologias de Saúde in Portuguese)
CED	Coverage with evidence development
CEESP	Commission for Economic and Public Health Evaluation (Commission d'évaluation économique et de santé publique in French)
CEPS	Economic Committee for Health Products (Comité Economique des Produits de Santé in French)
CHIF	Croatian Health Insurance Fund (Hrvatski zavod za zdravstveno osiguranje in Croatian)
CNEDiMTS	Medical Device and Health Technology Evaluation Committee (Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé in French)
COHERE Finland	Council for Choices in Health Care in Finland
COMEDIMS	Commission for Medicines and Sterile Medical Devices (Commission du médicament et des dispositifs médicaux stériles in French)
CODIMS	Committee for Sterile Medical Devices (Comité des dispositifs médicaux stériles in French)
CTIIMH-CRIDMI	Commission of Reimbursement of Implants and Invasive Medical Devices (Commission de Remboursement des Implants et Dispositifs Médicaux Invasifs in French)
CTM	Medical Technical Council (Conseil Technique Médical in French)
DHTC	Danish Health Technology Council (Behandlingsrådet in Danish)
DRG	diagnosis-related group
EHIF	Estonian Health Insurance Fund (Eesti Haigekassa in Estonian)
EMA	European Medicines Agency
EEA	European Economic Area
FDA	US Food and Drug Administration

FinCCHTA	Finnish Coordinating Center for Health Technology Assessment
G-BA	Federal Joint Committee (Gemeinsamer Bundesausschuss in German)
Hb-HTA	Hospital-based health technology assessment
HAS	French National Authority for Health (Haute Autorité de Santé in French)
HIQA	Health Information and Quality Authority
HTA	Health technology assessment
HTAR	Health Technology Assessment Regulation (EU) 2021/2282
HSE	Health Service Executive
ICER	incremental cost-effectiveness ratio
IF	innovation funding
INFARMED	National Authority for Medicines and Health Products (Autoridade Nacional do Medicamento e Produtos de Saúde in Portuguese)
IQWiG	Institute for Quality and Efficiency in Healthcare (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen in German)
IVDs	In vitro diagnostics
IVDR	In Vitro Diagnostic Regulation; Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices
JCA	joint clinical assessment
JSC	joint scientific consultation
KCE	Belgian Health Care Knowledge Centre (Kenniscentrum in Dutch, Centre d'Expertise in French)
LKF	Procedure and Diagnosis-Oriented Groups (Leistungsorientierte Krankenanstaltenfinanzierung in German)
LPPR	List of Reimbursable Products and Services (Liste des Produits et Prestations Remboursables in French)
MDs	medical devices
MDR	Medical Device Regulation; Regulation (EU) 2017/745 on Medical Devices
MEL	Individual Medical Services Catalogue (Medizinische Einzelleistungen in German)

MoH	Ministry of Health
MTP Council	Medical Technology Product Council
NEAK	National Health Insurance Fund in Hungary (Nemzeti Egészségbiztosítási Alapkezelő in Hungarian)
NICE	National Institute for Health and Care Excellence
NNGYK	National Centre for Public Health and Pharmacy in Hungary (Nemzeti Népegészségügyi és Gyógyszerészeti Központ in Hungarian)
NOMA	Norwegian Medical Products Agency (Statens legemiddelverk in Norwegian)
NUB	New Examination and Treatment Methods (Neue Untersuchungs- und Behandlungsmethoden in German)
OGYÉI	National Institute of Pharmacy and Nutrition in Hungary (Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet in Hungarian)
PNHTA-DM	National Program for Health Technology Assessment of Medical Devices (Programma Nazionale di Health Technology Assessment dei Dispositivi Medici in Italian)
RedETS	Spanish Network of Agencies for the Evaluation of Health Technologies and Services of the National Health System (RedETS) Española de Agencias de Evaluación de Tecnologías Sanitarias y Prestaciones del Sistema Nacional de Salud in Spanish)
RCT	randomised controlled trial
RHAs	regional health authorities
SGB V	Social Code Book V (Sozialgesetzbuch V in German)
STA	single technology assessment
TéF	Technology Assessment Department (Technológia-értékelő Főosztály in Hungarian)
TLV	The Dental and Pharmaceutical Benefits Agency (Tandvårds- och läkemedelsförmånsverket in Swedish)
VASPVT	State Accreditation Service for Health Care Activities under the Ministry of Health of the Republic of Lithuania (Valstybine akreditavimo sveikatos prieziuros veiklai tarnyba prie SAM in Lithuanian)
VLK	National Health Insurance Fund in Lithuania (Valstybinė ligonių kasa in Lithuanian)
WHO	World Health Organization

ZIN	National Health Care Institute in the Netherlands (Zorginstituut Nederland in Dutch)

1 Background

Medical devices (MDs) and in vitro diagnostics (IVDs) are integral to the modern healthcare system, enabling diagnosis, screening, management, monitoring, and treatment of various health conditions in previously unattainable ways. They range from relatively simple tools such as wound dressings and syringes to complex implantable devices and advanced diagnostic technologies capable of transforming patient outcomes. Their rapid evolution has played a central role in improving the quality of care, enhancing precision medicine, and enabling healthcare delivery across diverse clinical settings.

In Europe, the regulatory landscape for MDs, particularly high-risk devices, is structured quite differently from that for medicinal products (that is, drugs), and it stands apart from the regulatory model used by the United States (US) Food and Drug Administration (FDA) for medical devices. Unlike pharmaceuticals, which are subject to a centralised authorisation process coordinated by the European Medicines Agency (EMA), there is currently no single EU-level authority responsible for the comprehensive assessment, market authorisation, and post-market monitoring of MDs and IVDs. Instead, market access is governed by a decentralised system underpinned by conformity assessment through designated Notified Bodies.[1]

Notified bodies are independent designated organisations supervised by the Member State where they are located that examine the evidence of MD performance and production procedures to conclude on the effectiveness, safety, benefit and risk of MDs, among other factors.[2] Compliant devices receive the Conformité Européenne (CE) mark, which indicates that the device is meeting the specified safety, health, and environmental requirements for its category as dictated by the EU regulation.[1,3]

However, unlike medicinal products, where randomised controlled trials (RCTs) are considered the gold standard for generating clinical evidence, the development of medical devices in Europe has not historically relied on RCTs. As a result, such study designs have traditionally been used less frequently for medical devices.

1.1 Evolution of the European regulatory framework

Over the past decade, the European Commission and Member States have taken substantial steps to reform the regulation of MDs/IVDs in response to several high-profile device failures, public concern about inadequate scrutiny, and demands for stronger clinical evidence. The most significant outcomes of these efforts are the Medical Device Regulation (MDR) (EU regulation 2017/745)[4] and the In Vitro

Diagnostic Regulation (IVDR) (EU 2017/746)[5] that replaced the previous Medical Device Directives (MDD) that were in place for more than 25 years.[3] Aiming to improve patient safety, the MDR, which took full effect in May 2021, establishes a framework for categorising MDs according to medical purpose, duration of use, invasiveness and activity. Under the 2017 regulation, MDs are classified into Class I (low risk), Class IIa (moderate risk), and Classes IIb and III (high risk). Similarly, the IVDR classifies IVDs into four risk-based categories: Class A (lowest risk), Class B (low to moderate risk), Class C (moderate to high risk), and Class D (highest risk for individuals and public health).[6] MDR/IVDR also introduced particular requirements for thorough clinical investigations of high-risk MDs to ensure their safe and effective use.

1.2 The Health Technology Assessment Regulation (HTAR)

The clinical evidence required by the MDR is now complemented by joint clinical assessments (JCA) required by the Health Technology Assessment Regulation (HTAR) (EU 2021/2282). HTAR came into force on January 11, 2022, with full application from January 12, 2025.[7] It introduces provisions for JCA and joint scientific consultations (JSC), facilitating collaboration between device manufacturers (referred to as health technology developers in the regulation) and Health Technology Assessment (HTA) bodies. A driver of this regulation is the need to improve patient safety by ensuring that only devices with solid clinical evidence of safety and efficacy are reimbursed and used.

HTAR is being applied in an incremental fashion, starting with advanced therapy medicinal products (ATMPs) and new oncology drugs in 2025, orphan medicinal products in 2028, with all drugs, including vaccines, scheduled to be within scope by 2030.[8] Since 2026, HTAR has applied to a selection of high-risk medical devices (MDs) and in-vitro diagnostics (IVDs) with the first JCAs of MDs due for publication in 2027. It is outlined in the Regulation that, as of January 2025, the European Commission, after seeking recommendations from the Coordination Group (that is, the decision-making body), shall adopt decisions at least once every two years selecting MDs and in IVDs for JCAs based on one or more of the following criteria:

- unmet medical needs
- first-in-class status
- potential impact on patients, public health or healthcare systems
- incorporation of Artificial Intelligence (AI) machine learning, or algorithms
- significant cross-border relevance and
- major EU-wide added value.

This cooperative framework applies specifically to high-risk devices in Classes IIb and III for which the relevant expert panels have provided a scientific opinion in the

framework of the clinical evaluation consultation procedure pursuant to the MDR,[4] as well as to Class D IVDs, for which the relevant expert panels have provided their views in the framework of the procedure pursuant to IVDR.[5]

1.3 The role of HTA in reimbursement decision-making and the HTAR-driven change

Medical devices' CE marking and subsequent market access do not necessarily guarantee patient access across EU states.[9] In most cases, patient access requires a public or private process of reimbursement or procurement of the device. Reimbursement for medical devices can be defined as a financial payment from a public payer or a public or private insurer, often directed to a healthcare provider, to cover expenses incurred when using a medical device or conducting a specific procedure.[10]

To secure reimbursement, payers usually require evidence that the technology improves patient outcomes with acceptable cost effectiveness. Such evidence is frequently assessed through a national HTA process, which typically considers the device's clinical and economic benefits. The national HTA process for high-risk devices and diagnostics and its integration into reimbursement decision-making is highly divergent across the European Union (EU)/European Economic Area (EEA). In some regions, reimbursement decisions for devices are guided by national or regional HTA agencies. In other countries, a HTA is not necessarily required to make reimbursement decisions for devices.

JCAs aim to provide a single assessment of the clinical effectiveness and safety of high-risk MDs and IVDs, promoting consistent methodology, reduced duplication and facilitating faster patient access to these technologies.[11,12] Each country retains authority over its national reimbursement decisions, considering other factors such as healthcare priorities, budgetary implications, and cost-effectiveness.[11]

1.4 Rationale for this report and its structure

As the MDR, IVDR and HTAR reshape the regulatory landscape for high-risk MDs and IVDs, there is a pressing need to understand how these new regulations interact with existing HTA and reimbursement pathways across Europe and how each Member State is preparing for the HTAR. This report represents a collaborative project between the Health Information and Quality Authority (HIQA) and University College Cork (UCC) examining how safety and efficacy evidence is currently used to inform reimbursement decisions for high-risk MDs and IVDs, and how national systems are responding to the implementation of the recently applied HTA Regulation.

The report is structured around two complementary objectives:

1. To map existing decision-making pathways and oversight structures for reimbursement of high-risk MDs/IVDs across the EU/EEA and the UK, identifying common features and divergences. This objective was achieved through a scoping review, described in detail in Chapter 2.
2. To explore how national HTA bodies perceive, plan for, and adapt to the implementation of HTAR for high-risk MDs/IVDs, including the integration of JCAs into national frameworks. This objective was achieved through semi-structured interviews, described in detail in Chapter 3.

1.5 Relevance of the findings and expected contribution

The findings of this report are expected to contribute to European and national dialogue and policy development to support the operationalisation of the HTAR for high-risk MDs/IVDs. The report presents the current landscape for assessment and reimbursement of MDs/IVDs and the emerging strategies for adaptation in response to HTAR.

At the European level, this information offers an evidence-based overview of how Member States currently approach the evaluation and reimbursement of high-risk MDs/IVDs, and their early sentiment (and adaptations) towards HTAR. For Ireland, the findings provide timely and practical input to national strategic planning as the country continues to prepare for the effective implementation of HTAR for high-risk MDs/IVDs.

2 Mapping current decision-making pathways and reimbursement processes for high-risk medical devices in EU/EEA Member States and the UK: A scoping review

Key Points

- This chapter presents a scoping review of decision-making pathways, oversight structures, and reimbursement processes for high-risk medical devices (MDs) and in vitro diagnostics (IVDs) across EU/European Economic Area (EEA) Member States and the UK.
- The review was undertaken in the context of preparing for upcoming changes to the European regulatory and assessment landscape, specifically the Health Technology Assessment Regulation (HTAR). Since 2026, selected high-risk MDs/IVDs are subject to Joint Clinical Assessments (JCAs) at EU level.
- The aim of the review was to understand how countries currently assess and reimburse high-risk MDs/IVDs, and how comparative effectiveness and safety evidence is used to inform reimbursement decisions.
- The scoping review was undertaken in accordance with best-practice guidance. Searches included official organisational websites, academic databases, grey literature, and select health technology assessment (HTA)-focused resources. No language restrictions were applied. The findings were externally validated with national organisations, with feedback received from 30 of 34 contacted countries.
- Across the 34 countries reviewed, publicly available information on reimbursement pathways for high-risk MDs/IVDs was identified for 31 countries. Of the 31 countries with available information, 23 countries had some form of HTA process that could support reimbursement decision-making for high-risk MDs/IVDs. Eight countries had no identified HTA process for high-risk MDs/IVDs reimbursement.
- Among the countries with some form of HTA, the role of HTA varied considerably. In 10 countries, HTA was identified as a formal element of certain reimbursement pathways; in eight countries, HTA was optional, conditional, or used on an ad hoc basis; and in five countries, the formal role of HTA in reimbursement pathways was unclear.
- Reimbursement pathways generally involved four broad stages: identification or submission of a technology, prioritisation and assessment, development of a

recommendation or advice, and a final reimbursement or funding decision. However, the organisations involved and the influence of each stage differed substantially between countries.

- Formal prioritisation before HTA was identified in a limited number of countries. Prioritisation criteria commonly included expected patient benefit, disease severity, budget impact, innovation, availability of alternatives, uncertainty in the evidence base, and potential risks.
- The use of comparative safety and effectiveness evidence varied across countries. Some systems place strong emphasis on added clinical benefit compared with current care, while others also incorporate cost effectiveness, budget impact, organisational implications and wider social factors.
- Considerable variation was found in the level of centralisation of reimbursement decision-making. Twelve countries were identified as having generally centralised reimbursement frameworks, while six operated decentralised or mixed systems in which regional or hospital-level bodies retained substantial responsibility for procurement or implementation. Even in countries with generally centralised systems, local or hospital-level decision-making may still influence access to devices.
- Eight countries had formal mechanisms to address uncertainty in the safety and effectiveness evidence for high-risk MDs/IVDs. Most countries did not have clearly defined formal mechanisms for managing evidence uncertainty. This may be particularly important for innovative high-risk MDs where early evidence is limited but potential clinical benefit is substantial. Regional and local variation in procurement and reimbursement may also affect how JCA outputs are used in practice. Countries with decentralised or mixed systems may need to consider how EU-level evidence can be communicated and applied across regional or hospital-level decision-making structures.
- Overall, the findings show that reimbursement of high-risk MDs/IVDs across Europe is highly heterogeneous in terms of HTA integration, decision-making structures, centralisation, and approaches to evidence uncertainty. The findings are relevant to the implementation of the HTAR because they show that countries are starting from different positions. While JCAs may improve consistency in the clinical assessment of high-risk MDs/IVDs, their practical impact will depend on how national systems are structured to consider and use EU-level evidence.

The information in this chapter was published as an academic publication: *Alshaikh RA, Walsh KA, El-Komy F, Spillane S, Carrigan M, Larkin L, Harrington P, O'Neill M, Teljeur C, Ryan M, O'Driscoll CM. MAPPING current decision-making pathways and reimbursement processes for high-risk medical devices in EU/EEA member states and the UK: a scoping review. Int J Technol Assess Health Care. 2025 Oct 20;41(1):e78. doi: 10.1017/S026646232510319X. PMID: 41114469; PMCID: PMC12592967.*

2.1 Background

In Europe, the regulatory landscape for medical devices (MDs) and in vitro diagnostics (IVDs) is structured quite differently from that of medicinal products, and it differs from the regulatory model used by the US Food and Drug Administration (FDA) for medical devices. There is currently no comparable centralised body responsible for the assessment of all medical devices, like that provided by the European Medicines Agency (EMA) for medicinal products.[1] Regulation of MDs/IVDs in Europe is governed by a system of Notified Bodies and conformity assessment. Notified bodies are independent designated organisations supervised by the Member State in which they are located, and they serve to examine the evidence of medical device performance and production procedures to conclude on the safety, effectiveness, benefit and risk of medical devices, among other factors.[2] Compliant devices receive the Conformité Européenne (CE) mark, indicating that the device meets the specified safety, health, and environmental requirements for its category as dictated by EU regulation.[1,3] However, unlike the traditional expectation of randomised controlled trials (RCTs) for the assessment of medicinal products, MD development in Europe has not historically centred on RCTs; this has resulted in patient safety concerns, particularly for high-risk MDs/IVDs.[13]

High-profile adverse events such as the Poly Implant Prothèse (PIP) breast implant scandal [14] and complications associated with transvaginal mesh[15] further exposed weaknesses in earlier regulatory frameworks, underscoring the need for more stringent evidence requirements and post-market surveillance mechanisms. These incidents triggered regulatory reforms, including the introduction of the Medical Device Regulation (MDR) (EU regulation 2017/745)[4] and the In Vitro Diagnostic Regulation (IVDR) (EU 2017/746)[3,5]. The MDR and IVDR, which took full effect in

May 2021, categorise MDs and IVDs according to their risk[1] and also introduce particular requirements for thorough clinical investigations of high-risk devices.(6)

Patient access requires a public or private process of reimbursement or procurement of the device. Reimbursement for medical devices can be defined as a financial payment from a public payer, or a public or private insurer, often directed to a healthcare provider, to cover expenses incurred when using a medical device or conducting a specific procedure.(10) To secure reimbursement, payers usually require evidence that the technology improves patient outcomes with acceptable cost-effectiveness. Such evidence is frequently assessed through a national Health Technology Assessment (HTA) process, which considers the device's added clinical and economic benefits relative to current usual care.

The clinical evidence required by the MDR is now complemented by the Health Technology Assessment Regulation (HTAR) (EU 2021/2282), which came into force on 11 January 2022, and applies from 12 January 2025.(8) HTAR establishes a framework for Joint Clinical Assessment (JCA), aiming to provide a single assessment of the comparative clinical effectiveness and safety of high-risk MDs and IVDs, promote consistent methodology, reduce duplication, and facilitate faster patient access to these technologies.(11) HTAR implementation will take place in gradual phases, starting with oncology medicines and advanced therapy medicinal products in 2025, high-risk MDs/IVDs in 2026, and orphan medicines in 2028, with all new medicines within scope by 2030.(16) Each country retains authority over its national reimbursement decisions, considering other factors such as healthcare priorities, budgetary implications, and cost-effectiveness.(11) As the MDR, IVDR and HTAR reshape the assessment landscape for MDs/IVDs, there is a pressing need to understand how these new regulations interact with existing HTA and reimbursement pathways across Europe.

There are limited published reviews that describe the diversity of reimbursement pathways, oversight structures involved, and criteria for patient access to high-risk medical devices in Europe. In particular, there remains limited comparative analysis of how national systems consider safety and effectiveness evidence in guiding reimbursement decisions. Previous reviews have explored assessment and reimbursement frameworks specifically for Companion Diagnostics(17) and Digital

[1] The MDR categorises medical devices into Class I (low risk), Class IIa (moderate risk), and Classes IIb and III (high risk). The IVDR categorises IVD into Class A (lowest risk), Class B (low to moderate risk), Class C (moderate to high risk), and Class D (highest risk for individuals and public health).

Health Technologies;[12] however, to the best of the evaluation team's knowledge, none have focused on high-risk MDs/IVDs.

Therefore, this scoping review aims to provide a comprehensive understanding of the current decision-making frameworks and the key oversight structures governing the reimbursement of high-risk MDs/IVDs across the EU/European Economic Area (EEA)/ UK just prior to initiation of JCAs for these technologies in 2026. The review also specifically aims to summarise each country's approach to considering the evidence of comparative effectiveness and safety in the reimbursement decision, highlighting unique elements within each jurisdiction's pathway.

2.2 Methods

This reporting of this scoping review follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines to ensure a transparent and systematic approach.[18]

The protocol was developed in alignment with the PRISMA-P statement and has been informed by methodologies outlined in frameworks by Arksey and O'Malley (2005),[19] Levac et al. (2010),[20] and the Joanna Briggs Institute (JBI).[21] The protocol was established to outline the systematic process by which the pathways and oversight structures involved in the reimbursement of high-risk MDs and IVDs across the EU/EEA and the UK were examined. The protocol was made publicly available in the Open Science Framework (OSF) database.[22] There were no notable deviations from the planned protocol.

2.3 Research questions and objectives

The primary aim of this scoping review was to answer two research questions (RQ) as follows:

RQ 1: What are the key pathways, stages of decision-making, and oversight structures involved in the reimbursement of high-risk MDs and IVDs in the EU/EEA and the UK?

RQ 2: How are comparative effectiveness and safety data for high-risk MDs and IVDs used in reimbursement decisions in the EU/EEA and the UK?

These questions aimed to map the complex landscape of reimbursement pathways across various national contexts and construct an exhaustive overview of how comparative effectiveness and safety evidence are being considered in the decision-making process.

2.4 Criteria for considering publications for this review

The research questions were developed using the PCC (Population, Concept, Context) framework, guiding the identification and selection of publications relevant to these specific areas, as presented in Table 2.1.

Table 2.1 Population, Concept and Context for the research questions

PCC element	RQ1	RQ2
Population	Stakeholders (for example, HTA bodies and ministries of health) subject to the new HTAR framework, as well as in the UK, involved in advising on and or making reimbursement decisions for high-risk medical devices and diagnostics, including: ▪ National health authorities ▪ Health Technology Assessment (HTA) agencies	
Context	Key decision-making pathways, stages, and oversight structures involved in the reimbursement process.	The utilisation and assessment of comparative clinical safety and effectiveness data to guide the reimbursement decision.
Concept	▪ High-risk medical devices (classified as Class IIb and III under MDR Regulation 2017/745) and in vitro diagnostics (Class D under Regulation (EU) 2017/746) that are subject to joint clinical assessments under Article 7 of Regulation (EU) 2021/2282.	

2.4.1 Inclusion criteria

The types of publications that were eligible for inclusion in this scoping review were:

- Official reports, manuals, process guidelines, methodological handbooks, methodological guidelines, policy documents, website pages, and other relevant documents from HTA agencies, national health authorities, and other policymaking bodies involved in reimbursement decisions (for example, public health insurance organisations). Each document had to provide information about the decision-making processes and oversight structures involved in reimbursement and/or the criteria used in assessing MDs and/or IVDs for reimbursement. Sources in any language that describe the current policy as of the search date were included in the review.

- Peer-reviewed articles or preprint publications that describe or evaluate the decision-making processes, pathways, and oversight structures for reimbursing high-risk MDs and IVDs, assess or analyse the effectiveness, strengths, and limitations of the current regulatory and decision-making frameworks governing the reimbursement of high-risk MDs and in IVDs, or discuss how comparative safety and effectiveness data for MDs and IVDs are generated, assessed, and utilised in reimbursement decision-making. Publications from 2017 onwards, in any language, were included.
- Only documents and studies relevant to EU/EEA countries and the UK were considered, given the study's focus on contexts affected by HTAR, MDR and IVDR.

2.4.2 Exclusion criteria

Studies and documents were excluded if they did not meet the study's central focus on reimbursement of high-risk devices and in-vitro diagnostics within the EU/EEA and UK context. Specifically:

- Studies focused on countries outside the EU and EEA region and the UK were excluded.
- Guidelines/guidance documents focusing exclusively on methodological issues and providing no information on how these factors affect reimbursement decisions were excluded.
- Sources focused on non-high-risk devices and diagnostics that do not fall under the high-risk categories (Class IIb and III) or Class D IVDs that are subject to JCA were excluded. Reports that refer to medicinal products exclusively and/or all therapeutic products more generally were also excluded.
- Sources focused on disease-specific HTA processes and reimbursement conditions were excluded, except when such documents contributed broader insights into HTA practices and reimbursement decisions for high-risk medical devices.
- Sources focused on device-specific (addressing only a particular medical device or small group of devices) HTA processes and reimbursement conditions were excluded unless they provided generalisable information on HTA and reimbursement frameworks.
- Sources that exclusively focused on financial aspects of the reimbursement process without discussing HTA criteria or regulatory frameworks were excluded.

2.5 Search methods for identification of studies

Data for this scoping review were extracted from a wide range of sources to provide an exhaustive overview of the reimbursement processes for high-risk MDs and IVDs. These sources included official documents and organisational websites (see section 2.3.1), publications databases (see section 2.3.2), grey literature and other sources (see section 2.3.3). Of note, given the broad and sometimes inconsistent nature of the different information sources (that is, official websites, database searches and grey literature), the search process was iterative and often required the research team to cycle between different sources in order to establish a full and accurate picture of the national reimbursement pathway.

2.5.1 Organisations search

The websites of key organisations involved in HTA and policymaking were searched between August and November 2024, as listed in Appendix (Table S1). These organisations represent key institutions for HTA and reimbursement decision-making in EU/EEA countries and the UK. These websites were searched for reports, manuals, process guidelines, methodological handbooks, methodological guidelines, policy documents, website pages, and other relevant documents that describe reimbursement decision-making processes and oversight structures for high-risk MDs and or IVDs or discuss the consideration of comparative effectiveness and safety evidence in the reimbursement decision. No language restrictions were applied. For non-English language sources, DeepL Pro or Google Translate was employed for translation.

2.5.2 Database search

The following databases were searched on 3 September 2024 for peer-reviewed articles using the search strategy defined in the Appendix:

- Medline Complete (EBSCOhost), the search strategy defined in Appendix A, Table S2.
- Embase (Elsevier), the search strategy is defined in Appendix A, Table S3.
- The Cochrane Library (Wiley), the search strategy is defined in Appendix A, Table S4.
- International Network of Agencies for Health Technology Assessment (INAHTA) Database, the search strategy is defined in Appendix A, Table S5

2.5.3 Grey literature search

Google Scholar was searched for relevant sources between September and November 2024. Furthermore, selected HTA-focused journals, namely Value in Health and the International Journal of Health Care and Technology, were searched manually to identify relevant articles. Also, a Google search was conducted in November 2024; the search was limited to three pages.

2.6 Screening, data extraction and data analysis process

2.6.1 Study selection and screening

All identified citations were imported into Covidence, duplicates were systematically removed, and two reviewers independently screened the titles and abstracts to determine relevance based on the predefined inclusion and exclusion criteria. Each reviewer independently assessed the full text of potentially eligible studies, applying the inclusion and exclusion criteria at this stage as well. Any discrepancies in eligibility assessments were resolved by discussion, with the option to involve a third reviewer for cases where consensus was not immediately achievable. The complete selection process is detailed in the PRISMA-ScR flow diagram (Figure 2.1).

2.6.2 Data extraction and management

A standardised data extraction template was developed in Microsoft Excel specifically for this review. This template was used for all the sources identified and was designed to capture all essential information related to the research questions via detailed specific extraction questions. The template was first piloted on a subset of records to ensure its ability to answer the research questions and the specificity of the information extracted. Adjustments were made based on initial pilot results, and the final template was used to extract the data. The template is presented in Appendix A, Table S7.

Data extraction was conducted by one reviewer, and each entry was independently cross-checked by a second reviewer to ensure all relevant information was accurately captured. Any differences in interpretation were discussed to reach a consensus, with any disagreements resolved by discussion with a third reviewer.

2.6.3 Data analysis and presentation

The data extracted for this scoping review was descriptive in nature, answering specific questions related to the reimbursement process of high-risk MDs and IVDs in the EU/EEA and the UK. Therefore, narrative data synthesis was undertaken with information from official websites serving as the primary data source, while peer-reviewed articles constituted a secondary data source.

Extracted data were categorised into predefined themes aligned with the research questions. Key themes included decision-making pathways, oversight structure involved, the utilisation of comparative effectiveness and safety evidence.

Findings are presented in a descriptive format, organised by theme and aligned with our two research questions.

2.6.4 Quality appraisal

Consistent with established scoping review methodology,[21] this study did not conduct a formal quality appraisal of included publications.

2.6.5 Data validation

To confirm that the findings of this review accurately reflect the current national practices in reimbursing high-risk MDs and IVDs, a validation process was conducted between December 2024 and January 2025. Representatives from HTA organisations, ministries of health, or other relevant reimbursement decision-making bodies were directly contacted (via email) and asked to review and provide feedback on the national information. The list of the contacted organisations is presented in the Supplementary Table S8. Any additional information, comments, and modifications provided by the external organisation were incorporated into this report.

2.7 Results

2.7.1 Publication selection

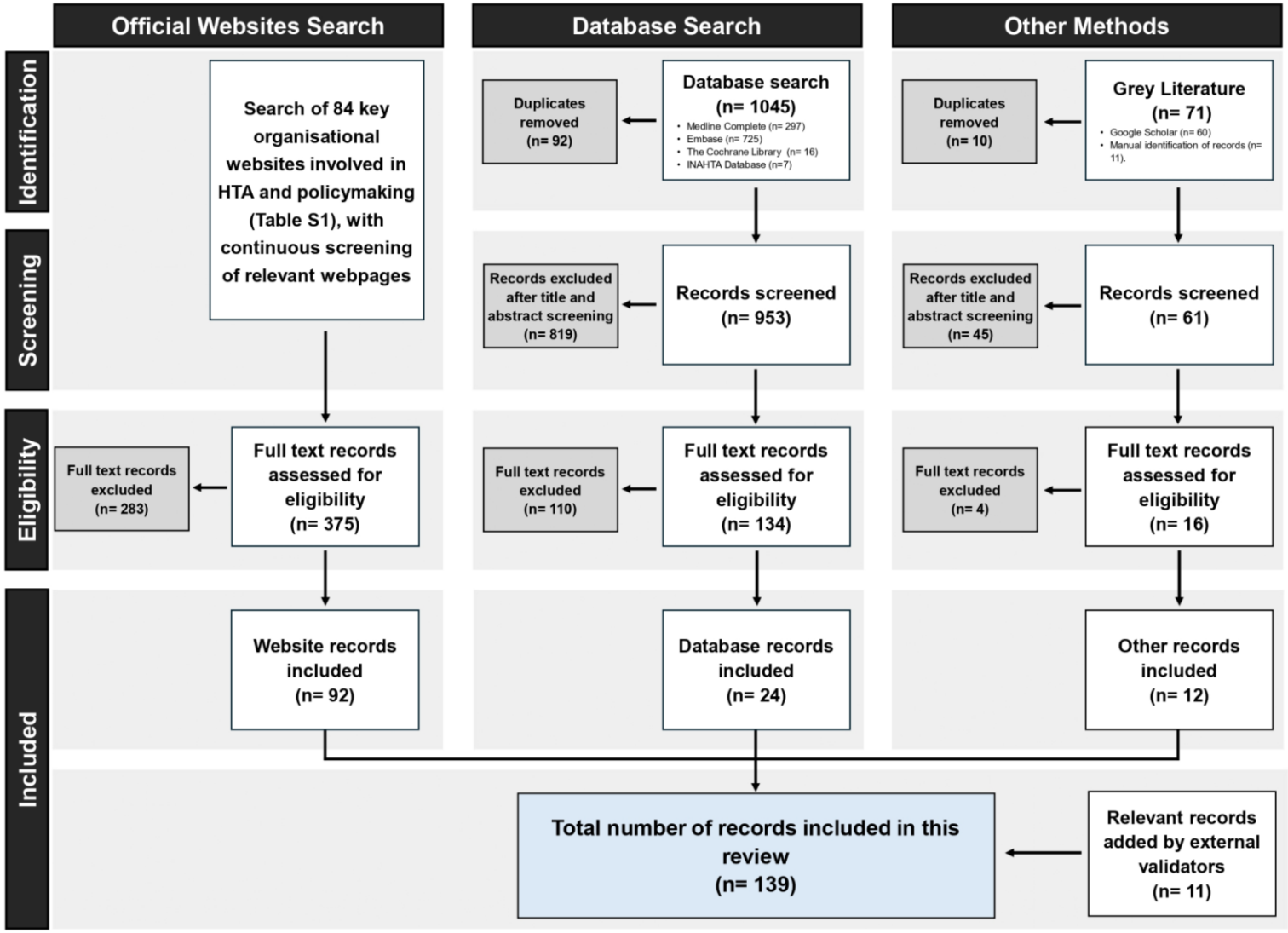
The records included in this study were identified from three primary sources: official websites, database searches and grey literature.

Overall, the official website search resulted in the retrieval of 375 unique records. Of these, 283 records were excluded after full-text assessment, and 92 records were included in the study (Figure 2.1).

For database search, a total of 1,045 records were identified, with 297 from Medline Complete (EBSCOhost), 725 from Embase (Elsevier), 16 from The Cochrane Library(Wiley), and 7 from the INAHTA Database (Supplementary Table S6). After the removal of 92 duplicates, 953 unique publications were screened. From these, a total of 819 publications were excluded based on the title and abstract screening, and the full texts of the remaining 134 records were assessed for eligibility. This resulted in the exclusion of 110 records and the inclusion of 24 publications in the study. The Medline Complete search was re-run on 20 January 2025, and three additional results were identified, which were excluded based on title and abstract screening.

The grey literature search resulted in the identification of 71 more records, 10 of which were duplicates. The titles and abstracts of the unique 61 records were screened, resulting in the exclusion of 45 records. The full texts of the remaining 16 records were assessed for eligibility, excluding a further four records (Figure 2.1), resulting in 12 records included based on the grey literature search.

Figure 2.1 PRISMA-ScR flow diagram of the records identification and screening process for the scoping review



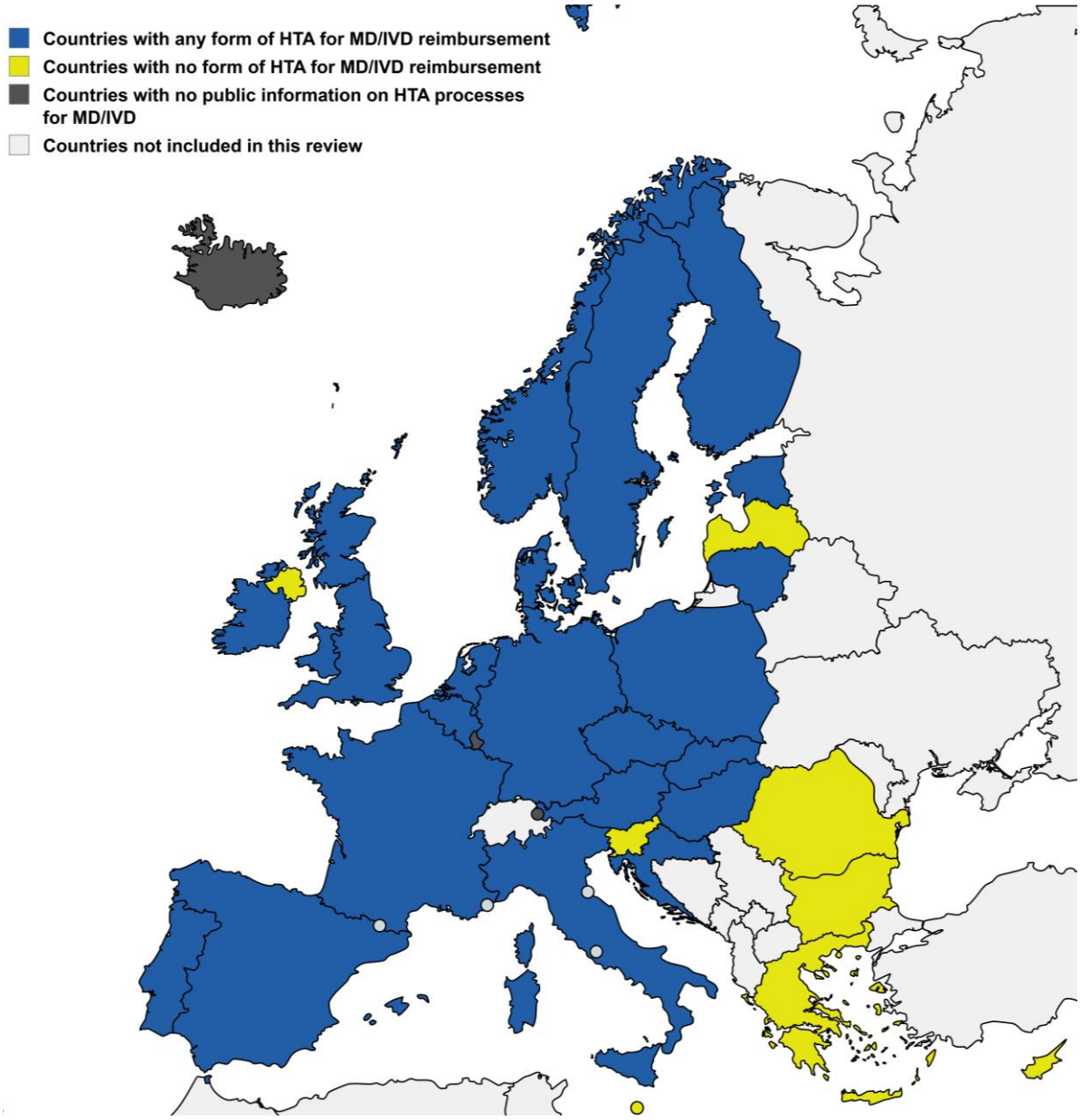
A comprehensive summary of the information for each country was sent for external validation to national organisations in 34 countries (with England, Scotland, Wales and Northern Ireland counted separately), and feedback was received from organisations in 30 countries (88% response rate). The organisations that provided feedback or verified the information are listed in Table S8. This validation process led to the inclusion of 11 additional records (publications, official website pages, and documents) provided by the external validators. As a result, a total of 139 records were incorporated into the study (Figure 2.1). References are cited in their respective location in the manuscript and supplementary materials.

2.7.2 Implementation of Health Technology Assessment for medical devices process across EU/EEA/UK

The information in this study examines the role of HTA in reimbursing high-risk MDs and IVDs across the EU, the EEA, and the UK. Specifically, the analysis includes all 27 EU Member States, Iceland, Liechtenstein, Norway, and the UK (Figure 2.2), totalling 34 countries (with England, Scotland, Northern Ireland, and Wales contacted separately). National organisations from the 34 countries were contacted for information verification; organisations from 30 countries reviewed the accuracy of the submitted information, while the remaining four provided no response or confirmation. A detailed list of verifying organisations is provided in Table S8.

Of the 34 countries in this review, we identified publicly available information on the HTA process for high-risk MDs and IVDs in 31 countries. However, no detailed public information on MD reimbursement pathways was found for three countries (Luxembourg, Liechtenstein and Iceland); these countries are highlighted in grey in Figure 2.2.

Figure 2.2 HTA Processes for Reimbursement of High-Risk MDs/IVDs Across EU/EEA and UK (as of November 2024)



Note - Countries are categorised according to the presence, absence, or lack of public information regarding HTA processes for MDs/IVDs reimbursement. Data was validated by 88% of the contacted countries, with a list of verifying organisations provided in Table S8.

The results show that HTA for high-risk MDs and IVDs is not established in all countries across EU/EEA/UK. Of the 31 countries with publicly available information, any form of HTA process for medical devices (including high-risk MDs and IVDs) was reported in the reimbursement decision-making in 23 countries (Table 2.2); these countries are highlighted in blue in Figure 2.2. Eight countries confirmed the lack of an established HTA process for MDs; these countries are highlighted in yellow in Figure 2.2. No information was found regarding HTA and reimbursement decision-making in the remaining three countries (Table 2.2).

Table 2.2 Reported HTA processes for reimbursement decisions of medical devices across EU/EEA/UK as of November 2024

Category*	Number	Countries
Countries with any form of HTA for high-risk MDs/IVDs.	23 countries	Austria, Belgium, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Italy, Lithuania, Netherlands, Poland, Portugal, Slovakia, Spain, Sweden, England, Scotland, Wales, Norway.
Countries with no form of HTA for high-risk MDs/IVDs.*	8 countries	Bulgaria, Cyprus, Malta, Latvia, Greece, Romania, Slovenia, Northern Ireland.
Countries with no public information on HTA processes for high-risk MDs/IVDs.	3 countries	Luxembourg, Liechtenstein, Iceland.

Key: EEA: European Economic Area; HTA: health technology assessment; IVDs: in vitro diagnostic medical devices; MDs: medical devices.

* The information for 88% of the countries was verified by national organisations listed in Table S8.

Due to information scarcity, countries without a reported HTA process for high-risk MDs and IVDs (n=8) and those with no publicly available information on HTA processes (n=3), will be excluded from further analysis in this review.

2.7.3 Key oversight structures involved in decision-making on patient access to medical devices in EU/EEA/UK

For the 23 countries with any form of HTA for MDs, the process summary and oversight structures involved in decision-making are summarised in Table 2.3. Generally, in these countries, the reimbursement process for high-risk MDs and IVDs is organised in a structured, step-wise approach with four main stages. The first stage is the topic identification stage, with or without a prioritisation step. In this stage, devices are identified for national introduction, and if a prioritisation stage exists, devices are selected for further evaluation based on different national prioritisation criteria.

The second step is the assessment (that is, HTA) stage, where the evidence of comparative safety and effectiveness of the device, among other factors, is assessed in order to generate an output (for example, recommendation, advice or conclusion). In this stage, there is considerable variability in how the assessment is done and how the evidence is considered. The third stage is the recommendation stage, where

different outcomes are concluded based on the assessment stage. In some cases, the assessment doesn't include a formal recommendation; in other cases, a clear recommendation regarding device reimbursement is provided.

Finally, the fourth and final step is the reimbursement decision, where a decision is made regarding funding. Depending on the national context, this decision may mainly depend on the outcome of the HTA assessment, consider the output in the context of other financial or organisational aspects, or be made independent of it.

Table 2.3 Overview of the oversight structures involved in the assessment and reimbursement of high-risk MDs and IVDs across the EU/EEA/UK, as of November 2024

Country (reimbursement pathway)	Initiation of the reimbursement process and prioritization		Assessment (HTA)	Post-HTA decision-making	Funding/ reimbursement decision	Ref.
	Initiation	**Prioritisation**				
Austria (Applications for new reimbursement groups under LKF)	Proposals can be submitted by public hospitals and regional hospital federations to the **Austrian Ministry of Health.**	Assessment proposals are prioritised by the **Austrian Ministry of Health** according to the (a) potential for true innovation, (2) financial implications, (3) the number of patients, and (4) the level of uncertainty or potential risks.	Selected interventions undergo STA/MTA by**AIHTA**.	The assessment **by AIHTA** includes scientific conclusions with recommendations.	Reimbursement decisions are made by the **Austrian FHC**. Purchasing decisions are handled at the hospital level or by centralised public hospital cooperations in the federal states.	(23,24)
Belgium	For MD, manufacturers or distributors submit the request to the **CTIIMH-CRIDMI** in **INAMI-RIZIV**. Minister of Social Affairs, professional associations and members of the CTIIMH-CRIDMI can also initiate the request.	No information	The **CTIIMH-CRIDMI** appraises the submission and formulates a provisional reimbursement proposal. In this stage, **KCE** scientific advice might be considered. However, MD	Manufacturer input is invited on the generated proposal in the assessment stage. Then, **CTIIMH-CRIDMI** formulates the final reimbursement proposal.	The **Minister of Social Affairs and Public Health** finalises the decision, pending budgetary approval **from**	(25–31)

			reimbursement is not legally bound to **KCE** recommendations.		**the Minister of Budget**.	
	For IVDs, manufacturers or distributors submit the request to the **CTM.**	The admissibility of the request is evaluated, but without a prioritization process.	**Internal evaluators** produce an evaluation report (HTA).	After the manufacturer's input, **CTM's Clinical Biology working group** discusses and validates the evaluation report, generating a reimbursement proposal.	The approved reimbursement proposal is forwarded for decision to the **Minister of Social Affairs and Public Health** and **the Council of State**.	
Croatia	The manufacturer, representative, or distributor submits the request to **CHIF's** expert committees and initiates the assessment. MoH or hospital management can also initiate the process.	Unclear	**CHIF** appraises manufacturer submissions for reimbursement decisions. In certain cases, HTA (performed **by Croatian MoH**) * might be requested by **CHIF**.	The assessments **by the Croatian MoH** include scientific conclusions and recommendations.	The final decision is made by **Croatian decision-makers**.	(32–34)

Czech Republic (Separately Billed Materials "ZUM")	Unclear	Unclear	Assessed and categorised by the **Public Health Insurance.**	Unclear	The **Public Health Insurance** manage the reimbursement.	(35–38)
Denmark	The manufacturer can submit the evaluation request.** Regional governments and hospital management can also submit the request.	Unclear	The HTA is performed **by the DHTC.**	The assessments by **DHTC** include scientific conclusions and recommendations.	The **regional governments' procurement organizations** and **the Regions Joint Procurement** are responsible for the procurement.	(39,40)
Estonia	Manufacturers or representatives make submissions for outpatient device reimbursement to the **EHIF**. Professional Association of Healthcare Providers can only make proposals regarding reimbursement criteria.	All submitted requests will be assessed.	**EHIF** assesses all requests for medical device reimbursement. In certain cases, the **University of Tartu HTA Centre** prepares HTA reports, with topics selected by the **Estonian HTA Expert Council** based on their relevance to national healthcare priorities.	**EHIF** assessments will conclude with a decision on reimbursement. **The University of Tartu HTA Centre** produces evaluation reports with a recommendation.	**EHIF** is responsible for funding and managing reimbursement processes.	(41,42)

	The submission process for inpatient high-risk devices is unclear.					
Finland	Unclear	Unclear	**COHERE Finland** primarily conducts national-level HTA**.** **FinCCHTA** primarily conducts hospital-level HTA.	The assessments **by FinCCHTA or COHERE Finland** include scientific conclusions and recommendations.	Reimbursement is undertaken by **Kela**.	(43–45)
France	Health technology developers submit application dossiers to the **Minister of Health** and send them simultaneously to **CNEDiMTS** for HTA evaluation.	Unclear	**CNEDiMTS** (one of the specialised Committees of HAS) performs national-level HTA. **CEESP (**specialised Committees at HAS) conducts health economic assessments for specific devices.	The assessments **by CNEDiMTS** include scientific conclusions and recommendations.	The device tariff is negotiated between the **CEPS** and the developer for devices with favourable reimbursement recommendations . Then, the **Minister of Health** makes the final reimbursement decision based on the opinions of the **CNEDiMTS** and the **CEPS.**	(46–50)

Germany **(for high-risk devices with a novel mechanism of action)**	The hospital submits an application to **InEK** for reimbursement. In parallel, the hospital, in agreement with the medical device manufacturer, submits the dossier to the **G-BA** for assessment.	Unclear	**G-BA** commissions the **IQWiG** to perform the HTA.	The assessments by **IQWiG** include scientific conclusions and recommendations.	The **G-BA** makes the final reimbursement decisions under the German **SHI** system.	(51–57)
Hungary	The manufacturer submits the application for reimbursement to the National Health Insurance Fund **(NEAK).** The ability of other stakeholders to initiate the process is unclear.	Unclear	**NEAK** requests a critical appraisal from **TéF** (a department of **NNGYK** responsible for HTA). The opinion of the **Health Professional College** is also requested.	**TéF** appraisals include scientific conclusions and recommendations; together with the **Health Professional College opinion,** they constitute the basis for reimbursement recommendations by **NEAK.**	Submissions with favourable reimbursement recommendations are forwarded to the **Ministry of Interior** for final decision**.**	(58–60)
Ireland	The **Department of Health** or the **HSE** may initiate the process by requesting an HTA.	Unclear	**HIQA** may conduct HTAs of MDs/IVDs, usually as a component of an innovative national programme.	HIQA HTAs include advice to the Minister for Health and the HSE.	Decisions to fund innovative national programmes are made by the Minister for Health, having considered the HTA advice.	(61,62)

Italy	The process is initiated when a new MD is integrated into the system by collaboration among the scientific community, physicians, patient associations, and manufacturers. The ability of specific stakeholders to initiate the process is unclear.	Unclear	**AGENAS** may conduct the HTAs of medical devices.	Unclear	Unclear	(63–65)
Lithuania	Only public or private legal entities seeking reimbursement can submit requests to **VASPVT**. Then, **VASPVT** will submit information on the applications received to the **HTA Committee** of the **Ministry of Health**.	The **HTA Committee** prioritises the evaluation according to a score-based system that considers (a) disease severity, (b) scientific validity, (c) treatment alternatives and (d) the expected impact. Technologies that score 21-30 points (1st priority) or 11-20 points (2nd priority) are	**VASPVT** conducts the HTA and then submits a report on the assessment to the **HTA Committee** for consideration.	The **HTA Committee** reviews HTA results and makes recommendations on reimbursement. The recommendation is submitted to the **Minister of Health**.	The **Minister of Health** evaluates recommendations and forwards decisions for reimbursement to the national health insurance fund **(VLK)**. **VLK i**mplements reimbursement decisions based on approvals.	(66–68)

		submitted for HTA. Technologies that score 0-10 points (3rd priority) are not assessed.				
Netherlands	The manufacturer, health insurers, scientific associations, patient organizations, or **ZIN** itself can initiate the assessments only in case of uncertainty about whether or not a treatment can be reimbursed from the Health Care Package.	Unclear	HTA is conducted by **ZIN**.	The assessments by **ZIN** include a final evaluation report with advice on the reimbursement.	The advice by **ZIN** is directed to the **Minister of Health, Welfare and Sport** on whether to include or exclude medical devices in the basic package.	(69–74)
Poland	The manufacturer submits an application for reimbursement to **MoH**. The ability of other stakeholders to initiate the process is unclear.	Unclear	The **MoH** may commission **AOTmiT** to appraise the manufacturer's data using "verification analysis". **AOTMiT can also perform HTA** in certain conditions. The verification analysis by **AOTmiT** includes a scientific conclusion. A **Transparency Council** reviews the	The recommendation is made by **The President of AOTMiT** based on the verification analysis, the Transparency Council's position, and the original application.	The recommendation is forwarded to the **Minister of Health,** who issues the final action on reimbursement.	(75–79)

			verification analysis and issues a position.			
Portugal	The manufacturer or its legal representative submits a financing request to **INFARMED** to initiate the process.	The financing request is validated in relation to a set of legal requirements (for example, specific technical characteristics of the medical device).	For valid requests, a technical opinion (clinical evaluation) is requested from **CATS**, a specialised unit in **INFARMED**. **CATS** report will include a conclusion regarding the technology's value relative to the comparator. Only devices with equivalent or added value compared to the defined comparators can proceed to the economic evaluation and price negotiation	Economic evaluation, and price negotiation is conducted by **INFARMED**.	The **Ministry of Health** is responsible for approving reimbursement recommendations if an agreement is reached in price negotiations.	(80–82)
Slovakia	The registration holder (for example manufacturer) applies for medical device categorization to the **Ministry of Health (MZSR).**	Unclear	As of August 2024, **NIHO** is responsible for assessments of medical devices after a request by **MZSR.**	The assessments by **NIHO** include scientific conclusions and recommendations.	Based on **NIHO's** recommendation, **MZSR** will negotiate reimbursement terms with the	(83–86)

	The ability of other stakeholders to initiate the process is unclear.				registration holder.	
Spain **(updating the content of the Common Portfolio of Services)**	Proposals are submitted by the Ministry of Health or the regional health administrations on their own initiative or at the request of interested third parties (for example, insurance companies and manufacturers).	Technologies are prioritised by the **Committee for Provision, Insurance and Financing**, using a scoring tool, the PriTec tool (https://pritectools.sergas.gal/). The prioritization criteria are clustered in five domains: (a) the disease (b) comparative results, (c) comparative costs (d) repercussions of implementation implications, and (e) dissemination issues.	HTA is performed by **RedETS**	The assessments by **RedETS** include scientific conclusions and recommendations.	The **National Health Care System** decides on the inclusion of the technology in the Common Portfolio of Services.	(64,87–90)
Sweden **(joint cooperation**	The process is initiated through horizon scanning programs (that involve consultation with experts)	The **MTP Council** prioritises the technologies for assessment.	**TLV** is responsible for conducting the HTA of selected devices at the	**TLV assessments** include scientific conclusions and recommendations.	The regions are responsible for securing access to medical	(91–93)

model for national assessment and procurement of medical technologies)		by the **MTP Council** to identify products that could be relevant for the national-level introduction.	Criteria include (a) severity of conditions, (b) expected patient benefit, and (c) resource impact.	request of the **MTP council.**	The **MTP Council** decides which technologies should be introduced nationally after an HTA and consultations with clinical experts.		technologies in healthcare through procurement.	
UK	England (new health technologies)	Topics are notified by the sponsors of medical technologies or other stakeholders (for example, NIHR, NHS, health, royal colleges, patients and healthcare organizations).	**NICE's prioritisation board** evaluates notified technologies and routes them to suitable assessment programs. Prioritisation criteria include cost effects and the potential disruptiveness of the expected benefit.	MD and simple diagnostics are routed to **MTEP. MTEP team** drafts the scopes and commissions an **EAG**.	HTA is performed by **EAG**.	The **Medical Technologies Advisory Committee** issues draft recommendations considering HTA results. After consultation and resolution, guidance is issued.	**NHS England** is responsible for the implementation of **NICE** guidance.	(94–99)
				Complex diagnostics are routed to the **DAP**. **DAP team** drafts scopes and commissions an **EAG**.		The **Diagnostics Advisory Committee** issues draft recommendations considering HTA results. After consultation and resolution, guidance is issued.		

	Scotland	Any member of the public can initiate the process by submitting a topic for HTA.	Unclear	**SHTG** assesses the proposed topics.	**SHTG** assessments include scientific conclusions and recommendations.	**NHS Scotland** is responsible for the implementation of **SHTG** advice.	(100,101)
	Wales	Any member of the public can initiate the process by proposing a topic for HTA.	**HTW** assesses the proposed topics against appraisal criteria and produces a Topic Exploration Report.	**HTW** assesses topics that meet the criteria to produce an Evidence Appraisal Report (EAR).	The **Appraisal Panel** within the **HTW** assesses the EAR and produces the HTW advice and guidance, which includes scientific conclusions and recommendations.	**NHS Wales** is responsible for the implementation of **HTW** advice.	(102,103)
Norway		**Manufacturers** can submit proposals for the assessment. Topics can also be identified through **NOMA's** early awareness system and through proposals by **hospitals**, **patient associations**, or **the public**.	Priority assessment is conducted by the **commissioner of HTA** (**"Ordering Forum"**), which consists of the chief medical directors from each of the four RHAs***. The prioritization is based on (a) the impact on healthcare system, (b) potential benefits, (c) associated risks,	All HTAs of medical devices are conducted by **NOMA,** except for mini-HTAs. Mini HTAs are conducted by clinicians and supporting units in hospitals.	HTAs by NOMA only include scientific conclusions and do not include recommendations on implementation. The **decision-making group "Decision Forum"** (consists of the chief executive officers of the four RHAs) decides whether the device should be reimbursed.	The devices can be reimbursed by the regional health authorities (specialist health care) or the National Insurance Scheme (primary health care).	(104–107)

		and (d) budgetary effect. The **commissioner** decides if the MD should be evaluated through a national HTA or mini-HTA or not assessed.				

Key: LKF (The Austrian procedure and diagnosis-oriented groups"Leistungsorientierte Krankenanstaltenfinanzierung"); **AIHTA -** Austrian Institute for Health Technology Assessment; **CTIIMH -CRIDMI** - The Commission of Reimbursement of Implants and Invasive Medical Devices; **INAMI -RIZIV -** National Institute for Health and Disability Insurance; **KCE** - Belgian Health Care Knowledge Centre; **CTM -** Medical Technical Council; **CHIF -** Croatian Health Insurance Fund; **MoH -** Ministry of Health; **DHTC -** Danish Health Technology Council; **FinCCHTA -** Finnish Coordinating Center for Health Technology Assessment; **COHERE Finland** - Council for Choices in Health Care in Health Care in Finland; **Kela** - Social Insurance Institution of Finland; **InEK -** Hospital Remuneration System; **G -BA** - Federal Joint Committee in Germany; SHI - Statutory Health Insurance in Germany; **IQWiG** - the Institute for Quality and Efficiency in Healthcare; **FHC -** Federal Healthcare Commission; **CNEDiMTS -** Medical Device and Health Technology Evaluation Committee; **HAS -** French National Authority for Health; **CEPS** - Economic Committee for Health Products; **CEESP -** The Commission for Economic and Public Health Evaluation in France; **EHIF** - Estonian Health Insurance Fund EHIF; **HSE -** Health service executive; **HIQA -** Health Information and Quality Authority; **AGENAS -** National Agency for Regional Healthcare Services; **SSN** - National Health Service in Italy; **VASPVT** - State Accreditation Service for Health Care Activities under the Ministry of Health of the Republic of Lithuania; **VLK -** National Health Insurance Fund in Lithuania; **AOTMiT -** Agency for Health Technology Assessment and Tarification; **INFARMED -** the National Authority for Medicament and Health Products; **NIHO -** National Institute For Value And Technologies In Healthcare; **MZSR -** The Ministry of Health of the Slovak Republic; **RedETS -** Spanish Network of Health Technology Assessment Agencies; **PriTec -** Prioritisation Technology Scoring Tool (Spain); **MTP Council** - Medical Technology Product Council in Sweden; **TLV -** The Dental and Pharmaceutical Benefits Agency; **NOMA -** Norwegian Medical Products Agency (previously called the Norwegian Medicines Agency); **TéF -** Technology Assessment Department in Hungary; **NEAK -** National Health Insurance Fund in Hungary; **NNGYK -** National Centre for Public Health and Pharmacy in Hungary; **ZIN -** the National Health Care Institute in the Netherlands; **CATS -** the Portuguese Commission for Health Technology Assessment; **NICE -** National Institute for Health and Care Excellence (England); **MTEP -** Medical Technologies Evaluation Programme (England); **DAP -** Diagnostics Assessment Programme (England); **EAG -** External Assessment Group; **HTW -** Health Technology Wales; **SHTG** - Scottish Health Technologies Group; **NHS** - National Health Service (UK).

† "Unclear" was used when some information was available but lacked sufficient detail to describe how prioritisation occurs. "No information" was used when no relevant description of prioritisation processes could be identified.

* HTA in Croatia was performed by the Agency of Quality and Accreditation in Health Care (the Department for Development, Research, and HTA) from 2009 until 2018 before being taken over by MoH on 01 January 2019.

** Before 2023, manufacturers could only submit assessment proposals if they demonstrated that the use of the technology would be cost-neutral or cost-saving. However, on 13 February 2023, this requirement was removed.

*** The four regional health authorities (RHAs) are: Central Norway Regional Health Authority ("Helse Midt-Norge"); Northern Norway Regional Health Authority ("Helse Nord"); Southern and Eastern Norway Regional Health Authority ("Helse Sør-Øst"); and Western Norway Regional Health Authority ("Helse Vest")

Different stakeholders in each country could initiate the reimbursement process for MDs and IVDs. In at least 17 countries (out of 23), the health technology developers, sponsors, distributors or their legal representatives could directly submit a request, application, or dossier to initiate the assessment and reimbursement process for certain types of MDs/IVDs. Other stakeholders (such as hospitals, patient associations, horizon scanning programmes, HTA bodies or the Ministry of Health, and scientific and professional associations) can also initiate reimbursement requests in at least 14 countries (Table 2.3).

After proposal submission, a formal prioritisation process before assessment was reported in at least nine countries (Austria, Estonia, Lithuania, Portugal, Spain, Sweden, England, Wales, and Norway; Table 2.3), with nationally unique selection criteria prioritising which technologies proceed to assessment. In six of these eight countries, prioritisation is conducted by an independent body or committee operating separately from the HTA-performing organisation (for example, Estonian HTA Expert Council in Estonia and MTP in Sweden; Table 2.3). The most common prioritisation criteria include:

- Clinical and patient outcomes (expected patient benefit, disease severity, patient number, and comparative effectiveness of the technology).
- Economic and resource impact (financial implications and resource use).
- Technological innovation and the presence of alternatives
- Scientific evidence uncertainty and associated risks.

Then, selected technologies, with or without prioritisation, proceed to the assessment stage. The HTA involves evaluating comparative safety and effectiveness, among other criteria unique to national requirements, as explained in previously. Depending on the national context, these assessments may rely on manufacturer submissions, incorporate independent evidence synthesis, or combine both approaches.

All 23 countries have at least one centralised pathway for conducting HTA. In 19 countries, assessments are carried out by independent bodies (for example, National Commission for the Evaluation of Medical Devices and Health Technologies (Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé; CNEDiMTS) in France and IQWiG in Germany). In contrast, in one country, HTA is conducted directly by governmental entities (Public Health Insurance body in the Czech Republic). Additionally, three countries (Belgium, Croatia and Estonia) have two organisations involved in the assessment of MDs/IVDs for reimbursement purposes. The first organisation is primarily responsible for appraising manufacturer-submitted evidence to generate reimbursement recommendations; these are the National Institute for Health and Disability Insurance (RIZIV-INAMI) in Belgium, the Croatian Health Insurance Fund (CHIF) in Croatia, and the Estonian Health

Insurance Fund (EHIF) in Estonia. The second organisation generally provides an independent evidence synthesis, separate from manufacturer submissions, mainly when submitted evidence is incomplete. These bodies include Belgian Health Care Knowledge Centre (KCE) in Belgium, the Ministry of Health in Croatia, and the University of Tartu in Estonia.

Generally, the assessment results include a scientific conclusion accompanied by a recommendation. In 19 out of 23 countries, the HTA recommendation is forwarded to a separate independent body (distinct from the HTA-performing organisation) to develop a final decision or recommendations regarding the reimbursement of the MDs/IVDs. In contrast, in one country (the Czech Republic), the HTA recommendations are produced by the reimbursement decision-making body itself (the Public Health Insurance body), which directly determines the reimbursement outcomes. In three countries (Belgium, Croatia, and Estonia), both approaches coexist; HTA can either be performed by an independent body and then forwarded to the decision-making authority or be produced directly by the reimbursement decision-making body (RIZIV-INAMI in Belgium, CHIF in Croatia, and EHIF in Estonia).

Finally, the recommendations and decisions of HTA are used, among other factors, to inform the reimbursement of devices by public health insurance funders. The health insurance funder (for example, Estonia and Lithuania) or the Ministry of Health (for example, Poland, Portugal, and Slovakia) usually oversees the integration of HTA recommendations into broader health policy decisions and procurement. In certain countries (for example, Denmark and Austria), the HTA and reimbursement decisions are decentralised to regional municipalities that independently decide, oversee and arrange the procurement of the device (Table 2.3).

Countries with no formal HTA processes for high-risk MDs and IVDs (Bulgaria, Cyprus, Malta, Latvia, Greece, Romania, Slovenia and Northern Ireland) may rely on central or local procurement processes without significant contribution of HTA to decision-making. This suggests that the reimbursement decisions in these settings may be largely influenced by financial considerations; however, the determination of what informs these decisions was beyond the scope of this review.

2.7.4 The role of HTA in reimbursement pathways of high-risk MDs and IVDs

For the countries with any form of HTA for high-risk MDs/IVDs in place (23 countries, with England, Scotland and Wales counted separately), the level to which HTA is integrated into reimbursement frameworks varies significantly. Table 2.4 provides an overview of how HTA is integrated into national reimbursement pathways for high-risk MDs/IVDs across these countries. This table categorises each

country according to the formal role of (or requirement for) HTA within their respective national reimbursement pathways for high-risk MDs/IVDs.

Table 2.4 Role of HTA in high-risk MDs/IVDs reimbursement pathways across countries with any form of HTA (as of November 2024)

HTA role in the reimbursement pathways of high-risk MDs/IVDs	List of countries	Number of countries
HTA is a formal element of certain reimbursement pathways	Austria, Germany, France, Belgium, Norway, Hungary, Sweden*, Spain, Lithuania, England.	10
HTA is not a formal part of any reimbursement pathway (forms an optional/conditional element)	The Netherlands,** Croatia, Estonia, Slovakia, Ireland, Italy, Scotland, Wales.	8
Unclear if HTA is a formal part of reimbursement pathways	Czech Republic, Denmark, Finland, Poland, Portugal.	5

Key: HTA – health technology assessment; IVDs – in vitro diagnostic medical devices; MDs – medical devices.

* Based on the Swedish Joint Cooperation Model for assessing and procuring medical technology.

** In the Netherlands, the reimbursement system for MDs/IVDs is open, allowing reimbursement without ZIN assessment, with ZIN acting as a referee in disputes between physicians, patients, and insurers regarding the inclusion of certain MDs/IVDs in health care packages.

For 10 countries, HTA is a formal element in specific national reimbursement frameworks for certain categories of MDs/IVDs (Table 2.4). On the contrary, eight countries have adopted an optional/conditional role for HTA of MDs, where HTA is not a formal component of any reimbursement pathway. However, HTAs might still be carried out for specific devices or under special circumstances on an ad hoc basis upon request from decision-makers (for example, ministries of health). For five countries, it was unclear if the HTA is a formal part of any reimbursement pathways for MDs/IVsD (Table 2.4).

Table 2.5 provides extended information for each of these countries, providing an overview of key national reimbursement mechanisms for high-risk MDs/IVsD, the role of HTA in each country's reimbursement process, factors considered in HTA recommendations and final decisions.

The data reflects considerable variability in the extent to which the HTA recommendations influence national reimbursement. For certain countries, the HTA recommendation might hold a legal mandate to be followed (such as technology appraisals in England), whereas in others, it is advisory and non-binding (such as in

Ireland). The assessments can be based on the information provided by the manufacturer, evidence synthesis from the HTA-performing body, or both. Different criteria for HTA assessment are adopted in each country, tailored to the national needs.

Table 2.5 Overview of key national reimbursement mechanisms of MDs/IVDs that involve HTA, the role of HTA in the process and utilisation of safety and effectiveness evidence for recommendation and reimbursement decisions for selected countries across the EU/EEA/UK as of November 2024

Country	Main reimbursement mechanisms for MDs and IVDs	Role of HTA in the process	Criteria considered for HTA and/or reimbursement recommendations	Ref.
Austria	**1. Procedure and diagnosis-oriented groups (Leistungsorientierte Krankenanstaltenfinanzierung; LKF)** for MD in the inpatient sector. **1.1. Individual medical services catalogue (Medizinische Einzelleistungen; MEL)** for specific services that receive an add-on tariff.	Selected interventions must undergo HTA to introduce new reimbursement groups within the system. FHC considers the HTA results when making reimbursement decisions.	The HTA recommendations consider: ▪ Comparative effectiveness (added benefit) ▪ Quality appraisals of effectiveness and safety data The reimbursement decisions consider: ▪ Comparative effectiveness and safety (HTA). ▪ Quality assurance and organisational aspects ▪ Costs ▪ Procedural aspects	(23,24)
Belgium	**1. Main list of reimbursable medical devices (the List).**	Invasive medical devices, including implants, must be evaluated by the CTIIMH-CRIDMI for reimbursement (except MD for oral cavity or facial area with an intraoral or extraoral visible part).	The HTA and reimbursement decisions consider some or all of these five criteria: ▪ Therapeutic value ▪ Price and reimbursement level ▪ Importance in medical practice ▪ Impact on healthcare costs ▪ Cost-effectiveness	(25–31)
	2. Nominative list for selected brand names of reimbursable devices.			
	3. Reimbursement of IVDs not linked to a medicinal product.	The application for reimbursement must undergo an appraisal by evaluators at CTM.	The reimbursement depends on the available budget and the appraisal results.	

Croatia	**Basic and additional lists** for reimbursement of medical devices covered by compulsory health insurance.	HTA is not a formal part of the reimbursement of medical devices. However, CHIF assesses the application. HTA (by MoH) may be performed ad-hoc, and the recommendation is not legally binding when done.	The reimbursement decisions are based on the manufacturer submission, which should include: ▪ Expert opinion on the comparative effectiveness of the device ▪ Proof of the technical characteristics and the demonstration of different and/or more efficient mechanisms of action ▪ Budget impact analysis in certain cases	(32–34)
Czech Republic	**Reimbursement for separately billed materials (ZUM).**	It's unclear if HTA is a formal part of any reimbursement pathway.	In the case of reimbursement of an innovative medical device, a budget impact analysis from the payer's perspective is required.	(35,38)
Denmark	**1. General reimbursement of medical devices**	It's unclear if HTA is a formal part of any reimbursement pathway. The DHTC performs HTA upon application of the manufacturer or health authorities' request. The HTA recommendations are not legally binding for the regional governments, but they are expected to follow.	HTA recommendations consider: ▪ The device is better than the comparator(s) (in terms of clinical effectiveness) and is cost-reducing, cost-neutral or considered cost-effective) ▪ Cost-effectiveness (the device is considered clinically equivalent to the comparator(s) at a minimum and is cost-reducing or cost-neutra.	(39,40)
Estonia	**1. Positive health service list** for reimbursement of high-risk MDs in the inpatient settings. **2. Positive list of medical devices** for reimbursement of high-risk MD for outpatient settings.	HTA is not a formal part of the reimbursement of medical devices. However, the EHIF assesses requests to amend the lists. HTA (by the University of Tartu HTA Centre) may be performed ad-hoc, and the recommendations may be used to inform decision-making.	The reimbursement decisions consider: • Cost-effectiveness • Medical necessity in Estonia	(41,42)

Finland	No information on different national mechanisms of reimbursement of MDs/IVDs.	It's unclear if HTA is a formal part of any reimbursement pathway. The legal mandate of HTA recommendations is also unclear.	HTA recommendations by FinCCHTA may consider: ▪ Clinical effectiveness. ▪ Costs and financial impact ▪ Safety ▪ Ethical considerations ▪ Organisational aspects, social effects and legislative implications	(43–45)
France	**1. DRGs** for reimbursement of most MD for individual use in the inpatient settings. **1.1. Positive intra-DRG lists** for reimbursement of specific MD under a brand name within the DRG.	HTA (by CNEDiMTS) is a formal part for nine specific categories of MD before they can be reimbursed under the "positive intra-DRG list".* HTA recommendations are the basis of reimbursement decisions.	HTA recommendations consider safety and effectiveness evidence for devices in the specified categories*, as they must meet at least one of the following requirements: ▪ Validation of clinical effectiveness ▪ Definition of particular technical specifications ▪ Assessment of the comparative effectiveness	(48,49)
	2. LPPR (Liste des Produits et Prestations Remboursables) for medical devices and services eligible for reimbursement in private settings, either at home or in private practices. **2.1. The additional list within the LPPR** includes the devices used in healthcare organisations that qualify for	Medical devices can be included in the LPPR list under a generic description (default inclusion) or brand name. The inclusion under a generic description is defined on the LPPR after the CNEDiMTS have performed an MTA. After that, any medical devices corresponding to a generic description do not require further HTA for reimbursement. For inclusion under a brand name, STA must be performed.	HTA recommendations by CNEDiMTS must deliver an opinion using two main components: ▪ The actual clinical benefit (ACB) ▪ The clinical added value (CAV) If the ACB is sufficient, the CNEDiMTS must then also assess the CAV compared to the most clinically relevant comparator. If the device is expected to have a significant economic impact and if the manufacturer claims a	(46–50)

	reimbursement outside the standard DRGs.	HTA recommendations are the basis of reimbursement decisions.	CAV of I to III, a health economic assessment is required.	
Germany	**1. The G-DRG system** for reimbursement of devices in the inpatient setting.	InEK must conduct assessments for reimbursement of MD that involves a new mode of action or is not represented by an existing DRG category. HTA recommendations are the basis of reimbursement decisions.	The reimbursement decisions consider the following aspects: ▪ The device's costs ▪ The device's clinical value	(54,64,108)
	2. Reimbursement of any new diagnostic or treatment procedure with a novel mechanism of action and involving high-risk (class IIb & III) or active implantable MD.**	HTA (benefit assessment; §137h SGB V) must be performed for these devices. HTA recommendations are the basis of reimbursement decisions.	The HTA recommendations only consider the following aspect: ▪ Added benefit (considering only patient-relevant outcomes, including mortality, morbidity, quality of life, and side effects) Cost-effectiveness is not formally assessed for medical devices or procedures in Germany	(52,53,55,57)
	3. Statutory Health Insurance (SHI) reimbursement for MD in the outpatient sector.	HTA must be performed for new interventions (including the device) before reimbursement decision-making.	The HTA recommendations and reimbursement decisions consider whether the new intervention (including the device) demonstrates sufficient comparative effectiveness.	(53)
Hungary	**General reimbursement for medical devices by the National Health Insurance Fund.**	HTA, in the form of technology appraisal of the manufacturer submission, must be performed (by TéF) to make reimbursement decisions on any new medical device.	HTA recommendations consider the following aspects: ▪ Health care priorities ▪ The severity of the disease ▪ Equality ▪ Cost-effectiveness and quality of Life ▪ Aggregated budget impact	(109)

			▪ National and international professional opinion	
Ireland	**Reimbursement of medical devices by HSE.**	HTA is not a formal part of any reimbursement pathway for high-risk MDs/IVDs. However, it may be conducted for certain medical devices and diagnostics at the request of the Department of Health or the HSE	HTA advice considers the following domains: ▪ Description of technology ▪ Burden of disease ▪ Clinical effectiveness and safety ▪ Cost effectiveness and budget impact ▪ Organisational aspects ▪ Patient and social aspects ▪ Ethical and medicolegal aspects	(62)
Italy	**DRG system** for reimbursement of devices in the inpatient setting.	HTA is not a formal part of any reimbursement pathways. No HTA is needed for reimbursement under standard DRG codes. Establishing a new DRG code typically involves collaboration among the scientific community, physicians, patient associations, and manufacturers.	Unclear	(63–65)
Lithuania	**General reimbursement for medical devices by the national health insurance fund**.	VASPVT and the HTA committee assess certain devices for inclusion into the reimbursement list.	HTA conducted by the VASPVT assesses the following: ▪ Technology purpose and use in other countries ▪ Health problem ▪ Clinical effectiveness ▪ Safety ▪ Economic aspects and benefits compared to comparators	(66–68)

			▪ Social, legal, and ethical aspects	
Netherlands[†]	**Reimbursement for medical devices by the national health insurance fund.**	HTA is not a formal part of reimbursement pathways, as MDs/IVDs can be reimbursed without HTA assessment by ZIN. However, ZIN acts as a referee in cases of disagreement over MDs/IVDs reimbursement between physicians, patients, and insurers regarding the treatment eligibility or effectiveness. Health insurers can only reimburse such treatments under basic insurance if ZIN provides a positive recommendation.	HTA and reimbursement recommendations consider the following aspects: ▪ The evidence of added value (for example, improved survival and quality of life) ▪ Alignment with legal criteria in daily practice ▪ In certain cases, cost-effectiveness and broader considerations like patient and societal benefits might be considered	(72,74,110)
Poland	**General reimbursement for medical devices by the national health insurance.**	It's unclear if HTA is a formal part of any reimbursement pathway. For certain devices, AOTMiT may perform HTA. However, the AOTMiT recommendation is not obligatory to be implemented throughout Poland.	HTA recommendations consider the following aspects: ▪ Health problem ▪ Target population ▪ Comparative effectiveness ▪ Safety assessments ▪ Non-clinical effects ▪ Economic impact	
Portugal	**General reimbursement for medical devices by the National Health Services.**	For MDs/IVDs, the reimbursement request must be validated in relation to the device's technical requirements. Further opinion (HTA) may be requested from CATS to make reimbursement decisions.	HTA recommendations consider the following aspects: ▪ Comparative added value ▪ For devices with equivalent value or added value, the evaluation proceeds to	(80–82)

				economic evaluation and price negotiation	
Slovakia		**Reimbursement of MDs and IVDs under institutional care.**	HTA is not a formal part of any reimbursement pathway. However, it may be used for certain medical devices. HTA assessments are only used to support decision-making; they don't constitute the decision.	The HTA considers the following aspects: ▪ Health problems and current use of technology ▪ Technical characteristics ▪ Clinical effectiveness and safety ▪ Economic assessment ▪ Ethical, organisational, social, patient and legal aspects	(83,86,111,112)
Spain		**Reimbursement of medical devices in the inpatient setting** (under the common Benefit Package)**.**	HTA by RedETS is a preliminary mandate for updating the content of the common package. HTA recommendations are the basis of reimbursement decisions.	The HTA and reimbursement decisions consider the following aspects: ▪ Comparative effectiveness ▪ Safety ▪ Cost-effectiveness, budget, organisational, social, and ethical impacts	(87,88)
Sweden		**National reimbursement of medical devices based on the joint cooperation model for assessing and procuring medical technology**.	HTA is conducted (by TLV) for selected technologies identified by the Medical Technology Product Council. However, reimbursement decisions are regional and not necessarily based on HTA.	The HTA recommendations consider the following aspects: ▪ Clinical evidence ▪ Health economic analysis	
UK	**England**	**Reimbursement of medical devices by NHS England.**	HTA by NICE is a formal part of reimbursement pathways for selected technologies.	HTA recommendations consider the following aspects: ▪ Clinical benefits, including comparative effectiveness outcomes	(94,96,113)

			Reimbursement decisions by NHS England are primarily based on NICE guidance; however, only technology appraisal guidance is legally binding.	▪ Cost analysis Reimbursement decisions by NHS England consider the following aspects: ▪ NICE guidance recommendations ▪ The cost impact of the technology on NHS England****	
	Scotland	**Reimbursement of medical devices by NHS Scotland.**	HTA is not a formal part of any reimbursement pathway. However, SHTG may conduct HTA for certain devices on an ad-hoc basis. NHS Scotland is required to consider the HTA recommendations in their reimbursement decisions if available.	HTA recommendations consider the following aspects: ▪ Comparative effectiveness ▪ Safety ▪ Cost-effectiveness ▪ Patients' and professionals' perspectives ▪ Broader impact on the healthcare system	
	Wales	**Reimbursement of medical devices by NHS Wales.**	HTA is not a formal part of any reimbursement pathway. However, HTW may conduct it for certain devices on an ad-hoc basis. NHS Wales is expected to follow HTW guidance or recommendations if available. Also, NICE's Technology Appraisal Guidance is legally binding in Wales.	HTA recommendations consider the following aspects: ▪ Comparative effectiveness ▪ Cost-effectiveness ▪ Other considerations (including equity, environmental sustainability, or other priority issues in Wales)	(102,103)
Norway		**Reimbursement of new medical devices under the managed introduction of new technologies in the specialist health care service (Nye metoder).**	HTA is a formal part of "**Nye metoder"** where selected medical devices are assessed by NOMA through a national HTA.	HTA recommendations consider the following aspects: ▪ Potential benefits ▪ The device's impact on the healthcare system ▪ Potential benefits	(104,105)

		The national-level assessments are used to inform decision-makers who may also take into account other factors.	▪ Associated risks ▪ Budgetary implications The reimbursement decisions consider three unique aspects of the Norwegian context: ▪ The benefit criteria ▪ The resource criteria ▪ The severity criteria	

Key: ACB – actual clinical benefit; **AOTMiT** – Agency for Health Technology Assessment and Tariff System; **CATS** – Health Technology Assessment Commission; **CAV** – clinical added value; **CHIF** – Croatian Health Insurance Fund; **CNEDiMTS** – National Commission for the Evaluation of Medical Devices and Health Technologies; **CTIIMH-CRIDMI** – Commission for Reimbursement of Implantable and Invasive Medical Devices; **CTM** – Technical Medical Council; **DHTC** – Danish Health Technology Council; **DRG** – diagnosis-related group; **EHIF** – Estonian Health Insurance Fund; **FHC** – Federal Health Commission; **FinCCHTA** – Finnish Coordinating Center for Health Technology Assessment; **G-DRG** – German diagnosis-related group; **HSE** – Health Service Executive; **HTA** – health technology assessment; **HTW** – Health Technology Wales; **InEK** – Institute for the Hospital Remuneration System; **IVDs** – in vitro diagnostic medical devices; **LKF** – performance-oriented hospital financing; **LPPR** – List of Reimbursable Products and Services; **MDs** – medical devices; **MEL** – individual medical services; **MoH** – Ministry of Health; **MTA** – multiple technology assessment; **NHS** – National Health Service; **NICE** – National Institute for Health and Care Excellence; **NOMA** – Norwegian Medical Products Agency; **RedETS** – Spanish Network of Agencies for Health Technology Assessment and Services of the National Health System; **SGB V** – German Social Code Book V; **SHI** – statutory health insurance; **SHTG** – Scottish Health Technologies Group; **STA** – single technology assessment; **TéF** – Department of Health Technology Assessment; **TLV** – Dental and Pharmaceutical Benefits Agency; **VASPVT** – State Health Care Accreditation Agency; **ZIN** – National Health Care Institute; **ZUM** – separately billed materials**.**

* The nine categories are (1) Intracranial stents used in angioplasty of atheromatous stenosis, (2) Conventional implantable cardiac defibrillators with endocardial lead (single-, dual-, and triple-chamber), (3) Implantable cardiac defibrillators without endocardial lead (single-, dual-, and triple-chamber), (4) Biological surgical heart valves, (5) Implantable devices for the treatment of pelvic organ prolapse by the vaginal route, (6) Implantable devices for the treatment of urinary incontinence by the vaginal route, (7) Devices for the treatment of pelvic organ prolapse by the abdominal route, (8) Intracranial flow diverter stents (9) Thrombectomy devices.

** The IQWiG conducts the HTA on behalf of the G-BA.

*** Class IIb devices fall under this rule only if they work by emitting energy.

**** For medical technology guidance, funding by NHS England requires that the technology has positive NICE guidance, cost-saving within 3 years of implementation (demonstrated through NICE modelling) and is affordable to the NHS (the cost should not exceed £20 million in any of the first 3 years).

† In the Netherlands, the reimbursement system for represents an open system, as the technologies can be reimbursed without a formal HTA assessment. However, the National Health Care Institute (Zorginstituut Nederland MDs/IVDs; ZIN) acts as a referee in cases of disagreement between physicians, patients, and health insurance companies when there is uncertainty about whether a new treatment qualifies for reimbursement under the Health Care Package or in case of uncertainty about whether it is sufficiently effective,

particularly when a new treatment is involved. In such cases, ZIN assesses the technology and issues an HTA assessment with a recommendation. Health insurers may only reimburse such treatment under basic insurance if ZIN has issued a positive assessment outcome.

The following section provides an extended overview of case studies in three countries where HTA plays a formal role in the reimbursement process for specific MDs/IVDs categories and three countries where HTA is not formally requested in the reimbursement pathways but might be performed upon request or on an ad hoc basis.

2.7.5 Countries with HTA as a formal part of reimbursement pathways for specified device categories

Austria, Germany, and France are examples of countries which rely heavily on adapted national Diagnosis-Related Group (DRG) systems to reimburse high-risk MDs in inpatient settings. These three countries also have an additional system for reimbursing MDs (or procedures/interventions, including the device) that are not included in the DRG or must be reimbursed under their brand name. The inclusion of a new DRG group, the introduction of high-risk MD with a novel mechanism of action, or the inclusion of specific devices under a brand name might necessitate a mandatory form of HTA for reimbursement decisions with unique criteria being assessed in each case.

2.7.5.1 Germany

In Germany, the majority of high-risk MDs/IVDs in inpatient settings are reimbursed as part of the German DRG system without specific assessment if they fall under an existing DRG category. The MDs/IVDs that German Diagnosis-Related Group (G-DRG) does not cover can be reimbursed under a specific financing programme for new examination and treatment methods ("Neue Untersuchungs- und Behandlungsmethoden", NUB) reimbursement scheme. High-risk MD (class IIb & III) or active implantable MDs with novel mechanisms of action must be subjected to benefit assessment (§137h SGB V) to ensure added value over existing technologies. Class IIb devices fall under this rule if they work by emitting energy (for example, heat or radiation).[55]

For these devices, Federal Joint Committee (Gemeinsamer Bundesausschuss; G-BA) assesses the added benefit through a structured benefit assessment process, focusing on patient-relevant outcomes such as mortality, morbidity, quality of life, and side effects. The assessment results are the primary tool guiding reimbursement decisions, as the device must demonstrate an "additional benefit" over existing treatments for reimbursement decisions. In most cases, the G-BA commissions IQWiG, the G-BA's centre of expertise in performing the assessment. Of note, cost-effectiveness is not formally assessed for medical devices or procedures in Germany.

2.7.5.2 France

Similarly, in France, medical devices for inpatient settings are mainly reimbursed under the French DRG system without specific assessment. However, for certain categories of medical devices, single technology assessments (STAs) have to be performed by the National Committee for the Evaluation of Medical Devices and Health Technologies (Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé, CNEDiMTS) one of the specialised Committees of the French National Authority for Health (Haute Autorité de Santé, HAS) before they can be included under their brand names on the "positive intra-DRG list" by the Minister of Health. This inclusion determines the reimbursement for these medical devices and their purchase, supply and use by all healthcare organisations.[47–49] These categories include:

- Intracranial stents used in angioplasty of atheromatous stenosis
- Conventional implantable cardiac defibrillators with endocardial lead
- Implantable cardiac defibrillators without endocardial lead
- Biological surgical heart valves
- Implantable devices for the treatment of pelvic organ prolapse by the vaginal route
- Implantable devices for the treatment of urinary incontinence by the vaginal route
- Devices for the treatment of pelvic organ prolapse by the abdominal route
- Intracranial flow diverter stents
- Thrombectomy devices

For devices belonging to any of these categories, CNEDiMTS must confirm, considering their invasiveness or the risks they may pose to human health, that they meet at least one of the following requirements: (a) validation of their clinical effectiveness, (b) definition of particular technical specifications, (c) assessment of their efficiency compared with available therapeutic alternatives.

Medical devices and services used in private settings (at home or in private practices) are reimbursed under the List of Reimbursable Products and Services (Liste des Produits et Prestations Remboursables; LPPR). The LPPR also includes medical devices used in inpatient settings that qualify for reimbursement outside the standard DRG structure, known as the "additional list".[48–50] Medical devices included under sections III (implantable medical devices, implants and tissue grafts of human origin) or V (and invasive devices not covered under Section III) of the LPPR may qualify for additional reimbursement outside the DRG framework by being included in the "additional list".

Devices included in LPPR by default are listed under a generic description established after a Multiple Technology Assessment (MTA) conducted by CNEDiMTS. A single medical device corresponding to a generic description does not require

further HTA for reimbursement. If generic inclusion is not possible (for example, innovative devices or those requiring follow-up), the device must undergo STA for brand-name inclusion.[48,49]

Similar to the German system, the assessment results are the primary tool guiding reimbursement decisions; however, the assessment criteria and process vary significantly. Using the safety and effectiveness data, the CNEDiMTS must deliver an opinion using two main components: the actual clinical benefit (ACB) and the clinical added value (CAV). Assessment of ACB is conducted considering two factors: the product's clinical benefit and public health benefit, which, if deemed sufficient, the CNEDiMTS must then also assess the CAV compared to the most clinically relevant comparator as major (I), high (II), moderate (III), minor (IV) or absent (V) CAV. If the device is expected to have a significant economic impact and claims a CAV of I to III, a health economic assessment is required, which is conducted by the Commission for Economic and Public Health Evaluation (Commission d'évaluation économique et de santé publique, CEESP), another specialised HAS Committee.[46–49]

2.7.5.3 Austria

Similarly, in Austria, most high-risk MDs and IVDs are reimbursed in the inpatient sector under the Austrian DRG system, which is known as "Leistungsorientierte Krankenanstaltenfinanzierung (LKF)." The LKF is structured around two main components: the core area, which is standardised national reimbursement for all hospitals, and the steering area, which allows adaptation based on the level of hospital care and Federal State criteria. Highly innovative, expensive MDs can be reimbursed (as part of a medical procedure or service) through the individual medical services catalogue (Medizinische Einzelleistungen, MEL), a positive list containing approximately 2,000 medical services.[23,24]

The inclusion of new medical services and devices in MEL is supported by HTA conducted by the Austrian Institute for Health Technology Assessment (AIHTA; formerly Ludwig Boltzmann Institute for HTA). The positive recommendation of the intervention is mainly based on (a) added benefit and comparative effectiveness and safety, which is the most influential factor in the recommendation, (b) quality assurance and organisational aspects, including provider capacity, infrastructure, and organisational requirements; (c) costs, (d) procedural aspects including the general criteria for adoption and (e) the recommendation from other countries on the adoption of the intervention or related medical services.

2.7.6 Countries with optional/conditional HTA components

For certain countries, the HTA is an optional or conditional component rather than a formal component of high-risk MDs/IVDs reimbursement pathways. The devices

might still be reimbursed without HTA advice. However, if a HTA is done, the recommendation supports the reimbursement decision-making.

2.7.6.1 Croatia

In Croatia, most MDs/IVDs (including high-risk devices) are reimbursed under the Croatian Health Insurance Fund (CHIF's) list regulated by Croatian legislation. HTA is optional and is not a mandatory part of the reimbursement pathway. The generated HTA recommendations are not legally binding and only aim to support policymakers at a national level.

Although the HTA is not a mandatory part of the process, the manufacturers are still requested to provide supporting documentation depending on the device type. If the reimbursement request is in relation to placing a new generation of the same type of device on the list, the submission should include (a) an expert opinion from a professional society at the Croatian Medical Association, another relevant professional society or the reference centre of the ministry responsible for health, that explains the scientific evidence of the advantages of the aids in relation to comparators and (b) proof of its technical characteristics and that it demonstrates different and/or more efficient mechanisms of action.

If the request for reimbursement is in relation to placing a new device on the list, the proposal must be additionally accompanied by (c) a study of the impact on the budget and (d) clinical studies that demonstrate the justification of the application of the new device. The CHIF appraises the documentation submitted by the manufacturer in order to issue reimbursement decisions.

In certain cases, HTA reports may be performed upon the request of CHIF, the Croatian Ministry of Health, or hospital management. The HTA process has been performed by the Agency of Quality and Accreditation in Health Care (the Department for Development, Research, and HTA) from 2009 until 2018. Ministry of Health (MoH) Croatia took over from the Agency on 01 January 2019.[32,34,114]

2.7.6.2 Denmark

In Denmark, the Danish Health Technology Council (DHTC; established in 2021 as a national HTA organisation) evaluates and recommends health technologies, including MDs and IVDs. Regional governments, hospital management, and companies can submit proposals for evaluation. Companies can submit proposals only if they demonstrate that the technology will be cost-neutral or cost-saving. Hospitals' or regional bodies' submissions are not required to show cost neutrality or savings (they can propose technologies that may lead to increased costs); however, they must provide a detailed account of the expenses associated with the technology.

The DHTC recommendations are not legally binding for the regional governments, but they are expected to follow them unless they have special reasons to deviate from them. The regional governments' procurement organisations and the Regions Joint Procurement (Regionernes Fælles Indkøb, or RFI) are responsible for the procurement procedures.

The HTA process considers the comparative effectiveness of the technology under assessment to generate one of three decisions: recommended, not recommended or recommended for knowledge acquisition.

If there is sufficient evidence and knowledge to conclude that the device (1) is considered clinically equivalent to the comparator(s) at a minimum and is cost-reducing or cost-neutral, or (2) is better than the comparator and is cost-reducing, cost-neutral or considered cost-effective, the DHTC will recommend the technology for implementation. On 13 February 2023, the requirement for companies to demonstrate cost saving or cost neutrality associated with using their health technology was removed based on a decision from the Board of the Danish Regions.

After the recommendation, the DHTC work is complete except if the Council has stipulated a time for reassessment or expiry of the recommendation or it resumes processing after a knowledge acquisition process.

2.7.6.3 Estonia

In Estonia, the Estonian Health Insurance Fund (EHIF) is responsible for funding and managing reimbursement processes for health care services, including high-risk MDs and IVDs. High-risk MDs and IVDs used in inpatient or outpatient settings are reimbursed under the positive health service list or the positive list of MDs, respectively. Manufacturers or representatives can make submissions for reimbursement for outpatient devices.

EHIF evaluates all the health services and health technologies which seek public reimbursement. Based on EHIF decisions, the Ministry of Social Affairs makes necessary changes in regulations (positive list of MDs, positive list of health services, etc). The decisions are influenced by cost-effectiveness and medical necessity. However, no formal HTA process is included in the reimbursement pathway.

In some cases, the University of Tartu HTA Centre might be commissioned to prepare HTA reports. Their work is done in close collaboration with EHIF and the Ministry of Social Affairs, who are financing these reports, and the topics are selected by the Estonian HTA Expert Council. The Council is also responsible for approving health technology evaluation reports and monitoring and ensuring the quality of the health technology evaluation process and reports. University reports are an important source of information when the data is unavailable from

submissions to make reimbursement decisions, but the technology is considered to be important for Estonia.[41,42]

2.7.7 Regional variations and the level of centralisation in the reimbursement framework and decisions implementation

As previously mentioned, all 21 countries with any form of HTA for high-risk MDs/IVDs (described in Table 2.3) have at least one mechanism for national-level HTA assessment and recommendation generation of these devices. However, the locus of authority and decision-making structures governing the reimbursement of high-risk MDs/IVDs vary significantly. This results in different levels of regional variability of medical device reimbursement. The level of centralisation in the reimbursement framework for each country is described in detail in Table 2.6 and further illustrated in Figure 2.3.

For the purpose of this review, countries are classified into two main categories:

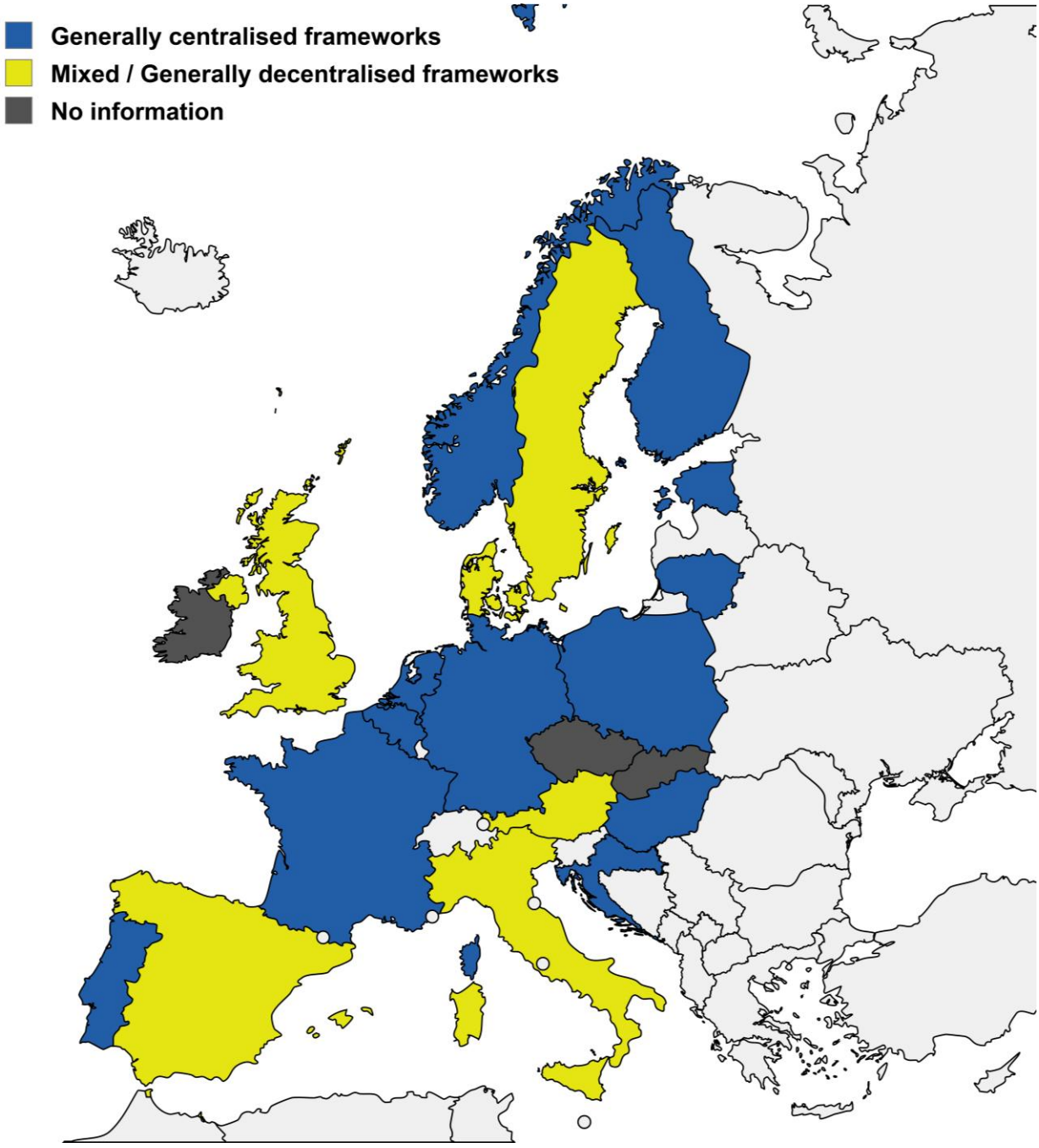
1. **Generally centralised reimbursement frameworks (12 countries):** where the vast majority of reimbursement decisions occur at the national level, with an expected homogeneous reimbursement and implementation throughout the country. In such cases, the national authority or authorities are responsible for evaluating and recommending reimbursement for medical devices based on medico-economic evidence, among other criteria. The national HTA recommendations are integrated into the decision-making process and usually (but not always) flow to another national authority for reimbursement decisions. These countries might still have auxiliary local decision-making pathways on hospitals, hospital associations, or regional levels that can introduce medical devices into the system, which might still result in regional variability (Figure 2.3).

2. **Mixed/generally decentralised reimbursement frameworks (six countries):** where the majority of medical devices are being adopted through regional or hospital-level device uptake, often with or without local assessment. While some countries within this category may have a national-level reimbursement scheme, it is typically secondary to regional or local hospital-level processes, resulting in more significant variability in how medical devices are adopted. Some of these countries might have limited integration of HTA overall in the reimbursement decisions of high-risk MDs and IVDs, which is explained below. For classification purposes, this category also includes countries with mixed systems, where centralised HTA takes place at the national level. However, reimbursement decisions are still made at the regional or local level. In these cases, national HTA recommendations might provide advice for local decisions, but regional authorities are ultimately responsible for decision-making. Decentralised systems may be more

adaptable to regional needs but may lack the standardisation required for efficient national-level coordination (Figure 2.3).

No information was found regarding the centralisation status of reimbursement decision-making in three countries (Ireland, Slovakia and Czech Republic; Figure 2.3).

Figure 22.3 Centralisation levels of reimbursement frameworks for MDs/IVDs across countries with any form of HTA for medical devices (as of November 2024).



Note: Countries are categorised according to the extent of centralisation of reimbursement frameworks. Only countries with reported forms of HTA for reimbursement of high-risk MDs/IVDs are described in this figure. Figure was created using mapchart.net.

Table 2.6 Regional variations in the reimbursement frameworks for high-risk MDs in the EU/EEA/UK as of November 2024

Country	Centralisation of reimbursement frameworks	Description of expected regional variations.
Austria	Decentralised/ Mixed	The implementation of reimbursement decisions (final purchasing decisions) is handled at the hospital level or by centralised public hospital cooperations in the federal states. The nine federal states manage healthcare delivery separately in the inpatient sector.
Belgium	Generally centralised	The Minister of Social Affairs and Public Health nationally implements the decision formulated by the CTIIMH-CRIDMI with budgetary approval from the Minister of Budget. However, hospitals can cover the cost of certain medical devices or procedures even when they are not officially reimbursed, as the national position on reimbursement is not always available when new devices enter the Belgian market.
Croatia	Generally centralised	National HTA reports are centrally processed by Croatian decision-makers.
Denmark	Decentralised/ Mixed	The recommendations from the DHTC are not legally binding for the regional governments, but they are expected to follow them unless they have special reasons to deviate from them. The regional governments' procurement organisations and the Regions Joint Procurement are responsible for the procurement and tendering procedures.
Estonia	Generally centralised	The EHIF oversees and funds medical services, including devices, through a national list of healthcare services. Based on EHIF evaluation and decisions, necessary changes in regulations (positive list of medical devices, positive list of health services, etc) are made by the Ministry of Social Affairs.
Finland	Generally centralised	FinCCHTA reports are generated jointly by the five university hospitals, resulting in national-level adaptation of technology. Also, after COHERE Finland's positive recommendations, Kela reimburses the technology nationally, resulting in generally centralised reimbursement. However, rapid HTA can be conducted at the 'WellBeing Services County' level for specific high-risk medical devices to support local reimbursement decisions.

France	Generally centralised	Generally, the French healthcare system is highly centralised, as reimbursement under DRG or LPPR after CNEDiMTS assessments has a centralised implementation. However, hospitals can still evaluate and procure medical devices through different local evaluation (hospital-based HTA) and reimbursement systems.
Germany	Generally centralised	Generally, G-BA decisions are centrally implemented. However, regional variations are still expected, especially in the NUB scheme, as regional or hospital-by-hospital approaches are used to price and reimburse hospital medical devices.
Hungary	Generally centralised	The National Health Insurance Fund decides on reimbursement after consulting the National Centre for Public Health and Pharmacy (NNGYK) and the Health Professions College. The decisions are centrally implemented. There are no regional differences in the reimbursement process for drugs or medical devices.
Italy	Decentralised/ Mixed	Patient's access to medical devices is arranged separately in different Italian regions. Unlike medicinal products, where reimbursement approval and procurement processes are centralised and strictly regulated, decision-making in relation to the purchasing of medical devices is left to individual hospital committees. The pricing of some devices (for example, knee prostheses and coronary stents) is decided nationally using reference prices. However, each region can adjust the price to suit local healthcare needs.
Lithuania	Generally centralised	Generally, the VASPVT assesses medical devices, and the recommendations are assessed and implemented centrally by the Minister of Health and VLK, respectively.
Netherlands	Generally centralised	The assessment and decision-making are generally centralised. The HTA is conducted by ZIN and the Minister of Health, Welfare and Sport to determine whether to include or exclude medical devices in the basic package.
Poland	Generally centralised	The Minister of Health centrally decides on reimbursement and reimbursement conditions after AOTMiT's assessment. However, decisions by AOTMiT may not necessarily be implemented throughout Poland, resulting in regional variation in technology reimbursement.

Portugal	Generally centralised	INFARMED generally develop national recommendations. The Minister of Health decides on the recommendations for approval and national reimbursement.
Spain	Decentralised/ Mixed	Medical devices can be assessed and procured independently in the 17 autonomous Spanish regions, with the authority to make decisions differently through regional executive and legislative mechanisms. Devices can also assessed nationally by RedETS before being reimbursed nationally by the Common Portfolio of Services of the Spanish NHS.
Sweden	Decentralised/ Mixed	Each of Sweden's 21 regions and 290 municipalities handles the provision and procurement of MD within their respective healthcare budgets. However, selected medical devices may undergo a national-level assessment by TLV, and the MTP Council makes reimbursement decisions for these selected devices through the joint cooperation model for assessing and procuring medical technology.
UK	Decentralised/ Mixed	The HTA is conducted separately at three different HTA organisations: NICE in England, SHTG in Scotland, and HTW in Wales. Reimbursement decisions are made in each of the four UK nations: NHS England, NHS Scotland, NHS Wales and Health and Social Care in Northern Ireland. There is no formal legal requirement for jurisdictions within the UK to adopt HTA recommendations or reimbursement decisions from other regions, with the exception of NICE's Technology Appraisal Guidance (TAG), which is legally binding in Wales. However, HTA recommendations from different UK regions may be considered on an ad hoc basis to inform local or hospital-level procurement decisions.
Norway	Generally centralised	The system for managed introduction of new technologies in the specialist health care service (Nye metoder) is responsible for the national introduction of new technologies. The national HTA is conducted by NOMA, and final decisions are made by the Decision Forum. The Decision Forum is a decision-making group in the national system consisting of the chief executive officers of the four Regional Health Authorities.*

Key: CTIIMH-CRIDMI - Commission of Reimbursement of Implants and Invasive Medical Devices; **MoH** - Ministry of Health; **DHTC** - Danish Health Technology Council; **EHIF** - Estonian Health Insurance Fund; **FinCCHTA** - Finnish Coordinating Center for Health Technology Assessment; **COHERE Finland** - Council for Choices in Health Care in Finland; **Kela** - Social Insurance Institution of Finland; **DRG** - Diagnosis-Related Group; **LPPR** - List of Products and Services Reimbursable by Health Insurance (France); **CNEDiMTS** - Medical Device and Health Technology Evaluation Committee (France); **G-BA** - Federal Joint Committee (Germany); **NUB** - New Examination

and Treatment Methods (Germany); **NNGYK** - National Centre for Public Health and Pharmacy (Hungary); **VASPVT** - State Accreditation Service for Health Care Activities (Lithuania); **VLK** - National Health Insurance Fund (Lithuania); **ZIN** - National Health Care Institute (Netherlands); **AOTMiT** - Agency for Health Technology Assessment and Tarification (Poland); **INFARMED** - National Authority for Medicament and Health Products (Portugal); **RedETS** - Spanish Network of Health Technology Assessment Agencies; **NHS** - National Health Service; **NICE** - National Institute for Health and Care Excellence (England); **SHTG** - Scottish Health Technologies Group; **HTW** - Health Technology Wales; **TAG** - Technology Appraisal Guidance (produced by NICE); **MTP Council** - Medical Technology Product Council (Sweden); **TLV** - Dental and Pharmaceutical Benefits Agency (Sweden); **NOMA** - Norwegian Medical Products Agency
Nye metoder - The Norwegian National System for Managed Introduction of New Health Technologies; **Decision Forum** - Norwegian national decision-making group comprising the chief executive officers of the four Regional Health Authorities

* The four RHAs in Norway are: Central Norway Regional Health Authority ("Helse Midt-Norge"); Northern Norway Regional Health Authority ("Helse Nord"); Southern and Eastern Norway Regional Health Authority ("Helse Sør-Øst"); and Western Norway Regional Health Authority ("Helse Vest").

2.7.8 Generally centralised reimbursement frameworks

As of November 2024, 12 of the 21 countries exhibit a generally centralised approach to decision-making where national-level HTA bodies generate recommendations regarding technology value (Figure 2.3). This is usually followed by a central implementation of recommendations by health ministries, national insurance funds, or relevant authorities (Table 2.6). However, even in these centrally governed systems, regional uptake of medical devices in selected hospitals or regions might exist. For instance, despite having a national system for assessing and reimbursing high-risk MDs/IVDs, in France, hospitals can independently evaluate and procure devices through hospital-based HTA (Hb-HTA), contributing to regional variability (Table 2.6). For example, at Assistance Publique–Hôpitaux de Paris (Greater Paris University Hospitals; AP-HP), the Comité des dispositifs médicaux stériles (CODIMS) evaluates innovative MDs based on practitioner referrals, issuing recommendations for device use within its 39 healthcare facilities. Manufacturers cannot ask for their medical devices to be assessed by CODIMS and are not involved in the assessment process, but they still have to provide the required technical data.

Also, in Germany, despite having a generally centralised system for HTA and reimbursement, the NUB scheme (new examination and treatment methods; Untersuchungs- und Behandlungsmethoden) allows hospitals to negotiate pricing and reimbursement locally, leading to variations in how medical devices are adopted. Similarly, Finland enables rapid HTAs at the 'Wellbeing County' level to support local decisions, complementing the central processes (Table 2.6).

2.7.9 Decentralised or mixed reimbursement frameworks

On the other hand, six countries (Austria, Denmark, Italy, Spain, Sweden and the UK) operate with primarily decentralised or mixed frameworks, where regional or hospital-level entities manage reimbursement decisions independently, even in the presence of a national HTA process (Figure 2.3). For example, in Italy, medical device reimbursement decisions are left to individual hospital committees, contributing to substantial regional heterogeneity in patient access.

Similarly, in Sweden, the 21 regions and 290 municipalities determine which MDs to procure based on their healthcare budgets, resulting in highly decentralised access to MDs. However, another central mechanism for assessing and procuring medical technologies in Sweden was introduced in January 2020. The joint cooperation model for assessing and procuring medical technology was established by the joint effort of the Swedish regions, aiming to unify the use of new medical technology throughout the country. The process is initiated through horizon scanning or theme scouting programs that involve consultation with experts to identify products that could be relevant for the national-level introduction. The Medical Technology Product

Council (MTP Council, a decision-making group that is a collective representative for the regions) plays a crucial role in evaluating the feasibility and need for new technologies most relevant to the national context. The selected technologies then undergo national health technology assessments by Dental and Pharmaceutical Benefits Agency (Tandvårds- och läkemedelsförmånsverket; TLV) at the request of the MTP council. The assessments made by TLV are based on the clinical evidence and health economic material provided by the manufacturer. The MTP Council makes the final decisions on which products should be introduced nationally after the TLV evaluation.

2.7.10 Efforts to centralise reimbursement pathways in Italy and Spain in response to HTAR.

Efforts to reduce fragmentation and centralise the implementation of reimbursement decisions (and therefore standardise patient access) are ongoing in Italy and Spain. For instance, Italy proposed a new National Program for Health Technology Assessment of Medical Devices (Programma Nazionale di Health Technology Assessment dei Dispositivi Medici in Italian; PNHTA-DM) to overcome challenges in the Italian decentralised system. In this proposal, the process of reimbursement can be initiated by regional hospitals, healthcare professionals, or other stakeholders. The evaluation proposals are submitted through a designated form via the Italian National Agency for Regional Healthcare Services (AGENAS) online notification system. AGENAS is the technical and scientific body of the Italian National Health Services that carries out research activities and supports the Ministry of Health and the Regions. The proposal will be compiled and reviewed twice a year by AGENAS. The selection criteria include the potential of the technology to meet previously unmet or only partially met needs, ethical and social considerations, and economic and organisational impact, especially in terms of consistent deployment and equitable access and economic implications, among other factors. The prioritised technologies will be evaluated following the AGENAS Manual of HTA Procedures, producing a final evaluation report with a recommendation for implementation. In case of evidence uncertainty, the technology can be recommended only for research programs to produce additional scientific evidence (recommended for research purposes only) or can be introduced under restricted reimbursement locations or conditions.

Similarly, at the time of writing, Spain published a draft royal decree on 12 August 2024 in relation to regulating HTA procedures in light of HTAR. The decree seeks to establish a national governance framework through the creation of the "Governance Council", which will oversee the coordination and alignment of HTA activities with national health policy objectives. Under this framework, two specialised offices, referred to as the Offices for the Evaluation of the Efficiency of Health Technologies,

are designated to perform clinical and economic evaluations, coordinate emerging technology assessments, and develop assessment methodologies. These include the Spanish Agency of Medicines and Health Products (Agencia Española de Medicamentos y Productos Sanitarios; AEMPS) for medicines and the Spanish Network of Agencies for the Evaluation of Health Technologies and Services of the National Health System (Red Española de Agencias de Evaluación de Tecnologías Sanitarias y Prestaciones del Sistema Nacional de Salud; RedETS) for other health technologies. Notably, these offices do not have decision-making authority but instead provide evidence to support downstream regulatory decisions. Finally, the "Health Technology Positioning Group" will aim to consolidate HTA outcomes and ensure that HTA results are integrated into regulatory decisions for reimbursement and uptake. The public consultation on the draft Royal Decree concluded on 20 September 2024. Following completion of this review, the Royal Decree was approved and entered into force.

Devices will be prioritised for HTA, considering a set of criteria that are set out in the EU regulation. The evaluations under the decree consider clinical and non-clinical aspects, including effectiveness, safety, cost-effectiveness, and budgetary impact. The HTA represent elements that inform the administration's decisions but do not constitute the decision itself. It is up to the "Positioning Group" to establish the connections between the HTA reports and the decision-making in the regulatory groups.

2.7.11 Potential mechanisms to address uncertainty regarding safety and effectiveness for high-risk MDs/IVDs

For countries with reported HTA for MDs/IVDs, there is significant diversity in how each country manages uncertainty in relation to comparative safety and effectiveness evidence. Such uncertainty may originate from clinical, economic, or safety data gaps, which may be incomplete or inconclusive. A summary of how countries deal with evidence uncertainty is presented in Figure 2.4. The countries can be generally grouped into the three following main categories:

1. Countries with an established formal mechanism for addressing evidence uncertainty (eight countries; Figure 2.4), where there is a dedicated reimbursement route in case of evidence uncertainty. For these countries, the funding mechanisms, reimbursement conditions and criteria in the context of uncertainty are summarised in Table 2.7. The funding decisions, in this case, are often linked to specific criteria, the most common being the potential added clinical benefit of the device, disease severity and the device's ability to address unmet or partially met clinical needs in the national context (Table 2.7).

2. Countries with no formal mechanism to address evidence uncertainty (two countries; Figure 2.4). The absence of a coverage mechanism to deal with evidence uncertainty was confirmed by the relevant contacted organisations (Table S8).

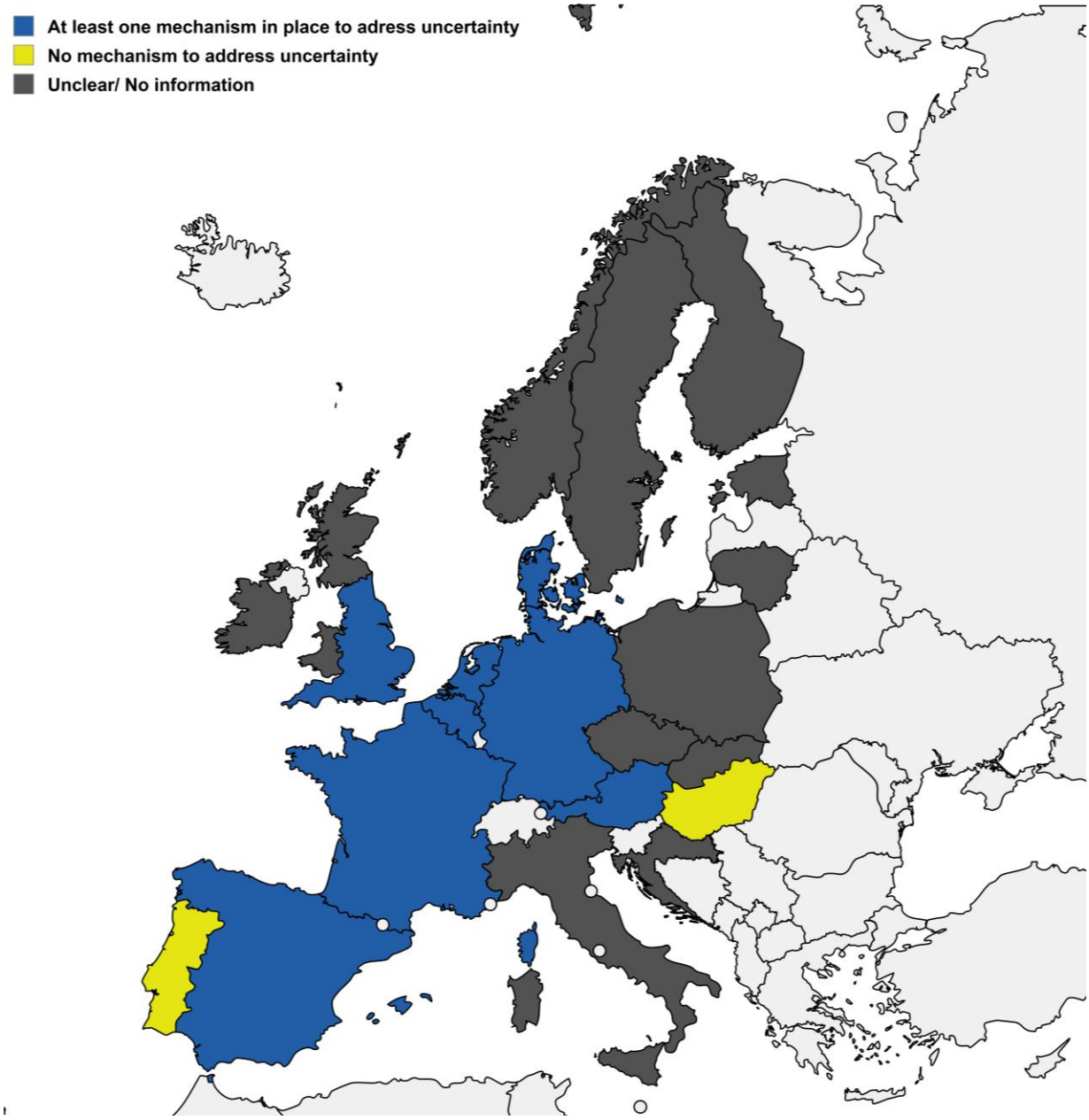
3. Countries with unclear processes or no information regarding the mechanisms for addressing uncertainty which might suggest the lack of a formal process (12 countries; Figure 2.4). This category also includes counties that might have a specific outcome for HTA in case of evidence uncertainty; however, no complementary mechanism for reimbursement has been identified.

In countries with an established formal mechanism for addressing evidence uncertainty, the devices can be reimbursed under different conditions aimed at addressing this uncertainty, including managed access agreements, reimbursement exclusively in research conditions, initiating clinical trials, and identifying evidence gaps with recommendations. The details of these countries are presented in Table 2.7.

For instance, in Austria, Belgium, Denmark and England, devices with potential benefits that meet the national criteria can be reimbursed under restricted conditions in specific healthcare facilities for restricted indications and periods with subsequent evidence generation (Table 2.7). The reimbursement decision is usually achieved after an assessment is conducted by the HTA-performing body, highlighting the evidence uncertainty.

Similarly, in Germany, if neither benefit, harm, nor ineffectiveness can be identified by the G-BA after assessment of the device, the G-BA can either wait for clinical studies which are ongoing elsewhere or initiate a clinical study in Germany to evaluate the device's benefit further. In such cases, the IQWiG will develop the study's fundamental design (PICO question, study design (RCT in most cases), study duration/length of follow-up, secondary outcomes, etc.). The study and the included device are then primarily funded by the G-BA (Table 2.7).

Figure 2.4 Formal mechanisms to address evidence uncertainty in the reimbursement of high-risk MDs/IVDs across the EU/EEA/UK (as of November 2024)



Note: Countries are categorised according to the presence or absence of mechanisms to address evidence uncertainty within their national frameworks. Only countries with reported forms of HTA for reimbursement of high-risk MDs and/or /IVDs are assessed (23 countries)

Table 2.7 Mechanisms to address the uncertainty of comparative safety and effectiveness evidence for MDs/IVDs in selected countries

Country	Mechanism(s) to address uncertainty	Criteria for eligibility and/or prioritisation	Summary of the process and reimbursement conditions	Ref.
Austria	**1. Recommended with restriction** after HTA assessment by AIHTA.	In case of evidence uncertainty, but the evidence suggests the possibility of additional benefit.	▪ The intervention (including the device) will be included as a fully reimbursable service but coupled with certain limitations (for example, it will only be available in selected hospitals with specific qualifications) ▪ The service might be subject to reassessment later after completion of registered, ongoing randomised clinical trials or fulfilling other conditions	(23,24)
	2. Preliminary exclusion after HTA assessment by AIHTA	In case the evidence of the clinical benefit is inconclusive or unavailable, and long-term effectiveness and safety are uncertain.	▪ The intervention is not reimbursed, but it may still be included in the hospital individual services catalogue as a new examination and treatment method (receive the XN-Code), allowing a three- to five-year monitoring and re-evaluation ▪ Updated assessments can be later conducted, leading to either (a) an inclusion as a reimbursable benefit, (b) prolongation of the preliminary status, or (c) the non-inclusion of medical service	
Belgium	**1. Category G (restricted clinical application (RCA) in the list**	In case there is uncertainty about the added value of a medical device compared with existing therapeutic alternatives.	▪ The decision includes restricted reimbursement conditions (specify healthcare centres or providers' requirements and the indications for which reimbursement is approved) ▪ The reimbursement decision includes a defined period for both reimbursement and re-evaluation ▪ The inclusion may also limit the number of devices reimbursed annually or in total, and criteria must be defined for inclusion on a nominative list	(25–31)
Denmark	**1. Recommendation for use in**	If the available data suggests that **(a)** the technology may be significantly better than	▪ This recommendation can include a recommendation for not using the technology in the health system until the results of the ongoing knowledge-acquisition process are available, a recommendation to use the technology	(40)

	knowledge acquisition after assessment by DHTC.	existing alternatives, but more key data is needed about its safety and cost-effectiveness, or **(b)** the technology may be highly cost-effective compared with existing alternatives, but there is insufficient evidence that it is as effective or safe as the comparator.	until the Council reassesses the recommendation based on the results of the knowledge-acquisition process or no recommendation in favour or against using the technology during the knowledge-acquisition stage (status quo) ▪ The reimbursement decision may also impose restrictions on location, specifying that the technology will be used at one or a few selected hospitals, and concurrently with this use, more knowledge will be collected to address insufficiencies ▪ The company is responsible for covering the costs of the knowledge acquisition phase. However, the Council may recommend that the five regional governments cover the expenses in exceptional cases	
France	**1. Temporary coverage under Article L165-1-5 of the French Social Security Code.**	For CE-marked innovative devices that are intended to treat serious or rare diseases or to address unmet medical needs.	▪ The devices are assessed for eligibility by CNEDiMTS. ▪ Reimbursement decisions for this scheme are made by the Ministers of Health and of Social Security following CNEDiMTS's Evaluation. ▪ The scheme offers one-year temporary reimbursements pending conventional reimbursement via the LPPR	(48,49, 115)
	2. Innovation Funding (IF) scheme.	For innovative medical devices, with limited early evidence but, are liable to provide a substantial benefit to health or reduce health expenditures.	▪ The applicant submits a proposal with a full draft protocol of the proposed study to HAS and to the Ministries of Health and of Social Security ▪ HAS assesses the application's eligibility based on the type of technology, the technology's innovative character, and the relevance of the clinical or health economic results ▪ Once HAS completes its review, it issues an opinion on the request, which could be one of three outcomes: recommended, not recommended, or recommended with observation	(48,49, 116,117)
Germany	**1. G-BA initiated clinical studies.**	If neither benefit, harm, nor ineffectiveness can be identified by the IQWiG assessment of a device, the	▪ IQWiG develops the study's fundamental design (PICO question, study design (RCT in most cases), study duration/length of follow-up, secondary outcomes, etc)	(52,117)

		G-BA can either wait for clinical studies (ongoing elsewhere) or initiate a clinical study in Germany.	▪ The study's funding will be provided by G-BA unless the manufacturer offers to finance the trial	
	2. Coverage with the evidence development scheme (CED) (§137e SGB V).	In case of evidence uncertainty, the CED scheme allows for the reimbursement of devices while additional evidence is being collected. The device must meet the criteria of "potential" (that is, promising effectiveness).	▪ A dossier is submitted for CED by manufacturers and those who apply the new procedures ▪ The G-BA makes the final decision on incorporation in the CED after the IQWiG assessment ▪ The study itself is funded by the G-BA ▪ Once the study is completed, the G-BA arrives at a final conclusion on general reimbursement	
The Netherlands	**Potentially Promising Care Pathway**	For innovative medical devices and services with uncertainty in the long-term value.	▪ Enables conditional reimbursement of devices strictly within research conditions. Devices approved under this scheme are not added to the basic healthcare package. Instead, funding is contingent on conducting parallel research to collect data on the device's safety, effectiveness, and cost-effectiveness during the reimbursement period ▪ At the time of writing, the program was closed to new applications; discussions were ongoing regarding the possibility of initiating a new iteration or reviving the program	(69,72, 117)
Spain	**Post-launch evidence-generation studies (Estudios de Monitorización)**	Quantitative prioritisation criteria are used for coverage decisions. The criteria include disease burden, innovation element, safety, financial and organisational aspects, costs and other implications.	▪ Technologies are identified by the National Commission of Provision, Insurance and Financing (CPAF) of the Ministry of Health and selected by the Directorate General of the common portfolio of services of the National Health System (NHS) and Pharmacy (DGPSPh), which are usually identified from previous HTA reports from RedETS ▪ Devices selected for coverage are reimbursed only with research in selected healthcare centres identified at the regional level	(118)

England	**1. Guidance recommendation for use only in Research after NICE assessment**	For technology with insufficient or uncertain evidence but with potential benefits.	▪ The recommendation comes without a requirement for NHS funding. The device is only recommended for use exclusively in research settings	(96)
	2. Guidance recommendation with data collection	For technologies that could provide substantial benefits to patients or healthcare systems. However, considerable uncertainty exists about whether the expected benefits are realisable in the NHS.	▪ The device may be fully or partially used as an option in the NHS during the evidence-generation period	

Key: AIHTA – Austrian Institute for Health Technology Assessment; **CED** – coverage with evidence development; **CNEDiMTS** – National Commission for the Evaluation of Medical Devices and Health Technologies; **CPAF** – National Commission of Provision, Insurance and Financing; **DGPSPh** – Directorate General of the Common Portfolio of Services of the National Health System and Pharmacy; **DHTC** – Danish Health Technology Council; **G-BA** – Federal Joint Committee (Gemeinsamer Bundesausschuss); **HAS** – French National Authority for Health (Haute Autorité de Santé); **HTA** – health technology assessment; **IF** – Innovation Funding; **IQWiG** – Institute for Quality and Efficiency in Health Care; **LPPR** – List of Reimbursable Products and Services (Liste des Produits et Prestations Remboursables); **NHS** – National Health Service; **NICE** – National Institute for Health and Care Excellence; **PICO** – population, intervention, comparator and outcome; **RCA** – restricted clinical application; **RCT** – randomised controlled trial; **RedETS** – Spanish Network of Agencies for Health Technology Assessment and Services of the National Health System; **SGB V** – German Social Code Book V.

Certain countries have innovative funding schemes that the manufacturer can apply for directly in case of evidence uncertainty (Table 2.7). If successful, the technology can receive temporary coverage pending further evidence collection. For instance, in France, innovative MDs that do not fit the standard reimbursement models can be reimbursed through two key schemes, the first being the Temporary Coverage under Article L165-1-5 of the French Social Security Code (CSS). This scheme allows for one-year temporary reimbursement for innovative devices intended to treat serious or rare diseases or to address unmet medical needs, pending conventional reimbursement via the LPPR. The CNEDiMTS determines eligibility based on a set of criteria that assess whether the device is intended for a serious or rare disease, if it addresses a partially or completely unmet medical need, its likelihood of significantly improving patients' health, and if it offers substantial and relevant clinical benefits with acceptable adverse effects. Reimbursement decisions for this scheme are made by the Ministers of Health and Social Security following CNEDiMTS's evaluation.[48,49,115]

A second scheme under the French system is the Innovation Funding (IF) Scheme, which offers partial or full funding for a limited period, contingent upon the manufacturer conducting a clinical or cost-effectiveness study, which must be comparative. The funding is aimed at gathering evidence to assess the value of the medical device in case of limited early evidence establishing that it is liable to provide a substantial benefit to health or reduce health expenditures. HAS assesses the device regarding a combination of specific criteria that cover the type of technology involved, the technology's innovative character, and the relevance of the clinical or health economic study proposed by the applicant. Once HAS completes its review, it issues an opinion on the request, which could be one of three outcomes: recommended, not recommended, or recommended with observation. The recommended applications are then transferred to the Minister of Health for funding decisions. [48,49,116,117]

A similar scheme also operates in the Netherlands in case of evidence uncertainty, where MDs/IVDs can be funded under the Potentially Promising Care pathway. This research programme enables the funding of the devices strictly within research conditions, where devices approved under this scheme are not added to the basic healthcare package. Instead, funding is contingent on conducting parallel research to collect data on the device's effectiveness, safety, and cost-effectiveness during the reimbursement period. It is worth mentioning that the program was closed to new applications at the time of writing; discussions are ongoing regarding the possibility of initiating a new iteration or reviving the program.

Similarly, the G-BA operate a coverage with evidence development (CED) scheme in case of evidence uncertainty, allowing for the reimbursement of devices while additional evidence is being collected. This voluntary process (§137e SGB V) can be initiated by submitting a dossier for CED by manufacturers and those who apply the new procedures. The IQWiG is responsible for HTA, evaluating whether the application meets the criteria of "potential" (that is, promising effectiveness). Subsequently, the G-BA makes the final decision on incorporation in the CED. Within such a program, the study itself is again funded by the G-BA, while reimbursement for non-study participants remains unchanged.[64] Once the study is completed, the G-BA arrives at a conclusion on general reimbursement.

2.8 Discussion

This review aimed to provide a comprehensive overview of the reimbursement pathways and decision-making frameworks for high-risk MDs and IVDs across the EU/ EEA and the UK.

The findings of this review are particularly relevant given the implementation of the HTAR, which mandates that Member States give "due consideration" to JCAs when making national reimbursement decisions. Unlike previous voluntary cooperation efforts, the HTAR requires countries to integrate JCA outputs into their decision-making processes.[9] This represents a significant shift, particularly for countries where HTA is not a formal part of reimbursement pathways yet or countries with developing or yet-to-be-developed HTA processes for high-risk MDs/IVDs. The degree to which national systems align with this requirement will determine the extent to which JCAs effectively harmonise clinical assessments across the EU/EEA.

The review also highlights the significant disparity between the HTA processes for medicines and those for MDs. Unlike medicines, where HTA is often a prerequisite for reimbursement decisions, with structured methodologies for assessing clinical and economic value, MDs follow more heterogeneous pathways. HTA for medical devices in many countries remains optional, advisory, or fragmented across regional and hospital-based processes, limiting its role in reimbursement decisions. This

structural misalignment indicates that there may be challenges for some Member States to comply with HTAR requirements for high-risk MDs/IVDs, unless changes to their national frameworks are implemented, achieving the HTAR's goal of harmonising evidence generation and ensuring consistent integration of JCAs for MDs/IVDs will be more complex compared to medicines.

With the implementation of the HTAR now in effect as of 12 January 2025, this review seeks to support ongoing knowledge-sharing and experience exchange among countries to facilitate the regulation's successful full implementation.

As the HTAR came into full effect for MDs/IVDs in 2026, countries are actively adjusting their processes to comply with the regulation. However, the extent and nature of these changes remain largely unclear, and further work is needed to capture how national frameworks are evolving in response. Continued research and engagement with national HTA bodies and decision-makers will be important to facilitate experience-sharing, identify best practices, and support a more coordinated approach to implementing JCA recommendations across the EU/EEA.

2.8.1 Summary of key findings and implications

2.8.1.1 Diversity in reimbursement pathways and HTA role in reimbursement decision

The reimbursement pathways for high-risk MDs/IVDs varied widely across the reviewed countries. Some countries had well-established, centralised HTA processes that were a formal part of reimbursement frameworks for MDs and IVDs. In these countries, technologies were assessed by a central HTA-performing body after submission by different stakeholders, with assessment criteria reflecting the national needs and healthcare priorities. The positive HTA recommendation was contingent on demonstrating added clinical benefit and, in certain cases, cost-effectiveness. Reimbursement decisions in these countries were primarily based on HTA recommendations and were made by independent national authorities, leading to a homogeneous introduction of technologies into the healthcare system. These countries are potentially well-positioned to integrate JCAs under the HTAR into their national frameworks, as they already have a robust HTA-guided reimbursement process in place. Furthermore, the HTAR's emphasis on harmonised clinical assessments aligns with their existing processes, potentially streamlining the adoption of JCAs.

Other countries had a more advisory HTA process, where HTA was not a formal part of the reimbursement pathways for high-risk MDs/IVDs. In these countries, HTA was generally undertaken in an ad-hoc and/or limited manner for high-risk MDs/IVDs. These countries may potentially face challenges integrating JCAs into their

processes, as reimbursement decision-making may not consistently use HTA advice or recommendations. Capacity-building and support, along with policy and or legislative changes, may be needed at a national level to ensure that HTA bodies can effectively utilise the outputs of JCAs and align national processes to comply with HTAR requirements.

The clear east-west divide in publicly available information about reimbursement processes is a notable pattern in this review. Western European countries with more established and centralised HTA frameworks generally make their reimbursement decision-making processes publicly available. Several Eastern European countries and smaller states across the EU/EEA had limited publicly available data, which may reflect limited structured HTA processes. Addressing these transparency gaps will be important for the successful implementation of HTAR and for knowledge sharing between Member States. In countries with no formal HTA process for high-risk MDs/IVDs, reimbursement decisions may be made through administrative or policy-driven processes, often without systematic clinical or economic evidence evaluation. In these countries, high-risk devices may be reimbursed through local procurement or ad hoc evaluations, leading to variability in patient access and limited reliance on evidence-based decision-making. The lack of a formal HTA process challenges the provision of equitable access to high-risk MDs/IVDs and the alignment with HTAR. These countries may require significant capacity-building and support, as well as policy and or legislative changes, to develop HTA systems and integrate JCAs into their reimbursement frameworks to comply with HTAR requirements.

2.8.1.2 Regional variations and equity in patient access to medical devices

This scoping review highlighted substantial regional variations in the reimbursement decision-making processes of high-risk MDs/IVDs, with countries having either centralised frameworks for HTA and reimbursement, decentralised approaches, or mixed systems.

Countries with mainly decentralised or mixed assessment and procurement decisions may have to integrate JCA in both regional and national frameworks to align with HTAR requirements, which may present additional challenges.

For instance, at least two countries in this review (Italy and Spain) have made substantial progress toward integrating HTA within the national reimbursement decision-making framework for high-risk MDs and unifying the reimbursement frameworks. In Italy, the proposed PNHTA-DM addresses long-standing issues associated with decentralisation by introducing a centralised, structured process for evaluating and prioritising MDs. Overseen by AGENAS, the programme plans to use criteria, the most important of which is the unmet medical needs to guide

assessments. The programme also integrates decision-making pathways to deal with evidence uncertainty, a unique aspect of the national assessment system. This marks a critical shift toward standardising reimbursement decisions and patient access across Italy's 20 regions.(65) Similarly, Spain's royal decree aims to establish a unified HTA framework for medical devices, aligning with the HTAR's objectives. The system includes bodies like the Governance Council and the Health Technology Positioning Group to oversee clinical and economic evaluations, ensuring transparency and stakeholder involvement. Both countries' efforts highlight the importance of centralised decision-making and evidence-based approaches in addressing regional disparities and evidence gaps. Both countries' developments demonstrate steps to align national structures to complement the HTAR's goals, providing an example for reforming decentralised systems to harmonise HTA processes while maintaining flexibility to address local healthcare needs.(119)

Even within countries with mainly centralised HTA systems, regional variations persist but to a lesser extent. For instance, in Germany, the NUB scheme allows hospitals to negotiate reimbursement for devices not covered by the Diagnosis-Related Group (DRG) system, leading to variability in access. Similarly, hospital-based HTA processes in France enable individual institutions to evaluate and procure devices independently, contributing to regional disparities. Similarly, in a survey of professionals practising hospital-based Hb-HTA in France (approximately 42% of the national healthcare supply in terms of bed capacity), the survey revealed that most respondents (91%) reported the existence of an established process specifically for evaluating innovative MDs in their institution. These processes often include a multidisciplinary committee to guide the selection and adoption of new devices intended for individual use. Additionally, nearly 24% of respondents mentioned having a dedicated HTA unit within their facility, which typically functions as a scientific committee tasked with summarising and interpreting evidence related to these devices.[119,120] While the regional nature of these systems allows for greater adaptation to regional healthcare needs, the differences in patient access across the country represent an equity challenge that the JCAs might aid in its resolution.[60]

2.8.1.3 Access to innovative devices and mechanisms to address evidence uncertainty

A critical challenge in patient access to MDs is the management of evidence uncertainty, especially for innovative devices that might have an expected significant added benefit or address unmet or partially met healthcare needs or other national priorities but have limited clinical trial data. Within the reimbursement frameworks for high-risk MDs/IVDs, at least eight countries in this review had established formal mechanisms to address evidence uncertainty.

These mechanisms included conditional reimbursement with evidence development or restricted access agreements, as described in countries such as France, Germany, and England. These schemes allow temporary reimbursement of innovative devices with expected added benefits. At the same time, additional evidence is collected, resulting in timely patient access to promising technologies while addressing evidence gaps through real-world data collection. Other countries employed specific innovation funding and research-based reimbursement, where innovative devices with incomplete or uncertain evidence can apply for particular schemes to be funded exclusively in research conditions. These schemes allow further evidence generation, with restricted patient access in clinical trials before broader adoption.

The mechanisms described above play a crucial role in facilitating access to cutting-edge technologies while minimising the risks associated with evidence gaps, particularly for patients with rare diseases or unmet medical needs. These mechanisms focus on timeliness of access by enabling faster access to innovative devices than traditional reimbursement pathways, which may require extensive evidence upfront. However, there may be some challenges with the successful development and implementation of such systems at the national level for some countries.

Indeed, the integration of JCAs into the well-established frameworks for addressing evidence uncertainty may not require significant adjustments. The JCAs can complement these frameworks by providing a standardised, EU-wide approach to clinical assessments. Still, each country might retain a form of local mechanism that prioritises the assessment of devices that are most important for their specific healthcare context, ensuring that national priorities are addressed without duplicating JCA efforts.

Of note, most countries in this review lacked formal mechanisms to address evidence uncertainty, relying instead on ad hoc evaluations or local procurement processes. This gap may hinder the timely adoption of certain innovative technologies that might partially or completely fulfil unmet medical needs. The introduction of JCA is expected to improve the quality of evidence for MDs/IVDs and reduce the level of uncertainty in national reimbursement decisions, over time. The structured nature of the assessment scope proposals, which is designed to align with policy-driven national needs, may indirectly shape industry practices.[120] By requiring manufacturers to address specific research questions relevant to multiple Member States, JCAs should encourage the generation of more relevant and robust evidence, reducing uncertainty in the evidence submitted for consideration. Additionally, the implementation of joint scientific consultations (JSC), which provides for early-stage consultation with the health technology developers, has the potential to improve the quality of clinical trial data for MDs/IVDs in the medium to

long term, which again enhances the evidence base available for reimbursement decisions.[13]

2.8.2 Strengths and limitations

A key strength of this review was its ability to capture the reimbursement pathways and HTA involvement for high-risk MDs/IVDs across 31 European countries, most of which will be affected by the HTAR. Also, the diversity of sources used to extract the data, which include official websites, national policy documents, publications and grey literature, ensures a well-rounded and evidence-based analysis. Another key strength of this review is the high verification rate by the national organisations, as information for 88% of the countries was verified by national organisations, providing a reliable and current portrayal of national processes.

However, one notable limitation of this review was the limited information on HTA involvement and reimbursement processes for MDs/IVDs for many countries. Also, while the lack of language restrictions in this review might be a strength, the reliance on translation software and or websites might limit the accuracy of the data. Additionally, direct engagement (for example, follow-up meetings) with HTA professionals was beyond the scope of this work, which might limit the ability of this review to capture the broader policy landscape and ongoing (but undocumented) changes within each country.

2.9 Conclusion

The introduction of the HTAR presents a unique opportunity for Europe to standardise clinical evaluations, enhance patient safety and improve access to high-risk MDs/IVDs with added benefits. However, the success of the HTAR, particularly for high-risk MDs/IVDs, may depend on the ability of individual countries to adjust their national frameworks to take into consideration the JCA reports.

This review highlighted the significant variations in how EU/EEA/UK countries integrated HTA into national reimbursement frameworks for high-risk MDs/IVD, how national decisions were implemented and how the uncertainty of evidence was assessed. Some countries had a well-established reimbursement framework for high-risk devices, where HTA was a formal process component, and reimbursement decisions were primarily based on HTA results. On the other hand, other jurisdictions relied on more ad-hoc HTA processes for high-risk devices, with reimbursement decisions not necessarily driven by HTA outcomes. Understanding these differences and sharing experiences can help optimise the use of HTAR-generated evidence. Further research is needed to capture ongoing reforms and anticipated changes in response to the HTA.

3 The early experiences of health technology assessment bodies in the implementation of the EU HTA Regulation (HTAR) for high-risk medical devices: A qualitative study

Key Points

- The Health Technology Assessment Regulation (HTAR) represents a major change in the assessment of high-risk medical devices (MDs) and in vitro diagnostics (IVDs) across Europe. Through Joint Clinical Assessments (JCAs), HTAR seeks to establish a common approach to evaluating comparative clinical effectiveness and safety while maintaining Member States' authority over national reimbursement decisions. Understanding how national HTA bodies are preparing for this transition is essential to supporting successful implementation.
- This chapter explored how national Health Technology Assessment (HTA) bodies across the EU/EEA were preparing for the implementation of the EU HTAR for high-risk MDs/IVDs. The study was designed to complement the findings of the preceding scoping review by examining how national stakeholders anticipated integrating Joint Clinical Assessments (JCAs) into existing assessment and reimbursement processes.
- To explore these issues, semi-structured interviews were conducted with representatives from 11 national HTA bodies across Austria, Belgium, Estonia, Finland, France, Germany, Ireland, Italy, Norway, Slovakia and Sweden. Interviews were undertaken between January and April 2025 and analysed using reflexive thematic analysis. Four overarching domains were identified: (1) current national structures and challenges, (2) anticipated adaptations in response to HTAR, (3) opportunities introduced by HTAR, and (4) perceived barriers to implementation.
- The participating countries represented a broad spectrum of HTA maturity, ranging from countries with well-established HTA systems for medical devices to countries where HTA remained an emerging or developing component of reimbursement decision-making.
- Participants described substantial variation in the maturity, organisation and integration of HTA for high-risk MDs/IVDs across Member States. While some countries operated formal, legally defined HTA processes linked to reimbursement decisions, others relied on more flexible, decentralised or

emerging systems. Participants consistently reported challenges associated with limited clinical evidence, poor-quality submissions, weak links between HTA and reimbursement decisions, and the absence of incentives for manufacturers to seek formal assessment. Furthermore, several countries were actively developing or strengthening national HTA structures for MDs. These reforms included creating more systematic assessment processes, introducing clearer criteria for device selection, and improving the link between national assessments and procurement decisions.

- Despite these differences, interviewees expressed broad support for the objectives of the HTAR and recognised its potential to improve the assessment of high-risk MDs/IVDs. Most participants expected that JCA reports would be incorporated into the clinical evidence component of national assessments. However, national assessments would still be required to address economic, organisational, ethical, legal and country-specific considerations that remain outside the scope of the JCA process.
- While most countries had not yet implemented major legal reforms, many participants acknowledged that legislative changes may ultimately be required to formally embed JCA outputs into national processes. Some countries have already introduced reforms designed with HTAR implementation in mind.
- Participants identified several opportunities associated with HTAR implementation. These included improving the quality of evidence available for reimbursement decisions, encouraging manufacturers to consider HTA requirements earlier during technology development, reducing duplication of effort across Europe. At the same time, interviewees highlighted a range of challenges that may affect successful implementation including regulatory and procedural uncertainty, methodological complexity, national relevance of European PICOs and potential timing misalignment between JCA outputs and national reimbursement cycles.
- The findings suggest that the success of HTAR implementation will depend not only on the quality of JCAs themselves, but also on how effectively European-level assessments can be integrated into diverse national decision-making frameworks. While participants viewed HTAR as a significant opportunity to improve evidence-based decision-making for high-risk MDs/IVDs, they emphasised the need for continued collaboration, capacity-building, methodological refinement, and stakeholder engagement during the implementation process.

The information in this chapter was published as an academic publication: *Alshaikh RA, Walsh KA, Spillane S, Harrington P, O'Neill M, Teljeur C, Ryan M, O'Driscoll CM.*

The Early Experiences of Health Technology Assessment Bodies in the Implementation of the European Union Health Technology Assessment Regulation for High-Risk Medical Devices: A Qualitative Study. Value Health. 2025 Dec 6:S1098-3015(25)06151-0. doi: 10.1016/j.jval.2025.11.013.

3.1 Introduction

Patient access to new health technologies often requires evidence that the technology provides positive patient-related and or economic outcomes compared with current treatment. This evidence is frequently assessed through a national HTA process.[121] In most European countries, HTA systems have been designed primarily around medicinal products, and have only been extended more recently to include medical devices (MDs) and in vitro diagnostics (IVDs).[13] Such extension has been fragmented, and often inconsistent as described in Chapter 2.

The regulatory environment for MDs and IVDs has undergone major reform over the past decade. HTAR (EU 2021/2282),[7] which entered full application on 12 January 2025, streamlines and standardises the assessment of health technologies, including medicines and high-risk MDs and IVDs, across the 27 EU Member States. For high-risk MDs/IVDs, the HTAR complements the MDR (EU regulation 2017/745)[4] and the IVDR (EU 2017/746),[5] which were primarily motivated by patient safety concerns and an ambition to improve evidence quality for MDs/IVDs. As of 2026, the HTAR has applied to a selection of high-risk MDs/IVDs as defined in the Regulation, which represents a critical shift in how clinical evidence of these devices are assessed in Europe.[7,122]

The HTAR establishes a framework for joint clinical assessment (JCA), joint scientific consultation (JSC), horizon scanning, and voluntary collaboration between Member States, aiming to improve patient access to innovative health technologies with added benefits, support evidence generation, and reduce duplication of effort for health technology developers (HTDs) and national HTA bodies.[7]

JCA is one of the cornerstones of the HTAR implementation, aiming to produce a single, EU-level clinical evidence report. JCAs are based on a dossier submitted by a HTD according to a pre-defined PICO (Population, Intervention, Comparison, and Outcome), which is subsequently appraised by HTA bodies in two Member States and must be used by all Member States when evaluating the relative efficacy and safety of health technologies, including high-risk MDs/IVDs. In parallel, HTAR preserves Member States' autonomy in evaluating non-clinical domains such as cost-effectiveness, budget impact, and broader health system considerations.[9]

Conformity with the HTAR requirements will support evidence-based decision-making and safeguard patient outcomes, particularly for high-risk technologies where safety considerations are paramount. To date, academic and policy attention has focused on the HTAR's design, its implications for medicinal product assessments, and the views of HTDs and European institutions.[122,123] However, questions remain about how national HTA bodies are preparing to adjust (or not, as

the case may be) their systems to accommodate JCAs for high-risk MDs/IVDs, and how this will affect national funding decisions.

Chapter 2 of this report presented a comprehensive scoping review that systematically mapped the existing HTA and reimbursement pathways for high-risk MDs/IVDs in EU/EEA Member States and the UK prior to the implementation of HTAR. That review revealed substantial variation in how HTA for high-risk MDs/IVDs was defined, structured, and integrated into reimbursement decisions. Some countries operated formalised national frameworks in which HTA outcomes directly informed coverage decisions; others relied primarily on decentralised or hospital-based procurement with limited national oversight. Collectively, these findings illustrated a landscape marked by heterogeneity and uneven maturity. The review also raised important questions about how national systems will interact with and adapt to the forthcoming EU-level processes established under the HTAR.

To explore these issues in greater depth, the current qualitative study was designed to complement the findings from the scoping review (Chapter 2). This study aimed to explore how selected Member States in the EU/EEA were planning to implement the HTAR, specifically for high-risk MDs/IVDs. Through a qualitative semi-structured interview study with representatives from national HTA bodies, the evaluation team examined how these bodies perceive the role of JCA, the changes they are undertaking (if any) in response to HTAR, and the challenges and opportunities associated with embedding EU-level evidence into national reimbursement systems, specifically for high-risk MDs/IVDs.

3.2 Methods

3.2.1 Study design and ethical approval

This qualitative study explored whether and how national systems are adapting their evidence assessment and reimbursement processes for high-risk MDs/IVDs in anticipation of JCA through semi-structured interviews with key stakeholders from HTA bodies. The study focused on representatives from national HTA bodies because these organisations are central to evidence generation, assessment, and interpretation under the HTAR through their involvement in the JCA process and are key contributors to the scientific and procedural components that inform reimbursement decisions. While HTA bodies do not typically design reimbursement processes in the Member States, they play a critical role in synthesising the evidence base and advising national payers or ministries of health. The reporting of this study was aligned with the Consolidated Criteria for Reporting Qualitative Research (COREQ) (Supplementary Table S9).[124] The study received ethical approval from University College Cork Social Research Ethics Committee (approval number: SREC 2024-206) and was conducted accordingly. The consent procedures aligned with the

General Data Protection Regulation (GDPR) and the University's research ethics policies.

3.2.2 Identification of participants, study settings and data collection

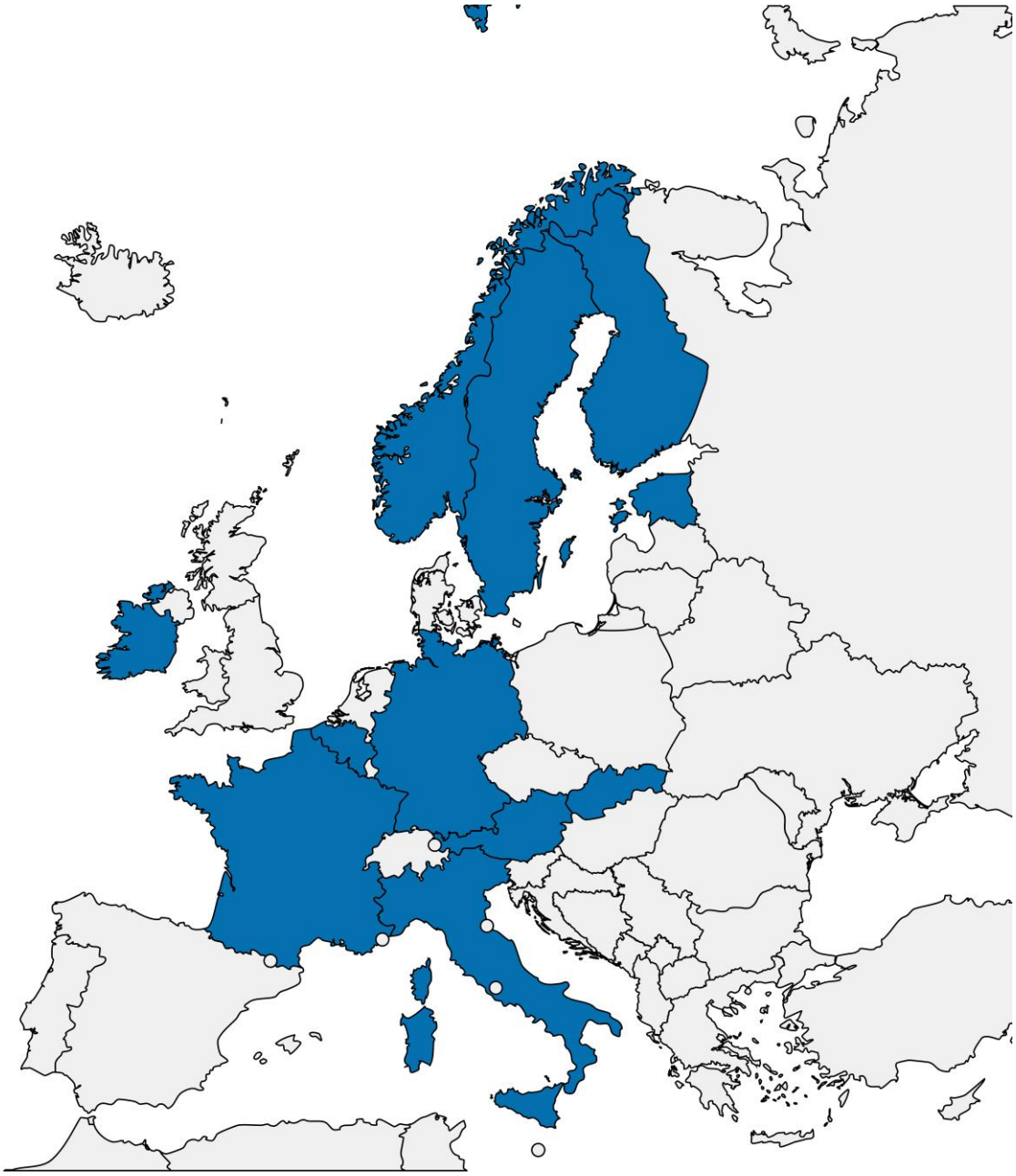
HTA bodies were first identified based on their engagement in a prior scoping review led by the evaluation team (Chapter 2),[125] which mapped national HTA and reimbursement frameworks for MDs/IVDs across all EU/EEA Member States and the UK. Of note, participants from the UK were excluded from the current qualitative study, given that the UK is not subject to the HTAR. Potential interview participants were identified by contacting national HTA bodies using publicly available information or the authors' networks. The invitations to participate were sent to participants representing HTA bodies in the 30 EU/EEA Member States.

The semi-structured interviews were conducted virtually via Microsoft Teams. Interviews were conducted by a member of the evaluation team (RA), and an independent research pharmacist working in an academic setting and collaborating with HIQA in the conduct of the interviews (Supplementary Table S9). The interviews were conducted in English and followed a pre-developed topic guide presented in the Supplementary Table S10. The topic guide was iteratively developed and informed by data from the scoping review (Chapter 2). Participants provided written informed consent, and all interviews were video- and/or audio-recorded with the participant's consent and transcribed verbatim. A pilot interview was conducted with a representative from HIQA to test the topic guide, but the data were not included in the thematic analysis.

3.2.3 Data analysis

All transcripts were pseudonymised before analysis, all identifying information was deleted, and each interview was assigned a randomly generated identifier. Reflexive thematic analysis, as described by Braun and Clarke was performed in a combined deductive-inductive manner.[126] An initial coding framework was built around key topics identified in the interview guide and was refined iteratively as new themes were identified from the analysis. Three coded transcripts were independently reviewed by a second researcher with experience in qualitative methodologies (Walsh KA), and discrepancies were resolved through discussion and agreement. The coding was done with NVivo® software (Release 14.23.3).

Figure 3.1 Geographic distribution of the 11 EU/EEA Member States that participated in the semi-structured interviews (in blue)



3.3 Results

This study explored the perspectives of representatives from national HTA bodies in selected EU/EEA Member States regarding the implementation of the HTAR for high-risk MDs/IVDs in their national frameworks. A total of 11 HTA bodies from 11 Member States agreed to participate in the interviews. Representatives of six Member States declined to participate, and there was no response to the request for an interview from 13 states. The participating HTA bodies represented Member States with varying levels of HTA maturity for MDs/IVDs, with some having well-established HTA systems and others where the HTA process is emerging or not yet fully integrated into reimbursement processes (as described in Chapter 2).[125]

The 11 interviews took place between January and April 2025, including a pilot interview, across 11 EU/EEA Member States: Austria, Belgium, Estonia, Finland, France, Germany, Ireland, Italy, Norway, Slovakia, and Sweden (Figure 3.1). A total of 15 participants were interviewed (four interviews had two participants), with an average of 12 years of experience in HTA and related fields. The demographic information of all participants is presented in Table 3.1.

Table 3.1 Characteristics of the HTA bodies represented (n =11) and interview participants (n = 15)

Characteristics of the HTA bodies represented (n=11)	HTA bodies represented, n
HTA bodies from member States with a formal HTA component within reimbursement frameworks for high-risk MDs/IVDs.*	6
HTA bodies from member States with an optional HTA component within reimbursement frameworks for high-risk MDs/IVDs.	5
Characteristics of interview participants (n =15)	**Participants, n**
Gender	
Female	12
Male	3
Other	0
Years of professional experience in HTA	
< 10	6
10-19	5
≥ 20	4
Area of expertise (as described by participants)	
Health economics and related fields	6
Medical devices, non-pharmaceutical assessments, and related fields	7
HTA, HTA methods, and related fields	2
Familiar with national plans for HTAR implementation	
Yes	15
No	0

Key: HTA – health technology assessment**; HTAR –** Health Technology Assessment Regulation**; IVDs –** in vitro diagnostic medical devices**; MDs –** medical devices**.**

Note: *Definitions of "formal" and "optional" HTA components were based on findings from Chapter 2.

The interviewees' views and perspectives were analysed using thematic analysis. Reflective themes were grouped into four overarching domains: (1) the current national structure and existing challenges of HTA and reimbursement for MDs/IVDs; (2) planned or expected adaptations in national structure in response to HTAR; (3) expected opportunities introduced by the HTAR; and (4) perceived challenges and barriers in adapting to HTAR requirements. The overarching domains identified and key themes and subthemes under each domain are presented in Figure 3.2. Furthermore, Figure 3.3 provides an expanded, detailed view of the two forward-looking domains (domain 3 and domain 4) with their themes and subthemes. Illustrative quotes are embedded within the text to highlight key insights from the participants within each domain; additional supporting quotations are presented in Table 3.2.

Table 3.2 Key quotes from participants across the four overarching domains

Overarching domain	Key quotes	Interview number
(1) The current national structure and existing challenges of HTA and reimbursement for MDs/IVDs.	*"Most of the time, the clinical data are quite limited, and the company asks for reimbursement anyway."*	Interview 5
	"The evidence-based standards for medical devices are categorically lower [than] evidence standards in drugs."	Interview 6
	"The quality of the dossiers that are submitted [for MD] is very poor, and the data are very scarce."	Interview 7
	"We don't have clear incentives yet on why the companies should submit their product for HTA."	Interview 2
	"For medical devices, we don't have this same obligation. So it has been more or less, not random, but not a very systematic process for getting the medical devices through this national HTA system."	Interview 2
	"I don't know why, but from the beginning, it was like for MD, the quality of data should be less than for medicines, but that's not true; it should be as good as for medicines. I mean, it might be a bit more difficult sometimes to get randomised control trials but we have to go there and to get there now.	Interview 7
(2) Planned or expected adaptations in	*"Maybe something changes in 2026 or 2027. But at this moment, we don't know how it will go."*	Interview 3

national structure in response to HTAR	*"We're not starting with medical devices just yet. But, we are having a dialogue with the [relevant national bodies] on how they will handle the JCA reports when they start arriving."*	Interview 4
	"I think we're still trying to figure out how we will incorporate it [the JCA] in our evaluation reports of the medical device …… But it comes with a lot of extra workloads just purely to make sure that we are legally covered because everything that has to change in our Regulation."	Interview 5
	"It will be very interesting to make this survey within one or two years when we will have the first assessment, the first JCA and the first JSC. I think it will be very interesting too."	Interview 7
	"I think we're still trying to figure out how we will incorporate it in our evaluation reports of the medical device, but yeah, it should be mentioned somewhere…. But, we're still trying to figure out how exactly that incorporation should be, but it's still in the step of evaluation for sure."	Interview 5
	"So in essence, these two processes [national assessments and JCA] are most likely to coexist and will only influence each other if possible without any real problems."	Interview 9
	"It [the JCA] has to be adapted in the law that covers our process, and that already is a long process, but we can't start it yet because we don't know what we should adapt."	Interview 5
	"The question will be in which time frame the topics for the HTAR will be announced, because we cannot change the national process, so we can only try to fit in evidence that is generated by this joint assessment into the process, because it is an annual process by law."	Interview 10
	"Since a couple of months back, I started even more to prepare a bigger part of the [organisation] for this. So, in the first years, we were just like a handful of people in the agency working with this, but now, as it's coming closer and closer, we're involving more people and spreading the knowledge."	Interview 4
(3) Expected opportunities introduced by the HTAR	*"But of course, work sharing, it's a new thing with the Regulation. There has been voluntary cooperation in Europe for years, but this is now in legislation that we collaborate on assessments on effectiveness, relative effectiveness and safety. That's something new!"*	Interview 2
	"I work in this position for 15 years now, and I think in the last three or four, five years I have had much more contact with European partners than in the 10 years before."	Interview 9

	"This is the biggest experiment in HTA in the world….. so many people have invested a lot into it, getting to where it is right now. "	Interview 6
	"I think we hope that it will increase the quality of the reimbursement demands. Because sometimes now, the evidence is not there or very, very weak."	Interview 5
	"It also makes HTA more visible and also visualises what HTA is and what the requirements are for HTA compared to CE marking, for instance."	Interview 2
	"We will also gain power by using our joint forces, we will be able in the field of pharmaceuticals at least to have a joint pressure that can be exerted on manufacturers, and this helps transparency."	Interview 9
	"And also, you know, avoidance of duplication of work because we have a lot of examples where different countries have assessed exactly the same technology."	Interview 2
	"Because less experienced [countries] will get more experience, and I know some of the countries in Europe do not have HTA agencies or are about to start them. So I think, without the Regulation, it might have been more difficult."	Interview 2
	"In a few years with the JCA process or the JSC process, [health technology developers] will maybe grow in the way they see clinical evidence building and that will be a good thing at some point …"	Interview 5
	"Once the topic comes up in one or the other way, that we say, look, there is already an assessment so that we wouldn't duplicate the work."	Interview 10
	"Also that the industry starts thinking earlier about what are the needs of HTA bodies, what [are] the data sets because currently I have the feeling that it's more about how to get the marketing authorisation, how to get the CE mark and then you know, then HTA bodies or payers start asking, OK, but what about comparison? Why did you do that kind of study? … . So I hope we are not asking them in a later stage, but those questions get more relevance in earlier stage, that companies understand that you have to start to provide the data."	Interview 8

	"…maybe a change in the way that the medical devices companies approach the clinical evidence that they would have to submit in order to get a reimbursement"	Interview 5
	"There should not be a link between the size of the manufacturers and the quality of the data …. We have a lot of work to convince the manufacturers that the world is changing."	Interview 7
	"So if I imagine the world ten years from now, when MDR is actually in place, and a category 2B and 3 does come with higher evidence standards. In this world, JCA on these medical devices will definitely be welcome and definitely useful. But as we get into that stage, I think there'll be loads of bumps on the way."	Interview 6
(4) Perceived challenges and barriers in adapting to HTAR requirements	*"I think that has been the biggest challenge, so many unknowns, ….. because the implementing act on joint clinical assessment for medical devices is still under development and also some of the guidance documents. So it's really hard to, you know, start to adjust the national processes and timelines because you don't know them at the EU level."*	Interview 2
	"In the meantime, if you imagine this two-year gap, there might be a change in the PICO code that is so substantial that the JCA no longer applies. Therefore, this might trigger the need for a reassessment at the European level, but we're already tied by the timelines of our legal processes."	Interview 9
	"We didn't really get started properly [until] maybe autumn last year because we were waiting for all the guidance on all the implementing acts to be published"	Interview 2
	"I think it's that we have quite a small HTA process here and not so many HTA experts. So we have the problem of how we can be a part of this new assessment because we don't have so many people to do this job."	Interview 3
	"I think the biggest challenge for us during these years of preparations has been that we don't have the resources to do this work."	Interview 4
	"But at the same time, the joint scientific consultation for HTA, it's more complicated than the scientific advice that the developer can ask the EMA for the regulatory purpose…… I think I see a lot of challenge here, because there' s study design. There's going to be a lot of challenge because also the joint scientific consultation is not mandatory, it's on demand. So let's say, OK, why if I have CE mark and I can be sold directly or by registering in a list in your country. Why have to ask for a parallel advice?"	Interview 11
	"We fear that we won't have enough time to be able to get the required information to insert into this PICO"	Interview 5
	"…Which is, I guess, one of the big criticisms of JCA, as such that it doesn't really give you answers."	Interview 6

	"The hot topic always is the comparators which will be chosen at EU level, will those actually be those that make sense in our country?"	Interview 8
	"I think that the most important challenge that we were thinking about from the very beginning was whether the medical device company would be able to submit enough evidence for JCA to be valuable? Because presently within [the] JCA process [it] is quite complex."	Interview 5

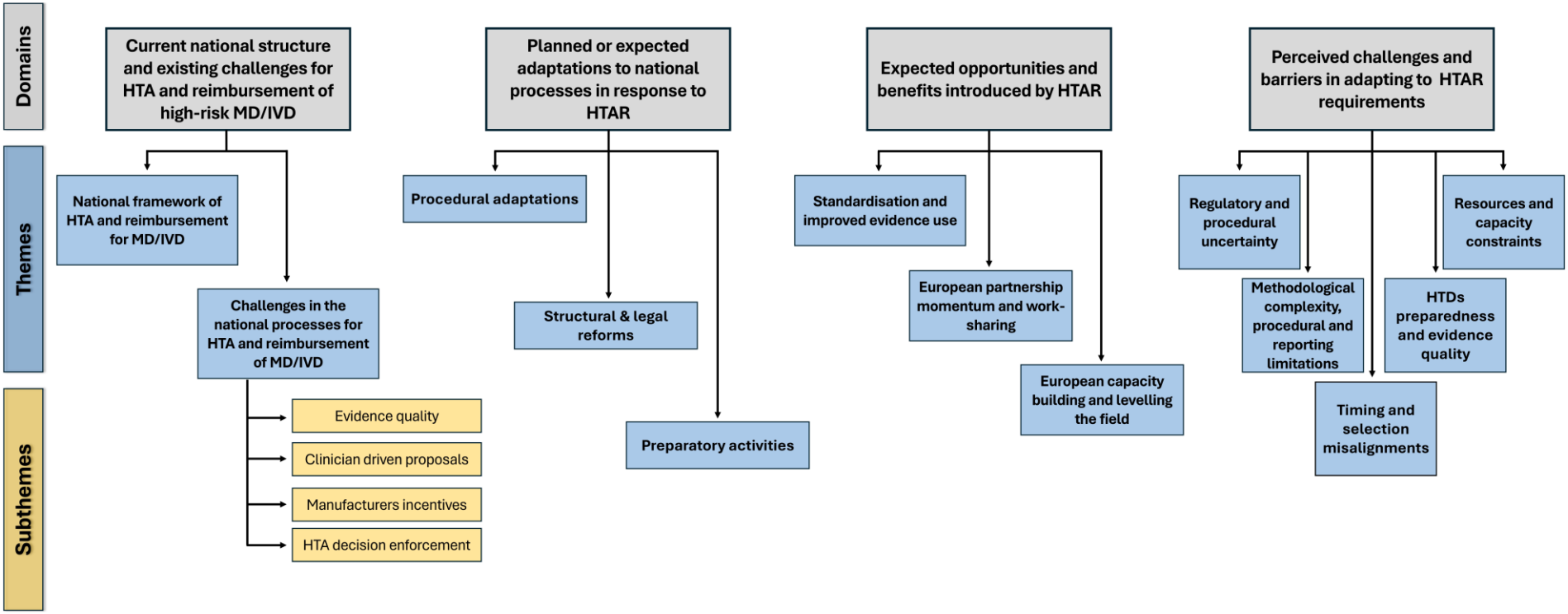
Key: CE – Conformité Européenne; **EMA** – European Medicines Agency; **EU** – European Union; **HTA** – health technology assessment; **HTAR** – Health Technology Assessment Regulation; **IVDs** – in vitro diagnostic medical devices; **JCA** – joint clinical assessment; **JSC** – joint scientific consultation; **MDs** – medical devices; **MDR** – Medical Device Regulation; **PICO** – population, intervention, comparator and outcome.

3.3.1 Domain 1: Current national structure and existing challenges of HTA and reimbursement for MDs and IVDs across the EU/EEA

Generally, participants described variable levels of development, maturity, structure and extent of integration of HTA into high-risk MDs/IVDs reimbursement pathways in their Member States. For all Member States represented in this study, there was at least one pathway for reimbursing high-risk MDs/IVDs, which involved HTA. The role of HTA in reimbursement decisions varied from a formal or essential component to a more ad-hoc or optional element, as was described previously in Chapter 2.[125]

For three Member States, the participants described their national HTA process for specific categories of medical devices as mandatory and performed within a legally defined timeline. The components of HTA were notably different between Member States. In three interviews, the participants highlighted that economic assessment is not routinely performed as a part of HTA for MDs/IVDs. In contrast, participants from the remaining eight Member States mentioned that economic assessment is a core component of HTA for MDs. Some participants noted that national HTA for MDs/IVDs was typically less standardised than HTA for medicinal products.

Figure 3.2 The thematic framework of findings from stakeholder interviews on the implementation of HTAR



Key: EEA – European Economic Area; **EU** – European Union; **HTA** – health technology assessment; **HTAR** – Health Technology Assessment Regulation; **HTD** – health technology developer; **IVDs** – in vitro diagnostic medical devices; **MDs** – medical devices. Domains, themes, and subthemes were identified across the ten EU/EEA Member States included in the analysis.

3.3.1.1 Emerging and evolving national HTA structures

Some participants, particularly those from Member States with less developed HTA frameworks (as described in Chapter 2),[125] described ongoing efforts to formalise HTA in reimbursement systems of high-risk MDs/IVDs and address longstanding issues with their national systems. These efforts aim to define criteria for device assessment, improve the translation of national assessments to local procurement decisions and expand the HTA for MDs. In these settings, HTA bodies had already begun revising internal procedures, building or expanding their HTA infrastructure, often starting from systems that had historically focused only on medicinal products.

"But we do have work to try to have a more strict link between the national decision and the procurement." [Interview 2].

In these contexts, the risk class of MDs is considered an important determinant of which medical devices could have a formal HTA component for reimbursement. However, these reforms are still in progress, with implementation challenged by multiple system deficiencies described in the following section.

"….trying to be more systematic and have more defined criteria on what should go through a national process of medical devices. But we haven't decided on the final criteria, but the risk class is definitely something that we are discussing" [Interview 2].

3.3.1.2 Current challenges in national processes for assessment and reimbursement of MDs/IVDs: a space for HTAR-driven improvement.

One of the most cited challenges for national MDs/IVDs assessment and reimbursement was the low quality of evidence available for decision-making (Table 3.2). This issue was raised by almost all participants, describing how dossiers submitted for MDs/IVDs reimbursement were often incomplete, lacked comparative data, or failed to meet basic evidence standards, specifically when submitted by smaller or early-stage companies (Table 3.2). The lower quality of evidence for devices was further described by several interviewees as a result of a systemic acceptance of a lower evidentiary bar for medical devices compared with medicinal products, creating difficulties for national HTA agencies to apply structured methods and diminishing their ability to produce high-quality assessments.

Furthermore, participants from four Member States described the link between HTA and reimbursement of high-risk devices as weak, where the procurement decisions are taken within decentralised or hospital-based systems, driven by clinical requests rather than national HTA review.

"But linkage with decision maker is still lacking because there's no direct link between the assessment and the decision maker, because especially as you know, for the medical device, once the medical device has the CE mark ….. it can be used in the healthcare services." [Interview 11].

Participants also emphasised that the absence of clear incentives for HTDs of CE-marked devices to pursue national assessment often contributes to the disconnection between assessment and reimbursement. In many national frameworks, these CE-marked devices can secure patient access by direct negotiations with hospitals, bypassing formal evaluation pathways altogether (Table 3.2).

3.3.2 Domain 2: Planned or expected adaptations in national structures in response to HTAR

In general, all the interviewees expressed optimism for HTAR implementation and described a variety of changes that have already happened, are underway, or are expected to happen in response to HTAR. These changes fell into three broad areas: (1) procedural adaptations of JCA, (2) structural and legal reforms, and (3) preparatory activities aimed at readiness and future alignment (Figure 3.2).

3.3.2.1 Procedural adaptations to incorporate JCA into national workflows

Multiple participants indicated that their HTA bodies were beginning to review or adjust their national steps and decision-making processes to accommodate the integration of JCA outputs. While the specific stage of preparedness varied, there was broad awareness that aligning with HTAR would require some procedural modifications at the national level. The general sentiment was positive, but participants expressed an intention to wait for further information, for example, finalisation of the HTAR implementing acts, before initiating any change.

However, there was an overwhelming agreement between all the participants that the JCA, if available at the time of national assessment, will be used at the clinical evidence assessment stage of HTA, with comparative safety and effectiveness components already undertaken at the European level.

"At this moment, we have plans that we use these assessments that are coming from the EU [the JCA], as the basic situation that we build our own assessment on." [Interview 3].

The utilisation of JCA in the assessment stage might need procedural restructuring in these Member States to allow the report to be considered. These adaptations may range from formalising how JCA would be used in assessments, adjusting HTA

methodologies, developing mechanisms for contextualisation, and clarifying roles and responsibilities between different working groups and bodies. These procedural changes were still being discussed at the time of the study, with potential adjustments expected in upcoming years (Table 3.2).

When considering a JCA during a national assessment, the majority of participants recognise the need for contextualisation of the European report to the national situation, where the JCA may need to be complemented by national assessment, including economic assessment, and or analysis of organisational, legal or ethical aspects and other country-specific criteria.

Several participants suggested that it's unlikely that the publication of JCA alone will trigger a national assessment or reimbursement process for MDs/IVDs. Instead, in these systems, the assessment and subsequent reimbursement will continue to be initiated based on existing national triggers (for example, HTDs' submissions, hospitals' or clinicians' submissions, horizon scanning or other currently defined initiators).

3.3.2.2 Structural and legal reforms to strengthen HTA capacity

While the HTAR is directly applicable across all EU Member States, some degree of procedural or legal adaptation may still be necessary within national frameworks to ensure operational integration. Most participants described the lack of any substantial legal or structural reforms in the current assessment and reimbursement frameworks and oversight structures involved for high-risk MDs/IVDs within their Member State. While many interviewees perceive the HTAR as a stimulus for broader HTA reform and an opportunity to overcome system deficiencies, structural or legal changes in these Member States have not yet been planned, and may potentially face some resistance.

[When asked if they would change anything in the legally defined process timelines to fit the JCA] "I'm not so sure because this process is so established and I think there will be a lot of resistance from many actors, they are very used to this process and it's working really well." [Interview 10]

On many occasions, participants from Member States further acknowledged that legal change might be required before JCAs could be formally embedded in national processes, as their HTA body is legally bound to an annual reimbursement process with specified criteria (Table 3.2). However, some Member States had already initiated significant structural and legislative adjustments to standardise the HTA process and support reimbursement decisions of high-risk MDs/IVDs. These adjustments were introduced with HTAR in mind and will support the integration of JCA into national decision-making.

"We wrote the law, and we already knew the HTAR is on the way. So, the way the law was written already had this [the HTAR] in mind. So everything sort of was accounted for" [Interview 6].

3.3.2.3 Preparatory activities aimed at readiness and future alignment

Even where formal reforms had not yet begun, most participants described different readiness activities that were performed or underway to prepare for the availability of JCA reports. These included the formation of national working groups to navigate HTAR, the mapping of existing HTA workflows, and internal knowledge-sharing initiatives (Table 3.2). Other participants highlighted the importance of active engagement at the European level, getting involved in pilot projects, participating in early PICO development exercises, monitoring the changes with medicinal products, and observing how JCAs would be received and operationalised before fully integrating them into national processes.

"We made the choice to be actively involved in the preparation, so for us, it's a way to get prepared. I mean to gain some experience and to get prepared." [Interview 7]

Finally, one participant further highlighted the need to develop a national protocol for disseminating JCA results to national stakeholders, including ministries, payers, and regional actors responsible for funding decisions.

"We have to establish a process of how to make all the actors in the system that are responsible for paying for, or making decisions, how to make them aware that these reports are available ……., so that even if there is an ongoing evaluation process of one of those devices, we will try to disseminate it to the ministry or to those who are generally involved in these processes." [Interview 10]

3.3.3 Domain 3: Expected opportunities introduced by the HTAR

All participants expressed strong optimism about the long-term potential of the HTAR to strengthen the existing relatively weak HTA practices for high-risk MDs/IVsD. While many acknowledged the challenges of implementing a harmonised process (discussed in detail under domain 4), interviewees consistently pointed to a range of anticipated benefits that can be grouped into three overarching opportunity themes: (1) standardisation and improved evidence generation for high-risk devices, and industry-level benefits; (2) work-sharing, efficiency and European partnership momentum; and (3) system-wide capacity building and levelling (Figure 3.3).

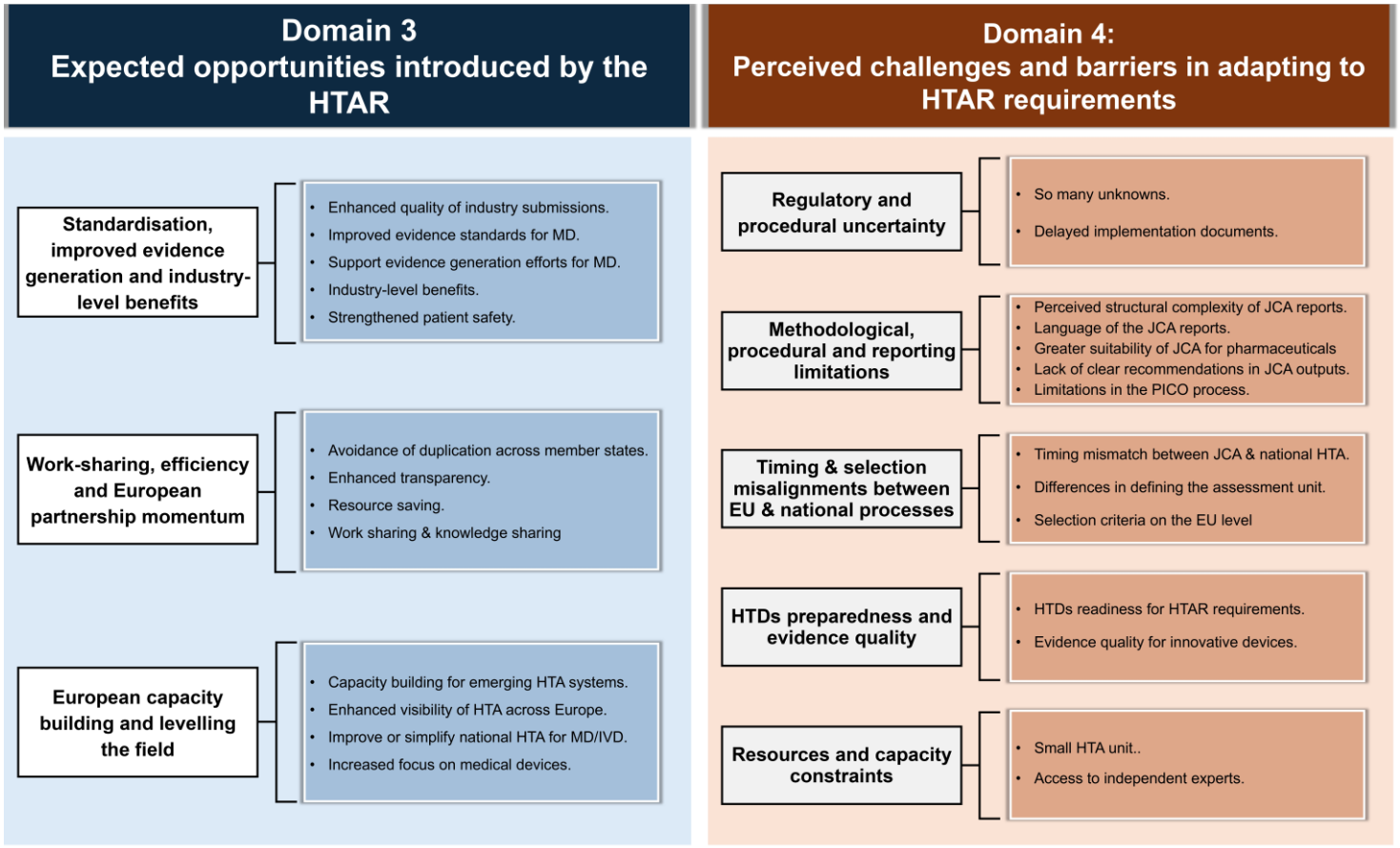
3.3.3.1 Standardisation, improved evidence generation for high-risk devices and or MDs more broadly

A recurring theme across all interviews was the recognition of the ability of the HTAR, via JSC and JCA, to support evidence-generation efforts and contribute to better and more consistent use of clinical evidence in medical devices' assessments. Several participants anticipated that the HTAR would support improved clinical trial design as developers would be required to meet pre-defined evidence requirements at the EU level. In the long term, this would improve the quality of dossiers submitted to support reimbursement applications for MDs, not only those assessed at the EU level but also those submitted for national assessment (Table 3.2).

"I think all the companies will take it more seriously that they need to produce good evidence, because now it's at the European level and not just on the individual company, country or whatever level." [Interview 10]

Several interviewees also suggested that the HTAR might shift the attention of small and medium-sized enterprises to consider HTA requirements earlier during device development, aligning clinical trial design with payer needs rather than focusing solely on regulatory approval.

Figure 3.3 Expanded visualisation of Domains 3 and 4 from Figure 3.2, highlighting participants' reported opportunities in adapting to the HTAR



Key: EU – European Union; **HTA** – health technology assessment; **HTAR** – Health Technology Assessment Regulation; **HTD** – health technology developer; **IVDs** – in vitro diagnostic medical devices; **JCA** – joint clinical assessment; **MDs** – medical devices; **PICO** – population, intervention, comparator and outcomes.

Note: The figure summarises the main themes and subthemes under two key forward-looking domains identified through interviews; (left) the expected opportunities and long-term benefits of the HTAR (domain 3), and (right) the perceived challenges and barriers to its implementation (domain 4).

Interviewees also suggested this shift in generation and utilisation of evidence for comparative safety and effectiveness for high-risk MDs/IVDs brought about by the HTAR would ultimately enhance patient safety by supporting more transparent, evidence-informed decision-making across Member States (Figure 3.3).

"These devices are selected for good reason …… these devices are not only high risk, they are usually high-priced devices, and you don't want to have these implanted in too many patients if the effects are not really well proven." [Interview 9]

3.3.3.2 Work-sharing, efficiency and European partnership momentum

The HTAR was widely seen as a mechanism for European work-sharing, enhancing cross-border collaborations, exchanging expertise and standardisation of clinical evidence assessment for high-risk devices. Participants frequently highlighted the opportunity provided by the HTAR to strengthen European collaboration, trust, and shared identity in health decision-making. Some viewed the HTAR as a symbol of greater alignment across Member States and a platform to move beyond siloed national processes. Interviewees expressed pride in contributing to a European-wide initiative and excitement about the shared learning and collaboration it could enable. Interviewees positively viewed the shift from voluntary collaboration under the European Network for Health Technology Assessment (EUnetHTA) to legally mandated coordination as a milestone for European partnership and HTA of medical devices.

"This is a huge step [the JCA]. It's a huge, huge achievement for the Member States. We know each other, we see each other, there's a lot of collaboration." [Interview 11]

3.3.3.3 European capacity building and levelling of the field

Interviewees repeatedly emphasised that the HTAR could help level the utilisation of evidence and the information available for decision-making, especially with regard to high-risk MDs/IVDs across Member States. It was believed that this will be achieved by boosting capacity in Member States with weaker or underdeveloped HTA systems. Furthermore, for Member States with limited staff or technical infrastructure, JCAs were seen as a practical way to access high-quality assessments that would otherwise be out of reach. Several participants described how their national systems could rely on EU-level outputs to fill capacity gaps.

"But as a representative of [a small country], and we have really small teams….. So we wouldn't have that kind of workforce to do all the work ourselves, so I do hope that these reports will help us and support our work." [Interview 8]

Even for Member States with developed HTA systems for MDs, participants noted that the HTAR would provide the opportunity to increase the number of devices assessed annually and improve or simplify national assessments. The HTAR was also seen as an opportunity to build institutional knowledge, enhance the visibility and recognition of HTA across Europe, and offer the chance to improve HTA methodologies for MDs.

3.3.4 Domain 4: Perceived challenges and barriers in adapting to HTAR requirements

While interviewees expressed strong enthusiasm for HTAR implementation, they also shared a range of concerns and uncertainties about the process and implementation roadmap. These challenges and potential roadblocks can be grouped under five core themes: (1) regulatory and procedural uncertainty, (2) methodological complexity, procedural and reporting limitations, (3) timing and selection misalignments between EU and national processes, (4) health technology developers' preparedness and evidence quality, and (5) resources and capacity constraints (Figure 3.3).

3.3.4.1 Regulatory and procedural uncertainty

A dominant concern among the interviewed participants was the considerable uncertainty around the procedural aspects of JCA for high-risk MDs/IVDs. The absence of detailed procedural guidance and a finalised implementing act for the JCA process for MDs/IVDs, at the time of the interview, was perceived as a difficulty for national bodies in adapting their systems or planning for integration. Participants also noted that this uncertainty was a primary reason for the "wait and see" sentiment they had expressed. Many Member States were reluctant to restructure national legislation or reimbursement pathways without clear knowledge of how JCA for high-risk MDs/IVDs would function (Table 3.2).

3.3.4.2 Methodological complexity and procedural and reporting limitations of the JCA process

Another central theme amongst anticipated roadblocks was challenges related to the design, methodology, procedures, reporting and scope of JCAs themselves. Participants expressed concerns about the PICO collection timeframe and the potential conflict of interest of clinical experts consulted during the collection process. In addition, the interviewees were concerned about the alignment of the consolidated PICO for JCA with the national process, considering the variability in clinical practice, treatment standards, and health system organisation across Member States. Furthermore, participants from Member States with later access to technologies expressed their concern regarding the relevance of the submitted PICO (defined early in the JCA process) by the time the reimbursement decision is made.

"Because in the meantime, if you imagine this two-year gap, there might be a change in the PICO code that is so substantial that ..., the JCA done two years ahead [no longer] applies." [Interview 6]

Additional concerns included the complexity and language of JCA reports, which may pose accessibility challenges and increase the workload in Member States where official documentation must be translated into national languages.

3.3.4.3 Timing and selection misalignments between EU and national processes

One of the most noted structural barriers was the potential mismatch between the timing of European JCA and fixed national HTA/reimbursement timelines and selection criteria. In several Member States, assessments must be completed within strict annual cycles, with deadlines set by law. If JCAs are not published in time to meet these cycles, they may be unusable, as a decision will be made anyway. Participants noted that without better timing coordination, the JCA process might be too late for some Member States.

"If you just add up the legally specified timelines, the European HTA process for medical devices will be too late for the national HTA." [Interview 9]

Another barrier is the unit of assessment for JCA of high-risk MDs/IVDs; while the EU process assesses a single device, representatives from different Member States expressed that they essentially assess a procedure (in which a device is being used) or a class of devices (device category). Procedural adaptations may be required to address this barrier.

"Joint clinical assessment is conducted by product, by single medical device, ……we don't assess specific products, because [devices are] reimbursed by class, not by specific product. [Interview 11]

3.3.4.4 Health technology developers' preparedness and the quality of available evidence

Several interviewees voiced concerns about the capacity of medical device HTDs, particularly small and medium-sized developers, to meet the evidence standards and trial design expected in JCAs.

"…. the level of readiness from the health technology developers for medical devices, which are probably less ready than the [Medicinal products] ones. As we said earlier, it's mostly small companies or small to medium-sized companies, and even bigger companies, that might not be completely ready for the HTAR." [Interview 7]

The participants also expressed concerns about the usability of JCAs when clinical evidence is limited, particularly for rapidly evolving technologies or highly innovative devices. Participants feared that weak evidence submissions could result in JCAs that offer limited value to national systems, forcing them either to reject technologies or seek additional data that may not be available.

3.3.4.5 Resources and capacity constraints

Resource limitations emerged as a significant challenge for participants from multiple Member States, particularly among smaller HTA bodies. Interviewees described being overstretched with current work, lacking staff dedicated to HTAR planning, or not having access to enough independent experts for PICO development or expert consultation. Some also noted that contributing to JCA production would divert resources from national priorities, particularly in systems with small teams.

Clinician engagement was also identified as a potential bottleneck. Participants from smaller Member States could see potential difficulty in recruiting expert advisors free from conflicts of interest, especially in specialised fields like diagnostics or surgical technologies.

"As a small country, we do not have so many experts, clinician experts who have no conflict of interest. That's also a challenge." [Interview 3]

3.4 Discussion

In this qualitative study, the evaluation team examined how selected EU/EEA HTA bodies perceive the transition in response to HTAR, and the challenges and opportunities they face during the process. While HTA bodies may not necessarily have the authority to make changes to national reimbursement processes, they can work with relevant stakeholders and contribute to procedural discussions or initiate preparatory work to inform potential adaptations of national assessment or reimbursement processes in anticipation of HTAR implementation.[127] These findings offer a ground-level view of how HTAR is being integrated into national systems at the early stage of implementation, building on earlier legal and policy analyses of HTAR implementation challenges.[123,128–130]

Member States are required to give due consideration to the JCA outputs,[9] to reduce duplication of effort; however, they retain independence with regard to national reimbursement decisions.[128] The interviewed participants expressed enthusiasm for JCA outputs for high-risk MDs/IVDs, a field with a historically low bar for evidence quality in Europe.[13] Participants could see the long-term opportunity HTAR brings for their Member States, and this optimism reflects a broad alignment with the core objectives of the HTAR.[131] HTAR will also bring the opportunity for work-sharing, enable more efficient use of resources, support more transparent, evidence-informed decision-making, and serve as a valuable catalyst for reform and a mechanism to improve equity, enabling these less-resourced Member States to access high-quality assessments.

While some Member States were proactively adapting their national legislation and reimbursement processes, others remained in early planning or observational phases. This wait-and-see position was mainly attributed to the awaited implementation documents and many procedural uncertainties.

Participants also identified many barriers to effective HTAR adaptation, including the misalignment between EU and national timelines. These timing mismatches have been raised by previous stakeholders and were reinforced by participants in our study, who expressed concern that JCAs may not align with national submission and decision-making windows.[122] As reflected by the interviewees, it will be essential to initiate dialogue around aligning timelines and clarifying the role and applicability of JCAs in systems with differing legal and procedural structures.

The collection of national PICOs, conflict of interest and the development of a consolidated European PICO for each JCA also raised notable concerns among interviewees, a concern repeatedly voiced by other stakeholders in a previous study.[132] Conflict of interest during PICO collection may arise when clinical experts involved in the PICO development process also have HTD ties or affiliations that

could influence the framing of the research question, which is particularly relevant for smaller Member States with limited numbers of experts. Concerns were also raised regarding the relevance of the consolidated PICOs at the national level, which reflects the importance of dialogue on the consolidation process to ensure the relevance of the final PICOs to all Member States is optimised.

Another recurrent challenge was the uncertainty surrounding HTD preparedness. Unlike medicinal product HTDs, many small and medium-sized HTDs have limited experience with comparative trial design or structured HTA submissions. This limited experience has also been reported as a barrier in previous studies examining national HTA submissions by HTD stakeholders.[133] This concern echoes broader commentary on the need to improve the quality of evidence for high-risk MDs/IVDs across Europe.[13]

The weaknesses in HTD-submitted evidence were not only seen as a burden on national systems but also as a key target for reform and as an area where the HTAR was seen as a catalyst toward higher standards (especially when combined with JSC), better alignment with regulatory pathways, and ultimately safer, more transparent decision-making for high-risk MDs/IVDs across Europe.

3.4.1 Strengths and Limitations

This study offers one of the first empirical studies of the views of HTA bodies across Member States on HTAR implementation for high-risk MDs/IVDs, based on interviews with stakeholders actively involved in national HTA systems and preparatory work for the HTAR. However, the sample does not represent all EU/EEA Member States, and those with less structured or no HTA systems for MDs/IVDs were found to be under-represented in the sample. Although the sample size might be considered small, it is important to note that qualitative studies can reach 'data saturation' within 12-13 interviews, particularly those with relatively homogenous study populations and narrowly defined objectives.[134]

Second, the timing of interviews conducted before full implementation might suggest that participants' views were not perhaps fully formed and may evolve as JCAs are completed and integrated. Therefore, ongoing monitoring of the change in the HTA/reimbursement frameworks and stakeholders' views might be needed to track how the views, practices, and system-level responses develop over time. Also, one potential limitation is that all interviews were conducted in English, which was not the first language for most participants, and could therefore have possibly influenced the depth of some responses. However, English is the working language of JCAs and is widely used in European HTA discussions. Finally, as with all qualitative research, findings are shaped by the perspectives of the interviewees and may not fully capture institutional or political dynamics not discussed during interviews.

3.5 Conclusion

Through interviews with national HTA stakeholders from 11 Member States, we identified substantial variation in system readiness, procedural expectations, and perceptions of the value and feasibility of JCA. The HTAR was perceived as a strategic opportunity to harmonise clinical assessment standards, reduce duplication, and strengthen capacity for assessment of high-risk MDs/IVDs, with the ultimate aim of improving clinical outcomes for European citizens.

However, participants raised concerns and perceived challenges that are responsible for a "wait-and-see" position that multiple Member States held. Meaningful implementation of the HTAR, specifically for high-risk MDs/IVDs, will require ongoing coordination, consultation and capacity-building. Finally, there is a need for a sustained commitment by all relevant stakeholders to balance EU-wide integration with the practical realities of national HTA and reimbursement systems of all Member States. Our findings suggest that the success of the HTAR for high-risk MDs/IVDs will depend not only on the technical quality of JCAs but also on how effectively they are aligned with diverse national decision-making frameworks.

4 Discussion

This study provides one of the first integrated analyses of how EU and EEA Member States approached the assessment and reimbursement of high-risk MDs/IVDs immediately prior to the implementation of HTAR, and how these structures positioned them for the transition to a coordinated European HTA framework under HTAR. This report combines the results from a comprehensive scoping review of national pathways supplemented with additional insights from semi-structured interviews with European HTA bodies representatives to understand the evolution of the HTA landscape for MDs/IVDs in each Member State in response to HTAR.

Published evidence examining implementation of HTAR for high-risk MDs/IVDs remains limited, with the majority of published work focused on implementation for medicines. However, most of these studies highlighted that the JCA has the potential to reduce duplication of clinical assessments, improve efficiency, and enhance the quality of evidence through early scientific dialogue and expert-led European assessments. Harmonised clinical evaluations may facilitate more timely reimbursement decisions, accelerate patient access to innovative technologies, reduce inequalities in access across and within Member States, and support national and regional decision-making. [135,136]

4.1 Diversity and fragmentation across Europe

Findings from the scoping review showed that the assessment and reimbursement of high-risk MDs/IVDs was highly heterogeneous across Europe. National systems differed in the availability of information, assessment process structure, the degree of formal HTA integration within reimbursement processes, the degree of decision centralisation and mechanisms to address evidence uncertainty. This was recently reflected by other studies that examine HTAR implementation.[137]

As previously highlighted, Western European countries with more established and centralised HTA frameworks generally made their reimbursement decision-making processes for high-risk MDs/IVDs publicly available. Several Eastern European countries and smaller states had limited publicly available data, which may reflect limited structured HTA processes for high-risk MDs/IVDs. In these countries, the reimbursement of MDs/IVDs often relied on alternative processes including regional or hospital-level decision-making, with limited national formal evaluation. Furthermore, most EU/EEA countries lacked formal mechanisms to address evidence uncertainty of high-risk MDs/IVDs, relying instead on ad hoc evaluations. This gap may hinder the timely adoption of certain innovative technologies that might partially or fully fulfil unmet medical needs. However, it is important to acknowledge that setting up such a system at a national level would require: a significant investment

in capacity and capability; collaboration between a diverse range of actors who may not have worked together previously; and possibly legislative changes.

This divergence in practice has several important implications. For manufacturers, it increases the complexity of market access and results in multiple, sometimes duplicative, submissions. For patients, it may lead to delayed or unequal access to innovative devices depending on national capacity, policy priorities, or evidence expectations. For HTA bodies and other reimbursement authorities, they may face unique challenges in terms of implementing HTAR for high-risk MDs/IVDs at a national level, which may be both individual to the Member State and distinct from issues relating to HTAR for medicinal products. These findings reinforce long-standing observations about the need for greater coordination and standardisation of evidence requirements for high-risk MDs/IVDs across Europe.

4.2 Preparedness and capacity for HTAR adaptation

Through interviews with national HTA stakeholders from 11 Member States, we identified substantial variation in system preparedness, procedural expectations, and perceptions of the value and feasibility of JCA. The HTAR is seen as a substantive opportunity to harmonise HTA for high-risk MDs/IVDs and, over time, improve the quality of evidence for MDs/IVDs and reduce the level of uncertainty in national reimbursement decisions, and ultimately improve the safety of these devices and enhance clinical outcomes for patients. There was optimism among HTA body representatives about the potential for the HTAR to reduce duplication and strengthen evidence consistency. However, preparedness to implement the new processes remained uneven. While some countries have begun internal coordination to prepare for JCA, many remained in an observational phase due to uncertainty about procedural details and limited national capacity.

Smaller HTA bodies in particular emphasised the need for EU-level support, training, and technical guidance. Participants also highlighted that the HTAR's success will depend on whether its outputs are usable and relevant within national decision frameworks. Alignment of timelines, clarity in the scope of assessments, and adaptability of consolidated PICOs were all raised as critical prerequisites for meaningful implementation. Similar issues have been highlighted in recent commentaries, which argue that the value of HTAR will ultimately depend on balancing European harmonisation with the preservation of Member States' responsibility for national reimbursement decisions.[138]

The findings also reinforce the potential for HTAR to strengthen national HTA capacity over time. For countries with less developed HTA systems, participation in the European process may provide access to shared expertise, common methodologies, and high-quality clinical assessments that would otherwise require

substantial national resources. Conversely, countries with established HTA programmes may benefit from reduced duplication of clinical assessment activities while contributing methodological expertise to the European system. However, as highlighted by participants, these potential benefits will only be realised if sufficient implementation support accompanies the early phases of the HTAR and if national processes evolve to effectively operationalise JCA outputs within existing reimbursement pathways. For high-risk MDs, where assessment and reimbursement systems remain considerably more heterogeneous than those for pharmaceuticals, this transition is likely to require greater organisational adaptation and coordination than has previously been required under voluntary European HTA collaboration.[138]

4.3 Implications for policy and practice

For European policymakers, these findings underscore the need to balance harmonisation with flexibility. While a common framework for JCAs promises to reduce duplication and improve efficiency, its success may depend on how well it accommodates the diverse institutional realities across Member States. The HTAR will require careful coordination of timelines, scope definitions, and evidence standards to ensure that joint outputs are usable and relevant at the national level for Member States.

From a methodological perspective, the findings highlight a continuing need for innovation in the assessment of MDs/IVDs. This includes developing standardised but adaptable approaches to real-world data use, comparative effectiveness assessment, and stakeholder involvement. Enhancing best-practice and transparency in assessments and encouraging early dialogue between health technology developers, regulators, and assessors could improve evidence quality and predictability for manufacturers, while ensuring timely, fair and sustainable patient access to MDs/IVDs with added benefit.

4.4 Relevance for Ireland

As of October 2026, Ireland does not have a centralised comprehensive national system for the health technology assessment, reimbursement, or procurement of high-risk MDs/IVDs. While HIQA conducts HTAs across a range of health technologies, including medical devices, its remit does not extend to the systematic evaluation of all high-risk devices prior to reimbursement or procurement. Instead, decisions on device adoption and funding are largely decentralised and fragmented across hospitals and local or regional procurement teams. A recent national review by HIQA highlighted broader governance challenges surrounding the introduction and oversight of high-risk medical devices in Ireland. The Independent Review of Governance at Children's Health Ireland (CHI), commissioned following concerns regarding the use of implantable medical devices, identified the need for stronger

governance structures, standardised policies and procedures, multidisciplinary oversight, robust medical device management systems, and improved monitoring and audit throughout the device lifecycle.[139] While the CHI review focused on clinical governance rather than reimbursement or HTA processes, its recommendations reinforce the importance of coordinated, evidence-informed approaches to the evaluation and management of high-risk medical devices within the Irish healthcare system. Together with the findings of this report, these observations highlight the value of clear governance arrangements that support consistent, transparent, and evidence-based decision-making across the medical device pathway. Of note, on foot of the CHI review, the HSE has established a System of Medical and in Vitro Diagnostic Device Regulation Compliance with a primary focus on patient safety. The system provides a process for the introduction of new MDs/IVDs that are likely to be used at scale across the healthcare system; this process will not hamper the necessary fast pace of introduction of innovative devices.

4.5 The path forward

The implementation of the HTAR for high-risk MDs/IVDs presents both challenges and opportunities for all Member States. To realise its full potential, implementation should be underpinned by transparent processes, capacity-building, and strong governance at both EU and national levels. Future studies that investigate the utilisation of the first JCAs for high-risk MDs/IVDs across different Member States could provide valuable evidence to guide Ireland's implementation efforts. Such evidence could also support the development of a coherent, centralised, and transparent approach to the assessment and reimbursement of MDs/IVDs while making the maximum use of JCA.

4.6 Strengths and limitations

This report provides one of the first comprehensive examinations of how high-risk MDs and IVDs were assessed for reimbursement across the EU/EEA and the UK immediately before the implementation of JCAs under the HTAR. Both bodies of work offer a detailed description of pre-existing national pathways and insight into how Member States are preparing for implementation of the Regulation.

A further strength is the breadth of evidence sources used. The scoping review drew on official national policy documents, HTA agency publications, grey literature, and peer-reviewed literature, providing a comprehensive overview of reimbursement pathways and decision-making structures. Importantly, the findings were externally validated by national organisations from 30 of the 34 countries contacted (88% response rate), substantially increasing confidence in the accuracy and currency of the information presented.

The qualitative component complements these findings by providing perspectives from HTA bodies representing a diverse range of national systems, including countries with well-established HTA frameworks, countries where HTA remains optional, and countries currently undergoing reform. This allowed the study to capture early implementation experiences, anticipated adaptations, and practical challenges that are not yet reflected in published literature.

Nevertheless, multiple limitations should be acknowledged. First, the availability of publicly accessible information on reimbursement pathways varied considerably between countries. Although extensive efforts were made to identify and validate national information, some countries had limited documentation describing their reimbursement processes or the role of HTA for MDs/IVDs, restricting the level of detail that could be reported.

Second, the qualitative interviews were conducted during the early implementation phase of the HTAR, before publication of all implementing acts and before JCAs for high-risk MDs/IVDs had commenced. Consequently, participants' views largely reflect anticipated implementation rather than operational experience, and national approaches may continue to evolve as implementation progresses.

Third, while the interview study included representatives from 10 Member States (excluding Ireland) with diverse HTA systems, not all EU/EEA countries were represented. The findings therefore provide insight into a broad range of national perspectives but may not capture every implementation challenge across Europe.

Finally, this work focused specifically on the use of comparative clinical evidence within HTA and reimbursement pathways for high-risk MDs/IVDs. Broader determinants of reimbursement decisions, including national pricing, procurement, political priorities, and wider healthcare system factors, were considered only where they interacted with HTA processes and therefore fall outside the primary scope of this report.

5 Conclusion

This report provides the first integrated overview of reimbursement pathways for high-risk MDs and IVDs across the EU/EEA and the UK immediately before implementation of the HTAR. The scoping review demonstrated considerable diversity in national HTA and reimbursement systems, while the qualitative interviews showed widespread support among HTA bodies for the objectives of the HTAR alongside recognition of important implementation challenges. Together, the findings suggest that although the HTAR has the potential to improve consistency, reduce duplication, and strengthen evidence-informed decision-making across Europe, successful implementation will depend on the ability of national systems to integrate JCAs within existing reimbursement processes.

References

1. Fink M, Akra B. Comparison of the international regulations for medical devices–USA versus Europe. Injury. 2023 Oct 1;54:110908. doi:10.1016/J.INJURY.2023.110908 PubMed PMID: 37365092.

2. Notified bodies for medical devices - European Commission [Internet]. [cited 2024 Nov 7]. Available from: https://health.ec.europa.eu/medical-devices-topics-interest/notified-bodies-medical-devices_en

3. French-Mowat E, Burnett J. How are medical devices regulated in the European Union? J R Soc Med. 2012;105(Suppl 1):S22. doi:10.1258/JRSM.2012.120036 PubMed PMID: 22508970.

4. European Union 2017/745. Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex [Internet]. 2017 [cited 2024 Nov 6]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32017R0745

5. European Union 2017/746. Regulation - 2017/746 - EN - Medical Device Regulation - EUR-Lex [Internet]. 2017 [cited 2024 Nov 29]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0746&qid=1732881554406

6. Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746. 2024.

7. European Union 2021/2282. Regulation (EU) 2021/2282 of the European parliament and of the Council of 15 december 2021 on health technology assessment and amending directive 2011/24/EU2021 [Internet]. 2021 [cited 2024 Nov 6]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2282

8. IMPLEMENTING THE EU HEALTH TECHNOLOGY ASSESSMENT REGULATION [Internet]. 2023. Available from: https://health.ec.europa.eu/health-technology-assessment_en doi:10.2875/246730

9. Ernst G, Stöger K. Give Due Consideration …: Some Thoughts on Member States' Obligations Under Article 13 of the HTA Regulation. Eur J Health Law. 2024 Mar 13;31(2):171–86. doi:10.1163/15718093-BJA10122 PubMed PMID: 38594024.

10. Finch M. Reimbursement Basics. In: Durfee W, Iaizzo P, editors. Medical Device Innovation Handbook [Internet]. 9.1. Institute for Engineering in Medicine and Earl E. Bakken Medical Devices Center, University of Minnesota,

Minneapolis, USA; 2024 [cited 2024 Nov 6]. Available from: https://pressbooks.umn.edu/mdih/chapter/reimbursement-basics/

11. Ernst G, Stöger K. Give Due Consideration …: Some Thoughts on Member States' Obligations Under Article 13 of the HTA Regulation. Eur J Health Law. 2024 Mar 13;31(2):171–86. doi:10.1163/15718093-BJA10122 PubMed PMID: 38594024.

12. Tarricone R, Petracca F, Weller HM. Towards harmonizing assessment and reimbursement of digital medical devices in the EU through mutual learning. npj Digital Medicine 2024 7:1. 2024 Oct 1;7(1):1–12. doi:10.1038/s41746-024-01263-w

13. Hulstaert F, Pouppez C, Primus-de Jong C, Harkin K, Neyt M. Gaps in the evidence underpinning high-risk medical devices in Europe at market entry, and potential solutions. Orphanet J Rare Dis. 2023 Dec 1;18(1). doi:10.1186/S13023-023-02801-7 PubMed PMID: 37491269.

14. Reyal F, Feron JG, Detour SL, Pourcelot AG, Valentin M, Phillippe AC, et al. The impact of poly implant prothèse fraud on breast cancer patients: A report by the institut curie. Plast Reconstr Surg. 2013 Apr;131(4):690–5. doi:10.1097/PRS.0B013E3182827605, PubMed PMID: 23542243.

15. Toye F, Izett-Kay M, Barker KL, McNiven A. The experience of women reporting damage from vaginal mesh: a reflexive thematic analysis. EClinicalMedicine. 2023 Apr 1;58. doi:10.1016/j.eclinm.2023.101918

16. New EU rules for health technology assessments become effective | European Medicines Agency (EMA) [Internet]. 2025 Jan [cited 2025 Aug 17]. Available from: https://www.ema.europa.eu/en/news/new-eu-rules-health-technology-assessments-become-effective

17. Govaerts L, Simoens S, Van Dyck W, Huys I. Shedding Light on Reimbursement Policies of Companion Diagnostics in European Countries. Value in Health. 2020 May 1;23(5):606–15. doi:10.1016/j.jval.2020.01.013 PubMed PMID: 32389226.

18. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. Ann Intern Med. 2018 Oct 2;169(7):467–73. doi:10.7326/M18-0850 PubMed PMID: 30178033.

19. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol. 2005 Feb;8(1):19–32. doi:10.1080/1364557032000119616

20. Levac D, Colquhoun H, O'Brien KK. Scoping studies: Advancing the methodology. Implementation Science. 2010 Sep 20;5(1):1–9. doi:10.1186/1748-5908-5-69/TABLES/3 PubMed PMID: 20854677.

21. Peters MDJ, Godfrey CM, McInerney P, Soares CB, Khalil H, Parker D. The Joanna Briggs Institute reviewers' manual 2015: methodology for JBI scoping reviews. The Joanna Briggs Institute; 2015.

22. Alshaikh RA, Walsh KA, El-Komy F, Spillane S, Carrigan M, Larkin L, et al. Protocol for a scoping review of the current decision-making pathways and oversight structures for reimbursement of high-risk medical devices in the EU/EEA and the UK [Internet]. 2025 Mar 12. doi:10.17605/OSF.IO/65BDK

23. FAQ | Austrian Medical Devices Registry [Internet]. [cited 2025 Jan 2]. Available from: https://medizinprodukteregister.at/FAQs#toc-are-medical-devices-reimbursed-in-austria-in-the-out-patient-sector-in-the-in-patient-sector-and-how-does-it-work

24. Goetz G, Panteli D, Busse R, Wild C. Reimbursement decisions for medical services in Austria: an analysis of influencing factors for the hospital individual services catalogue between 2008 and 2020. BMC Health Serv Res. 2022 Dec 1;22(1):1–13. doi:10.1186/S12913-022-07531-3/TABLES/6 PubMed PMID: 35168631.

25. Justel databank [Internet]. [cited 2024 Dec 27]. Available from: https://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2014062503&table_name=loi

26. Reimbursement of implants and invasive medical devices | RIZIV [Internet]. [cited 2024 Dec 27]. Available from: https://www.riziv.fgov.be/nl/professionals/individuele-zorgverleners/verstrekkers-van-implantaten/terugbetaling-implantaten-en-invasieve-medische-hulpmiddelen

27. Reimbursement of implants and invasive medical devices | INAMI [Internet]. [cited 2024 Dec 27]. Available from: https://www.riziv.fgov.be/fr/professionnels/professionnels-de-la-sante/fournisseurs-d-implants/remboursement-des-implants-et-des-dispositifs-medicaux-invasifs#.WilO_a2WyUk

28. Baeyens H, Pouppez C, Slegers P, Vinck I, Hulstaert F, Neyt M. Towards a guided and phased introduction of high-risk medical devices in Belgium [Internet]. 2015 [cited 2024 Dec 27]. Available from: https://kce.fgov.be/en/publications/all-reports/towards-a-guided-and-phased-introduction-of-high-risk-medical-devices-in-belgium

29. Van Voorde C DE, Van Den Heede K, Obyn C, Quentin W, Geissler A, Wittenbecher F, et al. Conceptual framework for the reform of the Belgian hospital payment system [Internet]. 2014 [cited 2024 Aug 25]. Available from: https://kce.fgov.be/en/publications/all-reports/conceptual-framework-for-the-reform-of-the-belgian-hospital-payment-system doi:10.57598/R229C.

30. Camberlin C, Obyn C, Neyt M. Transversal Budget Impact Analysis [Internet]. 2023 [cited 2024 Dec 27]. Available from: https://kce.fgov.be/en/publications/all-reports/transversal-budget-impact-analysis

31. In vitro diagnostic medical devices (IVD): reimbursement request | INAMI [Internet]. [cited 2025 Jan 6]. Available from: https://www.inami.fgov.be/fr/professionnels/autres-professionnels/fabricants-et-distributeurs-d-implants-de-div-et-d-autres-dispositifs-medicaux/dispositifs-medicaux-de-diagnostic-in-vitro-div-demande-de-remboursement

32. Josipović I. DECISION PROMULGATING THE MEDICAL DEVICES ACT I hereby promulgate the Medical Devices Act passed by the Croatian Parliament at its session on 14 June 2013. The President of the Republic of Croatia. 2013.

33. Agency for Quality and Accreditation in Health Care, Croatia The Croatian Guideline for Health Technology Assessment Process and Reporting [Internet]. 2011. Available from: www.aaz.hr

34. Rulebook on the procedure for placing orthopedic and other aids on the basic and additional list of orthopedic and other aids and determining the prices of orthopedic and other aids [Internet]. ; 2019 [cited 2024 Dec 27]. Available from: https://narodne-novine.nn.hr/clanci/sluzbeni/2019_07_69_1438.html

35. General Health Insurance Company of the Czech Republic (VZP) [Internet]. [cited 2025 Feb 24]. Joint methodologies of General Health Insurance Company of the Czech Republic (VZP CR) and Association of Health Insurance Companies of the Czech Republic (SZP CR) for uncategorized ZP. Available from: https://www.vzp.cz/poskytovatele/ciselniky/zdravotnicke-prostredky/spolecne-metodiky-vzp-cr-a-szp-cr-pro-nekategorizovane-zp

36. Ministry of Health of the Czech Republic [Internet]. [cited 2025 Feb 24]. Commission for the Categorization and Reimbursement Regulation of Medical Devices. Available from: https://ppo.mzcr.cz/workGroup/121

37. Ministry of Health of the Czech Republic [Internet]. [cited 2025 Feb 24]. Commission for assessing the deployment of medical devices and capacities covered by public health insurance. Available from: https://ppo.mzcr.cz/workGroup/66

38. General Health Insurance Company of the Czech Republic (VZP) [Internet]. [cited 2025 Feb 24]. Inclusion, change and increase in the price and reimbursement of ZUM in the Reimbursement Catalogue of VZP – ZP . Available from: https://www.vzp.cz/poskytovatele/ciselniky/zdravotnicke-prostredky/zarazeni-zmena-a-navyseni-ceny-a-uhrady-zum-v-uhradovem-katalogu-vzp-zp

39. The Danish Health Technology Council's methods guide for the evaluation of health technology. 2023.

40. The Danish Health Technology Council's process guide 2021. 2021.

41. Estonian Health Insurance Fund. List of Health Care Services and General Information on Amending the List [Internet]. [cited 2024 Sep 9]. Available from: https://www.tervisekassa.ee/en/partner/list-health-care-services

42. Estonian Health Insurance Fund. Medical devices [Internet]. [cited 2024 Sep 9]. Available from: https://www.tervisekassa.ee/en/people/medical-devices

43. Oulu University Hospital [Internet]. [cited 2024 Sep 9]. National Assessment Network. Finnish Coordinating Center for Health Technology Assessment (FinCCHTA). Available from: https://oys.fi/fincchta/kansallinen-arviointiverkosto/

44. Oulu University Hospital [Internet]. [cited 2024 Sep 9]. Proceedings. Finnish Coordinating Center for Health Technology Assessment (FinCCHTA). Available from: https://oys.fi/fincchta/katsauksia-ja-suosituksia/

45. Council for Choices in Health Care in Finland (COHERE Finland) [Internet]. [cited 2024 Dec 29]. Council for Choices in Health Care in Finland (COHERE Finland). Available from: https://palveluvalikoima.fi/en/frontpage

46. Ghabri S, Josselin JM, Le Maux B. Could or Should We Use MCDA in the French HTA Process? Pharmacoeconomics. 2019 Dec 1;37(12):1417–9. doi:10.1007/S40273-019-00846-W/METRICS PubMed PMID: 31565761.

47. Pesqué R, Percheron R, Cordonnier AL, Steelandt J, Paubel P, Pineau J, et al. Accès au marché des dispositifs médicaux innovants : articulation entre évaluations nationales et hospitalières. Ann Pharm Fr. 2020 Mar 1;78(2):189–97. doi:10.1016/J.PHARMA.2019.10.002 PubMed PMID: 31806152.

48. Pathway of medical devices in France Description of the publication Title Pathway of medical devices in France [Internet]. Available from: https://dpi.sante.gouv.fr

49. Haute Autorité de Santé - National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS*) [Internet]. [cited 2024 Dec 27]. Available from: https://www.has-sante.fr/jcms/c_2036238/en/national-committee-for-the-evaluation-of-medical-devices-and-health-technologies-cnedimts?portal=p_3058934&userLang=en

50. Omelyanovsky V V., Otstavnov SS, Musina NZ, Dombrovskii VS. Introduction of medical products into healthcare practice and costs reimbursement: European experience. FARMAKOEKONOMIKA Modern Pharmacoeconomics and Pharmacoepidemiology. 2018 Aug 15;11(2):59–66. doi:10.17749/2070-4909.2018.11.2.059-066

51. Federal Joint Committee - Gemeinsamer Bundesausschuss (G-BA) [Internet]. [cited 2024 Aug 24]. FAQ on the procedure according to § 137h SGB V: Methods with high-risk medical devices. Available from: https://www.g-ba.de/themen/methodenbewertung/bewertung-erprobung/137h/beratungsangebot/faq/#welche-konsequenzen-ergeben-sich-wenn-festgestellt-wird-dass-weder-der-nutzen-noch-die-schadlichkeit-oder-die-unwirksamkeit-der-methode-unter-anwendung-des-medizinprodukts-als-belegt-anzusehen-ist

52. Institute for Quality and Efficiency in Health Care (IQWiG) [Internet]. [cited 2024 Dec 30]. Assessments according to §137h SGB V . Available from: https://www.iqwig.de/en/about-us/methods/results/assessments-according-to-137h/

53. Olberg B, Fuchs S, Matthias K, Nolting A, Perleth M, Busse R. Evidence-based decision-making for diagnostic and therapeutic methods: The changing landscape of assessment approaches in Germany. Health Res Policy Syst. 2017 Oct 17;15(1):1–11. doi:10.1186/S12961-017-0253-1/TABLES/2 PubMed PMID: 29041939.

54. Institute for Quality and Efficiency in Health Care (IQWiG) [Internet]. [cited 2024 Aug 24]. When and how does IQWiG assess non-drug interventions? Available from: https://www.iqwig.de/en/presse/in-the-focus/assessment-of-non-drug-interventions/2-when-and-how-does-iqwig-assess-non-drug-interventions/

55. Federal Joint Committee (Gemeinsamer Bundesausschuss - G-BA) [Internet]. [cited 2024 Aug 24]. The benefit assessment of medicinal products in accordance with the German Social Code, Book Five (SGB V). Available from: https://www.g-ba.de/english/benefitassessment/

56. Evidence requirements for the authorization and reimbursement of high-risk medical devices in the USA, Europe, Australia and Canada: An analysis of seven high-risk medical devices - Repository of AIHTA GmbH [Internet]. 2013 [cited 2024 Dec 30]. Available from: https://eprints.aihta.at/1017/

57. The Federal Ministry of Justice [Internet]. [cited 2024 Dec 30]. Ordinance on the requirements for the assessment of new examination and treatment methods with high-risk medical devices according to Section 137h of the Fifth Book of the Social Code (Medical Device Methods Assessment Ordinance - MeMBV). Available from: https://www.gesetze-im-internet.de/membv/__2.html

58. Health Technology Assessment (Methodological Recommendations) [Internet]. 2023 Sep [cited 2024 Sep 13]. Available from: https://ogyei.gov.hu/dynamic/NNGYK_TeF_Modszertani_Ajanlasok_20230928

59. National Centre for Public Health and Pharmacy [Internet]. 2018 [cited 2024 Sep 13]. What we do. Available from: https://ogyei.gov.hu/what_we_do_

60. Németh B, Csanádi M, Kaló Z. OVERVIEW ON THE CURRENT IMPLEMENTATION OF HEALTH TECHNOLOGY ASSESSMENT IN THE HEALTHCARE SYSTEM IN HUNGARY. Int J Technol Assess Health Care. 2017;33(3):333–8. doi:10.1017/S0266462317000071 PubMed PMID: 28434433.

61. Medical Devices [Internet]. [cited 2025 Jan 13]. Available from: https://www.hpra.ie/homepage/medical-devices

62. HSE website - Health Service Executive - HSE.ie [Internet]. [cited 2025 Jan 13]. Available from: https://www.hse.ie/

63. DECREE-LAW 19 June 2015, n. 78 [Internet]. 2015 [cited 2025 Feb 20]. Available from: https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legge:2015-06-19;78!vig

64. Beck ACC, Retèl VP, Bhairosing PA, van den Brekel MWM, van Harten WH. Barriers and facilitators of patient access to medical devices in Europe: A systematic literature review. Health Policy (New York). 2019 Dec 1;123(12):1185–98. doi:10.1016/J.HEALTHPOL.2019.10.002 PubMed PMID: 31718855.

65. Tarricone R, Amatucci F, Armeni P, Banks H, Borsoi L, Callea G, et al. Establishing a national HTA program for medical devices in Italy: Overhauling a fragmented system to ensure value and equal access to new medical

technologies. Health Policy (New York). 2021 May 1;125(5):602–8. doi:10.1016/J.HEALTHPOL.2021.03.003 PubMed PMID: 33820679.

66. The State Accreditation Service for Health Care Activities under the Ministry of Health. [Internet]. [cited 2024 Dec 23]. Health technology assessment. Available from: https://techmed.vaspvt.gov.lt/sveikatos-technologij%C5%B3-vertinimas/sveikatos-technologij%C5%B3-vertinimas/

67. Lithuanian Parliament. Order of the Minister of Health of the Republic of Lithuania No. V-208 on the procedure for reimbursement of medical devices [Internet]. 2016 Jan [cited 2024 Dec 29]. Available from: https://www.e-tar.lt/portal/lt/legalAct/f1c0e290c01e11e5a6588fb85a3cc84b/asr

68. Lithuanian Parliament. Order on the Approval of the Description of the Procedure for the Evaluation of Applications for Contracts from Orthopaedic Undertakings and Economic Operators and for the Publication of Information on the Submission and Evaluation of Such Applications [Internet]. 2019 Feb [cited 2024 Dec 29]. Available from: https://www.e-tar.lt/portal/lt/legalAct/cb4a957036a411e99595d005d42b863e/asr

69. Care Innovation Stories: An exploration of four innovation examples in healthcare [Internet]. 2021 Jun [cited 2024 Sep 25]. Available from: https://www.zorginstituutnederland.nl/publicaties/rapport/2021/06/25/kpmg-rapport-zorginnovatieverhalen

70. The Netherlands: Recent and planned changes in pharmaceutical pricing and reimbursement and overview of the medical devices system.

71. Zorginstituut Nederland [Internet]. [cited 2024 Sep 25]. Electrostimulators for chronic pain | Insured care | Dutch Healthcare Institute. Available from: https://www.zorginstituutnederland.nl/Verzekerde+zorg/elektrostimulators-bij-chronische-pijn-zvw

72. Assessment State of Science and Practice 2023 [Internet]. 2023 Apr [cited 2024 Sep 29]. Available from: https://english.zorginstituutnederland.nl/publications/reports/2019/04/23/assessment-of-established-medical-science-and-medical-practice%E2%80%99---a-technical-modification

73. Assessment of "established medical science and medical practice": a technical modification. 2019 Apr.

74. Package management in practice 4: Package management as solid basis for appropriate care. 2023 Mar.

75. Koperny M, Konieczna M, Głowik P, Siwiec J, Dziurda D, Sejbuk K, et al. Health Technology Assessment Guidelines for Medical Devices. 2021.

76. Medical devices assessment guidelines [Internet]. [cited 2024 Sep 16]. Available from: https://www.aotm.gov.pl/en/guidelines/medical-devices-assessment-guidelines/

77. Tajstra M, Dyrbus M, Grabowski M, Rokicki JK, Nowak M, Gasior M. The use of remote monitoring of patients with cardiac implantable electronic devices in Poland. Polish Heart Journal (Kardiologia Polska). 2022;80(4):479–81. doi:10.33963/KP.A2022.0050 PubMed PMID: 35176170.

78. Health technology assessment guidelines. Medical devices. Products for prophylactic and therapeutic use PART I [Internet]. Warsaw; 2021 Jun [cited 2024 Dec 29]. Available from: https://www.aotm.gov.pl/wp-content/uploads/2022/04/Wytyczne-Oceny-Technologii-Medycznych.-Wyroby-medyczne-czesc-I.pdf

79. Agency for Health Technology Assessment and Tariff System (AOTMiT) [Internet]. [cited 2024 Sep 16]. Assessment of reimbursement applications. Available from: https://www.aotm.gov.pl/en/medicines/assessment-of-reimbursement-applications/

80. Vinhas J, Dias S, Gouveia AM, Correia A, Dias C V, Sousa D, et al. Pharmacotherapeutic assessment methodology, Version 3.0. Committee for Health Technology Assessment [Internet]. 2023 [cited 2024 Sep 19]. Available from: https://www.infarmed.pt/documents/15786/1963929/METOD_AFT_v3.0_ENvf_fev2023/b0cb1c54-adca-721a-6466-75ba04cdd542

81. HTA Country/Area Profile (Portugal) [Internet]. 2020 [cited 2024 Sep 19]. Available from: https://cdn.who.int/media/docs/default-source/health-economics/hta-country-profiles-2020-21/hta-country_area-profile_portugal.pdf?sfvrsn=720b2741_3

82. Caldeira S, Santos C, Furtado C, Cossito M. PORTUGAL. PPRI Conference. Vienna; 2019.

83. National Institute for Health Outcomes (NIHO) [Internet]. 2021 [cited 2024 Aug 19]. How does the system work in Slovakia? Available from: https://niho.sk/ako-funguje-system-na-slovensku/

84. Ministry of Health of Slovakia [Internet]. [cited 2024 Aug 19]. Law 358 on the Scope and Terms of Medical Device Regulation. Available from: https://www.slov-lex.sk/ezbierky/pravne-predpisy/SK/ZZ/2021/358/20240801

85. 1. National Institute for Health Outcomes (NIHO) [Internet]. [cited 2024 Aug 19]. Published projects on Health Technology Assessment. Available from: https://niho.sk/publikovane-projekty/

86. Notification procedure of medical devices in Slovakia | ŠÚKL [Internet]. [cited 2024 Dec 30]. Available from: https://www.sukl.sk/en/medical-devices/instructions/registration-notification-procedure-of-medical-devices-in-slovakia?page_id=1718

87. Serrano-Aguilar P, Asua-Batarrita J, Molina-López MT, Espallargues M, Pons-Rafols J, García-Armesto S, et al. The Spanish Network of Agencies for Health Technology Assessment and Services of the National Health System (RedETS). Int J Technol Assess Health Care. 2019;35(3):176–80. doi:10.1017/S0266462319000205 PubMed PMID: 31006412.

88. EUnetHTA WP7 research and analysis activity 1: Final report An analysis of HTA and reimbursement procedures in EUnetHTA partner countries: final report.

89. Varela-Lema L, Atienza-Merino G, López-García M. [Priority setting of health interventions. Review of criteria, approaches and role of assessment agencies]. Gac Sanit. 2017 Jul 1;31(4):349–57. doi:10.1016/J.GACETA.2016.09.015 PubMed PMID: 28057389.

90. 2018 - PriTec Tool: Adaptation for the selection of technologies to be assessed prior entry into the health care benefits basket. - Axencia de Coñecemento en Saúde [Internet]. [cited 2025 Jan 15]. Available from: https://acis.sergas.es/cartafol/2018---PriTec-Tool-Adaptation-for-the-selection-of-technologies-to-be-assessed-prior-entry-into-the-health-care-benefits-ba?print=1

91. The MTP Council [Internet]. [cited 2024 Sep 23]. National Joint Introduction - Collaborative medicine technology. Available from: https://samverkanmedicinteknik.se/ordnat-inforande/national-joint-introduction

92. Dental and pharmaceutical benefits agency (TLV) [Internet]. [cited 2024 Sep 23]. Nationally ordered introduction of medical technology products - Dental and pharmaceutical benefits agency TLV. Available from: https://www.tlv.se/medicinteknikforetag/nationellt-ordnat-inforande-av-medicintekniska-produkter.html

93. Dental and pharmaceutical benefits agency (TLV) [Internet]. 2024 [cited 2024 Sep 23]. HTA regulation - Dental and pharmaceutical benefits agency TLV. Available from: https://www.tlv.se/medicinteknikforetag/hta-forordningen.html

94. Diagnostics Assessment Programme manual [Internet]. 2011 Dec [cited 2025 Jan 31]. Available from: https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-diagnostics-guidance/Diagnostics-assessment-programme-manual.pdf

95. National Institute for Health and Clinical Excellence (NICE) [Internet]. NICE; [cited 2025 Jan 31]. Diagnostics Assessment Programme process timeline . Available from: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-diagnostics-guidance/process-timeline

96. NICE health technology evaluations: the manual [Internet]. 2023 Oct [cited 2024 Aug 19]. Available from: https://www.nice.org.uk/guidance/pmg36/resources/nice-health-technology-evaluations-the-manual-pdf-72286779244741

97. NICE health technology evaluations: the manual | Guidance | NICE.

98. Medical Technologies Evaluation Programme [Internet]. [cited 2025 Jan 31]. Available from: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-medical-technologies-evaluation-programme

99. Early value assessment interim statement Process and methods [Internet]. 2022 Dec [cited 2024 Aug 21]. Available from: https://www.nice.org.uk/guidance/pmg39/resources/early-value-assessment-interim-statement-pdf-72286784283589

100. Scottish Health Technology Group Products. 2022 Aug.

101. A mechanism for the consideration of SHTG national advice on health technologies: a guide for NHS Boards [Internet]. 2024 [cited 2025 Jan 29]. Available from: https://shtg.scot/media/2443/20230623-consideration-of-national-advice-on-health-technologies_a-guide-for-boards-v20.pdf

102. Appraisal Process Guide - Health Technology Wales [Internet]. 2024 Aug [cited 2025 Jan 27]. Available from: https://healthtechnology.wales/wp-content/uploads/Appraisal-Process-Guide.pdf

103. Health Technology Wales [Internet]. [cited 2024 Oct 30]. Our Appraisal Process - Health Technology Wales. Available from: https://healthtechnology.wales/about/our-appraisal-process/

104. Guidance criteria for management of medical devices in the National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway (Nye metoder) [Internet]. 2018 Jan [cited 2024 Dec 29]. Available from:

https://www.nyemetoder.no/48ff64/siteassets/documents/om-systemet/guidance-criteria-for-handling-medical-devices-in-nye-metoder.pdf

105. Odd HA, Helga F. PPRI Pharma Profile Norway [Internet]. 2022 [cited 2024 Aug 23]. Available from: https://ppri.goeg.at/system/files/inline-files/PPRINorway2022_final.pdf

106. Guidelines for the submission of documentation for single technology assessments (STAs) of medical devices and diagnostic interventions [Internet]. 2021 [cited 2024 Aug 23]. Available from: https://www.fhi.no/globalassets/guidelines-for-the-submission-of-documents-for-stas-2021.pdf

107. Norwegian Ministry of Health and Care Services. Principles for priority setting in health care – Summary of a white paper on priority setting in the Norwegian health care sector [Internet]. 2017 Jan [cited 2024 Dec 25]. Available from: https://www.regjeringen.no/contentassets/439a420e01914a18b21f351143ccc6af/en-gb/pdfs/stm201520160034000engpdfs.pdf

108. Busse R, Blümel M, Knieps F, Bärnighausen T. Statutory health insurance in Germany: a health system shaped by 135 years of solidarity, self-governance, and competition. The Lancet. 2017 Aug 26;390(10097):882–97. doi:10.1016/S0140-6736(17)31280-1/ATTACHMENT/8F54E6D4-6F3C-437E-9BD2-BBFD980A666F/MMC1.PDF PubMed PMID: 28684025.

109. 28/2010. (V. 12.) EüM Decree on the professional criteria and policy priorities to be applied in the procedure related to the inclusion of health technologies used in curative and preventive procedures in health insurance financing [Internet]. 2010 [cited 2025 Jan 15]. Available from: https://net.jogtar.hu/jogszabaly?docid=a1000028.eum

110. Advising on and clarifying the contents of the standard health care benefit package | About us | National Health Care Institute [Internet]. [cited 2025 Jan 29]. Available from: https://english.zorginstituutnederland.nl/about-us/working-methods-and-procedures/advising-on-and-clarifying-the-contents-of-the-standard-health-care-benefit-package

111. Act of 13 September 2011 on the scope and conditions of reimbursement of medicines, medical devices and dietetic foods under public health insurance and on amendment and supplementation of certain acts [Internet]. [cited 2025 Jan 7]. Available from: https://www.slov-lex.sk/ezbierky/pravne-predpisy/SK/ZZ/2011/363/#poznamky.poznamka-1ca

112. Announcement of the Ministry of Health of the Slovak Republic for manufacturers of medical devices that will be subject to the categorization of

special medical materials [Internet]. [cited 2025 Jan 7]. Available from: https://www.health.gov.sk/Clanok?oznam-kk-szm-20121009

113. National Health Service [Internet]. [cited 2025 Jan 31]. Understanding routes to NICE health technology assessment - AI and Digital Regulations Service for health and social care. Available from: https://www.digitalregulations.innovation.nhs.uk/regulations-and-guidance-for-developers/all-developers-guidance/understanding-routes-to-nice-health-technology-assessment/

114. Huic M, Tandara Hacek R, Svajger I. HEALTH TECHNOLOGY ASSESSMENT in CENTRAL, EASTERN, and SOUTH EUROPEAN COUNTRIES: CROATIA. Int J Technol Assess Health Care. 2017;33(3):376–83. doi:10.1017/S026646231700054X PubMed PMID: 28803589.

115. Innovation funding: submission of an application for exceptional funding for an innovative product [Internet]. 2015 Apr [cited 2024 Dec 12]. Available from: https://www.has-sante.fr/jcms/p_3238091/fr/submission-of-an-application-for-exceptionnal-funding-for-an-innovative-product

116. Innovation funding: submission of an application for exceptional funding for an innovative product [Internet]. Available from: www.has-sante.fr

117. Federici C, Reckers-Droog V, Ciani O, Dams F, Grigore B, Kaló Z, et al. Coverage with evidence development schemes for medical devices in Europe: characteristics and challenges. Eur J Health Econ. 2021 Nov 1;22(8):1253–73. doi:10.1007/S10198-021-01334-9 PubMed PMID: 34117987.

118. Serrano-Aguilar P, Gutierrez-Ibarluzea I, Díaz P, Imaz-Iglesia I, González-Enríquez J, Castro JL, et al. Postlaunch evidence-generation studies for medical devices in Spain: the RedETS approach to integrate real-world evidence into decision making. Int J Technol Assess Health Care. 2021;37(1):e63. doi:10.1017/S0266462321000295 PubMed PMID: 33942712.

119. Royal Decree XXXXXXX/2024 of X of XXXXXXXX regulating the assessment of health technologies (TEXT AND MAIN SUBJECT TO A HEARING AND PUBLIC INFORMATION PROCEDURE) [Internet]. 2024 [cited 2024 Sep 21]. Available from: https://www.sanidad.gob.es/normativa/audiencia/docs/DG_54_24_Solicitud_informacion_publica_RD_EVALUACION_TECNOLOGIAS_SANITARIAS.pdf

120. Guidance on the scoping process List of abbreviations Abbreviation Definition BSC Best Supportive Care CE Conformité Européenne CHMP Committee for Medicinal Products for Human Use.

121. Fontrier AM, Kamphuis B, Kanavos P. How can health technology assessment be improved to optimise access to medicines? Results from a Delphi study in Europe: Better access to medicines through HTA. European Journal of Health Economics. 2024 Aug 1;25(6):935–50. doi:10.1007/S10198-023-01637-Z/TABLES/5 PubMed PMID: 37917290.

122. 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 Apr 10;15:1369508. doi:10.3389/FPHAR.2024.1369508/BIBTEX

123. Hwang TJ, Vokinger KN. New EU regulation on health technology assessment of cancer medicines. Lancet Oncol. 2022 Feb 1;23(2):e58. doi:10.1016/S1470-2045(22)00008-0 PubMed PMID: 35114127.

124. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. International Journal for Quality in Health Care. 2007 Dec 1;19(6):349–57. doi:10.1093/INTQHC/MZM042 PubMed PMID: 17872937.

125. Alshaikh RA, Walsh KA, El-Komy F, Spillane S, Carrigan M, Larkin L, et al. Mapping current decision-making pathways and reimbursement processes for high-risk medical devices in EU/EEA Member States and the UK: a scoping review. Under review. 2025.

126. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3(2):77–101. doi:10.1191/1478088706QP063OA

127. Willemsen A, Rutten-van Mölken M, al Dulaimi R, Schelleman H, Goettsch W, Timmers L. Preparing for the EU HTA Regulation: Insights from the Dutch Perspective. Journal of Market Access & Health Policy 2025, Vol 13, Page 35. 2025 Jul 24;13(3):35. doi:10.3390/JMAHP13030035

128. Tanner S, Coady R, Lisica A, Falla E, van Engen A. The EU Health Technology Assessment Regulation Halo Effect: Are Cross-Functional Teams Ready? J Mark Access Health Policy. 2025 Mar 1;13(1):3. doi:10.3390/JMAHP13010003 PubMed PMID: 39990182.

129. Arcà E, Barlassina A, Eze A, Strammiello V. Enhancing Patient Engagement in HTA: Using Consensus Research to Overcome PICO Scoping Challenges Under the EU HTAR. J Mark Access Health Policy. 2025 Jun 2;13(2):27. doi:10.3390/JMAHP13020027.

130. Goetz G, Schandelmaier S, Busse R, Wild C, Panteli D. Implementation of the EU's Health Technology Assessment regulation: Where does existing methods guidance require concretization and what are the relevant methodological options? Int J Technol Assess Health Care. 2025 Feb 6;41(1). doi:10.1017/S0266462324004793, PubMed PMID: 39909858.

131. Overview - European Commission [Internet]. [cited 2025 May 23]. Available from: https://health.ec.europa.eu/health-technology-assessment/overview_en

132. Akehurst RL, Abadie E, Renaudin N, Sarkozy F. Variation in Health Technology Assessment and Reimbursement Processes in Europe. Value in Health. 2017 Jan 1;20(1):67–76. doi:10.1016/j.jval.2016.08.725 PubMed PMID: 28212972.

133. Hulstaert F, Pouppez C, Primus-de Jong C, Harkin K, Neyt M. Evidence gaps for drugs and medical devices at market entry in Europe and potential solutions [Internet]. Belgian Health Care Knowledge Centre (KCE); 2021 [cited 2025 May 23]. (KCE Reports). Available from: https://kce.fgov.be/en/evidence-gaps-for-drugs-and-medical-devices-at-market-entry-in-europe-and-potential-solutions doi:10.57598/R347C

134. Hennink M, Kaiser BN. Sample sizes for saturation in qualitative research: A systematic review of empirical tests. Soc Sci Med. 2022 Jan 1;292:114523. doi:10.1016/J.SOCSCIMED.2021.114523 PubMed PMID: 34785096.

135. Meregaglia M, Costa F, Cavallaro L, Armeni P, Otto MH. Implementing the EU HTA regulation and joint clinical assessment: a multi-stakeholder perspective from Italy. Int J Technol Assess Health Care. 2026 Apr 13;42(1):e39. doi:10.1017/S026646232610364X PubMed PMID: 41968829.

136. Willemsen A, Rutten-van Mölken M, al Dulaimi R, Schelleman H, Goettsch W, Timmers L. Preparing for the EU HTA Regulation: Insights from the Dutch Perspective. J Mark Access Health Policy. 2025 Sep 1;13(3):35. doi:10.3390/JMAHP13030035 PubMed PMID: 40860954.

137. Severens H, Dillon A, Meyer F, Jommi C, Iga L, Canonico PL, et al. Paving the road for a successful EU HTA Reform implementation. Global & Regional Health Technology Assessment. 2025 Jan 1;12(1):194. doi:10.33393/GRHTA.2025.3502 PubMed PMID: 40895154.

138. Adams R, Stanak M. How the HTAR will contribute to a value-based decision-making for medicinal products across the EU. Br J Clin Pharmacol. 2026. doi:10.1002/BCP.70437;SUBPAGE:STRING:FULL

139. Health Information and Quality Authority. Review on governance of implantable medical devices at CHI, including use of non-CE marked springs in

surgery at CHI at Temple Street [Internet]. 2025 [cited 2026 Jul 26]. Available from: https://www.hiqa.ie/reports-and-publications/key-reports-investigations/review-governance-implantable-medical-devices

Appendix

List of supplementary Tables

Table S1.Population, Concept and Context for the research questions 152
Table S2. Search strategy of Medline database via EBSCOhost..... 157
Table S3. Search strategy of Embase database via Elsevier 161
Table S4. Search strategy of the Cochrane Library 162
Table S5. Search strategy of the INAHTA Database..... 163
Table S6. Results and search date of databases search 163
Table S7. Templates for data extraction from the included sources 164
Table S8. List of countries and official organisations from which information verification was received 166
Table S9. Consolidated criteria for reporting qualitative research (COREQ) checklist 168
Table S10. Interview topic guide..... 173

Table S1.Population, Concept and Context for the research questions

Country		Organisation	Website*
International		EUnetHTA	https://www.eunethta.eu/
		WHO	https://www.who.int/
		The Pharmaceutical Pricing and Reimbursement Information (PPRI) network	https://ppri.goeg.at/ppri_country_information
1.	**Austria**	Austrian Institute for Health Technology Assessment	https://aihta.at/page/homepage/en
		Federal Ministry of Social Affairs, Health, Care and Consumer Protection	https://www.sozialministerium.at/
		Umbrella Association of Social Insurance Institutions	https://www.sozialversicherung.at/
2.	**Belgium**	Belgian Health Care Knowledge Centre	https://kce.fgov.be/en
		Belgian National Institute for Health and Disability Insurance	https://www.inami.fgov.be
3.	**Bulgaria**	Bulgarian Drug Agency	http://www.bda.bg/
		National Health Insurance Fund	http://www.nhif.bg/
		National council on prices and reimbursement of medicinal products	https://ncpr.bg/en/ncprmp/about-council.html
4.	**Croatia**	Croatian Health Insurance Fund	https://hzzo.hr/
		Agency for Quality and Accreditation in Health Care and Social Welfare	https://aaz.hr/
		Agency for Medicinal Products and Medical Devices of Croatia	https://www.halmed.hr/en/
5.	**Cyprus**	Ministry of Health	https://www.moh.gov.cy/
		Health Insurance Organization	https://www.gesy.org.cy/
6.	**Czech Republic**	State Institute for Drug Control	http://www.sukl.cz/
		Czech Health Research Council	http://www.azvcr.cz/

		Ministry of Health	https://mzd.gov.cz/en/the-ministry-of-health/
7.	**Denmark**	Danish Medicines Agency	https://laegemiddelstyrelsen.dk/en/
		Danish Health Authority	https://www.sst.dk/en
		Danish Health Technology Council	https://behandlingsraadet.dk/in-english
		Danish Medicines Council	https://medicinraadet.dk/om-os/in-english
8.	**Estonia**	Estonian Health Insurance Fund	https://www.tervisekassa.ee/en
		Ministry of Social Affairs	https://www.sm.ee/en
		Centre for Health Technology Assessment	https://ut.ee/en/unit-health-information-analysis
9.	**Finland**	Social Insurance Institution of Finland	http://www.kela.fi/web/en
		Finnish Medicines Agency	https://www.fimea.fi/
		The Ministry of Social Affairs and Health	https://stm.fi/en/frontpage
		Finnish Coordinating Center for Health Technology Assessment	https://oys.fi/fincchta/en/finccchta/
10.	**France**	National Health Insurance Fund	https://www.ameli.fr/
		Haute Autorité de Santé	https://www.has-sante.fr/
11.	**Germany**	Federal Ministry of Health	https://www.bundesgesundheitsministerium.de/
		Institute for Quality and Efficiency in Health Care	https://www.iqwig.de/en
		Joint Federal Committee	https://www.g-ba.de/english/
12.	**Greece**	National Organization for Healthcare Provision	https://www.eopyy.gov.gr/
		Ministry of Health	https://www.moh.gov.gr/
		National Organisation of Medicines	https://www.eof.gr/web/guest
13.	**Hungary**	National Health Insurance Fund	http://www.neak.gov.hu/

		National Institute of Pharmacy and Nutrition	https://ogyei.gov.hu/
14.	**Ireland**	Health Service Executive	https://www.hse.ie/eng/
		Health Information and Quality Authority	https://www.hiqa.ie/
		Health Products Regulatory Authority	https://www.hpra.ie/
		National Centre for Pharmacoeconomics	https://www.ncpe.ie/
15.	**Italy**	Italian Medicines Agency	https://www.aifa.gov.it/
		Ministry of Health	https://www.salute.gov.it/
		National Agency for Regional Healthcare Services	https://www.agenas.gov.it/
16.	**Latvia**	National Health Service of Latvia	http://www.vmnvd.gov.lv
		State Agency of Medicines of the Republic of Latvia	https://www.zva.gov.lv/
17.	**Lithuania**	National Health Insurance Fund	https://www.vlk.lt/en
		State Health Care Accreditation Agency	https://vaspvt.lrv.lt/en/
18.	**Luxembourg**	National Health Fund	https://cns.public.lu/en.html
		Ministry of Health, Directorate of Health/Division of Pharmacy and Medicines	https://m3s.gouvernement.lu/en.html
19.	**Malta**	Medicines Authority	https://medicinesauthority.gov.mt
		Directorate for Pharmaceutical Affairs	https://healthservices.gov.mt/en/pharmaceutical/Pages/pharmaceutical-affairs.aspx
20.	**The Netherlands**	National Health Care Institute	https://www.zorginstituutnederland.nl/
		Ministry of health, wellbeing and sport	https://www.rijksoverheid.nl/ministeries/ministerie-van-volksgezondheid-welzijn-en-sport
21.	**Poland**	National Health Fund	https://www.nfz.gov.pl
		Agency for Health Technology Assessment and Tariff System	https://www.aotm.gov.pl/

22.	**Portugal**	Directorate-General for Health	https://www.dgs.pt/
		National Authority for Medicines and Health Products	https://www.infarmed.pt/
23.	**Romania**	National Health Insurance House	http://www.cnas.ro/
		National Agency for Medicines and Medical Devices	http://www.anm.ro/
24.	**Slovakia**	Ministry of Health of the Slovak Republic	http://www.health.gov.sk/
		National Institute for Value and Technology in Health	https://niho.sk/
25.	**Slovenia**	Health Insurance Institute of Slovenia	https://www.zzzs.si/
		Agency for Medicinal Products and Medical Devices of the Republic of Slovenia	https://www.jazmp.si/en
		Ministry of health	https://www.gov.si/en/state-authorities/ministries/ministry-of-health/
26.	**Spain**	Spanish Agency for Medicines and Health Products	https://www.aemps.gob.es/
		Spanish Network of Agencies for Assessing National Health System Technologies and Performance, Ministry of Health	https://redets.sanidad.gob.es/en/conocenos/quienesSomos/home.htm
27.	**Sweden**	Dental and Pharmaceutical Benefits Agency	https://www.tlv.se/
		National Board of Health and Welfare	https://www.socialstyrelsen.se/en/
		Swedish Agency for Health Technology Assessment and Assessment of Social Services	https://www.sbu.se/en/
		National Collaboration on Medical Technology	https://samverkanmedicinteknik.se/
		Swedish Medical Products Agency	https://www.lakemedelsverket.se/sv
28.	**United Kingdom**	National Health Service	https://www.nhs.uk/
		National Institute for Health and Care Excellence	https://www.nice.org.uk/
		Scottish Health Technologies Group	https://shtg.scot/

		Health Technology Wales	https://healthtechnology.wales/
		Medicines & Healthcare products Regulatory Agency	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
		Health and Social Care Board (HSCB) Northern Ireland	https://online.hscni.net/
29.	**Liechtenstein**	Office of Public Health in Liechtenstein	https://www.llv.li/de/landesverwaltung/amt-fuer-gesundheit
30.	**Iceland**	Icelandic Medicines Agency	https://www.ima.is/
		Ministry of Health	https://www.government.is/ministries/ministry-of-health/
31.	**Norway**	Norwegian Medical Products Agency	https://www.dmp.no/en
		Norwegian Regional Health Authority	https://www.helse-nord.no/?lang=en_US

* It is important to highlight that the provided URLs represent the official URL and initial starting points for the search. However, as our research progressed, the evaluation team were directed to additional organisations, websites, and reports that offered relevant information.

Table S2. Search strategy of Medline database via EBSCOhost

Database Name : Medline via EBSCOhost

Date search was run: September 02 2024

#	Query	Limiters/Expanders	Last Run Via	Results
S21	S5 AND S10 AND S19	Limiters - Publication Date: 20170101-20241231 Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	297
S20	S5 AND S10 AND S19	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	1,225
Concept 3: Decision making pathway				
S19	S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	74,308
S18	AB (("decision making" OR "decision-making") n2 (process* OR pathway* OR framework*)) OR TI (("decision making" OR "decision-making") n2 (process* OR pathway* OR framework*))	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	31,391
S17	AB ("oversight structure*" OR "governance structure*") OR TI ("oversight structure*" OR	Expanders - Apply equivalent subjects	Interface - EBSCOhost Research Databases Search Screen - Advanced Search	1,283

	"governance structure*")	Search modes - Proximity	Database - MEDLINE Complete	
S16	AB joint n1 assessment* OR TI joint n1 assessment*	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	1,414
S15	AB ("health technology assessment*" OR HTA OR HTAR) OR TI ("health technology assessment*" OR HTA OR HTAR)	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	9,098
S14	AB ("medical device* regulation*" OR (MDR n2 regulation*) OR "EU MDR" OR (regulation* n2 "2017/745") OR (regulation* n2 "2021/2282")) OR TI ("medical device* regulation*" OR (MDR n2 regulation*) OR "EU MDR" OR (regulation* n2 "2017/745") OR (regulation* n2 "2021/2282"))	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	487
S13	(MH. "Health Care Rationing")	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	12,144
S12	(MH "Decision Making, Organizational")	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	11,247
S11	(MH "Technology Assessment, Biomedical+")	Expanders - Apply equivalent subjects	Interface - EBSCOhost Research Databases Search Screen - Advanced Search	12,418

		Search modes - Proximity	Database - MEDLINE Complete	
Concept 2: reimbursement				
S10	S6 OR S7 OR S8 OR S9	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	884,126
S9	AB (reimburs* OR fund*) OR TI (reimburs* OR fund*)	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	608,604
S8	(MH. "Health Expenditures+")	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	26,895
S7	(MH "Reimbursement Mechanisms+")	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	38,672
S6	(MH "Costs and Cost Analysis+")	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	272,324
Concept 1: High risk medical devices				
S5	S1 OR S2 OR S3 OR S4	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	2,144,850
S4	TX ("High* risk" OR high-risk OR "Class III" OR "class IIb") AND ("medical device*" OR diagnostics)	Expanders - Apply equivalent subjects	Interface - EBSCOhost Research Databases Search Screen - Advanced Search	168,853

		Search modes - Proximity	Database - MEDLINE Complete	
S3	MH "Diagnostic Techniques and Procedures+/AE/IS/ST")	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	382,767
S2	(MH "Equipment Safety")	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	10,458
S1	(MH "Equipment and Supplies+")	Expanders - Apply equivalent subjects Search modes - Proximity	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - MEDLINE Complete	1,692,217

Table S3. Search strategy of Embase database via Elsevier

Database Name: Embase via Elsevier

Date search was run: September 03 2024

#	Query	Results
#22	#5 AND #10 AND #20 AND [2017-2024]/py	725
#21	#5 AND #10 AND #20	1,873
#20	#11 OR #12 OR 13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19	67,802
#19	(('decision making' OR 'decision-making') NEAR/2 (process* OR pathway* OR framework*)):ab,ti	37,489
#18	'oversight structure*':ab,ti OR 'governance structure*':ab,ti	1,538
#17	(joint NEAR/1 assessment*):ab,ti	953
#16	'health technology assessment*':ab,ti OR hta:ab,ti OR htar:ab,ti	15,387
#15	(regulation* NEAR/2 ('2017/745' OR '2021/2282')):ab,ti	96
#14	(mdr NEAR/2 regulation*):ab,ti	241
#13	'medical device* regulation*':ab,ti OR 'eu mdr':ab,ti	621
#12	'organisational decision making'/exp	111
#11	'biomedical technology assessment'/exp	18,482
#10	#8 OR #9 OR #10 OR #11	1,115,423
#9	reimburs*:ab,ti OR fund*:ab,ti	692,183
#8	'health care cost'/exp	358,366
#7	'reimbursement'/exp	69,033
#6	'cost'/exp	427,766
#5	#1 OR #2 OR #3 OR #4	5,960,265
#4	('high* risk':ti,ab,kw OR 'high risk':ti,ab,kw OR 'class iii':ti,ab,kw OR 'class iib':ti,ab,kw) AND ('medical device*':ti,ab,kw OR diagnostics:ti,ab,kw)	5,506
#3	'diagnostic procedure'/mj	18,193
#2	'device safety'/mj	3,001
#1	'devices'/exp	5,937,142

Table S4. Search strategy of the Cochrane Library

Database Name: The Cochrane Library **Date search was run:** September 03 2024		
#	**Query**	**Results**
#1	(("High risk" OR high-risk OR "Class III" OR "class IIb") AND ("medical device" OR "medical devices" OR diagnostics)) (Word variations have been searched)	8150
#2	(reimburs* OR fund*):ti,ab,kw (Word variations have been searched)	45822
#3	(medical NEXT device* NEXT regulation*):ti,ab,kw (Word variations have been searched)	15
#4	(MDR NEAR/2 regulation*):ti,ab,kw (Word variations have been searched)	4
#5	("EU MDR"):ti,ab,kw (Word variations have been searched)	4
#6	(regulation* NEAR/2 ("2017/745" OR "2021/2282")):ti,ab,kw (Word variations have been searched)	4
#7	("health technology assessment" OR "health technology assessments" OR HTA OR HTAR):ti,ab,kw (Word variations have been searched)	1552
#8	(joint NEAR/1 assessment*):ti,ab,kw (Word variations have been searched)	131
#9	("oversight structure" OR "governance structure" OR "oversight structures" OR "governance structures"):ti,ab,kw (Word variations have been searched)	23
#10	(("decision making" OR "decision-making") NEAR/2 (process* OR pathway* OR framework*)):ti,ab,kw (Word variations have been searched)	1459
#11	#3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10	3184
#12	#1 AND #2 AND #11 with Cochrane Library publication date from Jan 2017 to present	16

Table S5. Search strategy of the INAHTA Database

Database Name: INAHTA Database **Date search was run:** September 03 2024	
Search Strategies	Search 1: (medical devices)[abs] AND (high risk OR high-risk)[abs] AND (reimburs*) Search 2: ((medical devices)[abs] AND (high risk OR high-risk)[abs])[abs] AND (fund*)[abs] Search 3: "high risk medical devices"

Table S6. Results and search date of databases search

Databases	Number of results	Date searched
Medline Complete	297	03/09/2024
Embase	725	03/09/2024
The Cochrane Library	16	03/09/2024
INAHTA Database	7	03/09/2024
Total	1045	
Total after duplicates removed	**953**	

Table S7. Templates for data extraction from the included sources

Country *		
Document name/title	**Source A**	**Source B**
Document identifier *(for example, PMID or DOI for published articles)*		
URL		
Organisation		
Authors		
Funding		
Date of publication/ Date of access		
Original language of the document		
Translated (Yes/No)		
Summary of the methods (for publications)		
RQ1 What are the key decision-making pathways, stages of decision-making and oversight structures involved in reimbursing high-risk medical devices and diagnostics in the EU/EEA and the UK.		
1.1. What are the different schemes or pathways of reimbursement of high-risk medical devices and in-vitro diagnostics.		
1.2. Who initiates the process of reimbursement in each pathway		
1.3. What are the stages of decision-making and oversight structures involved in each stage for each pathway.		
1.4. What are the factors taken into consideration during reimbursement decision		
1.5. Are there specific provisions for emergency use or expedited pathways for particular devices? If yes, what are they. What are the different schemes or pathways of reimbursement		
1.6. Are there any regional variations in the reimbursement process within the country.		

(RQ2) How are the comparative safety and effectiveness data of high-risk medical devices and diagnostics used for reimbursement decisions in EU/EEA and the UK.		
2.1. How is comparative safety and effectiveness evidence data being considered for reimbursement decisions		
2.2. How is the uncertainty of comparative safety and effectiveness addressed during decision decision-making *(for example, is there a provisional approval, approval for research only, approval with managed access or the capacity to require and/or fund clinical trials).*		
2.3. After reimbursement, is there a monitoring period? *If yes, describe the different stages and oversight structures involved in the process until a final reimbursement decision is made.*		
2.4. How is the uncertainty of comparative safety and effectiveness addressed during decision-making.		

Table S8. List of countries and official organisations from which information verification was received

Country		National organiSations that provided information verification
1	**Austria**	Austrian Institute for Health Technology Assessment (AIHTA)
2	**Belgium**	National Institute for Health and Disability Insurance (RIZIV-INAMI)
3	**Bulgaria**	National council on prices and reimbursement of medicinal products
4	**Croatia**	Croatian Agency for Medicinal Products and Medical Devices of Croatia
5	**Cyprus**	Medical and Public Health Services at the Ministry of Health
6	**Czech Republic**	State Institute for Drug Control (SÚKL)
7	**Denmark**	Danish Health Technology Council
8	**Estonia**	Estonian Ministry of Social Affairs
9	**Finland**	Finnish Medicines Agency (Fimea) Finnish Coordinating Center for Health Technology Assessment (FinCCHTA)
10	**France**	French National Authority for Health (Haute Autorité de Santé; HAS)
11	**Germany**	Institute for Quality and Efficiency in Healthcare (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen; IQWiG)
12	**Greece**	National Organization For Health Care Services (EOPYY)
13	**Hungary**	National Centre for Public Health and Pharmacy (Nemzeti Népegészségügyi és Gyógyszerészeti Központ; NNGYK)
14	**Ireland**	Health Information and Quality Authority (HIQA)
15	**Italy**	National Agency for Regional Health Services (Agenas)
16	**Latvia**	State Agency of Medicines of the Republic of Latvia
17	**Lithuania**	State Accreditation Service for Health Care Activities under the Ministry of Health of the Republic of Lithuania (VASPVT). National Health Insurance Fund (VLK)
18	**Malta**	Directorate for Pharmaceutical Affairs (DPA)
19	**The Netherlands**	National Health Care Institute (ZIN)
20	**Portugal**	National Authority of Medicines and Health Products, I.P (INFARMED)

21	**Romania**		National Agency For Medicines And Medical Devices Of Romania
22	**Slovakia**		National Institute for Value and Technologies in Healthcare (NIHO)
23	**Slovenia**		Agency For Medicinal Products And Medical Devices Of The Republic Of Slovenia (JAZMP)
24	**Spain**		The Spanish Agency of Medicines and Medical Devices (AEMPS) Spanish Network of Agencies for the Evaluation of Health Technologies and Services of the National Health System (RedETS)
25	**Sweden**		The Dental and Pharmaceutical Benefits Agency (Tandvårds- och läkemedelsförmånsverket; TLV)
26	**United Kingdom**	**England**	National Institute for Health and Care Excellence (NICE)
		Scotland	Scottish Health Technologies Group (SHTG)
		Wales	Health Technology Wales (HTW)
27	**Norway**		Norwegian Medical Products Agency (NOMA)

Table S9. Consolidated criteria for reporting qualitative research (COREQ) checklist

Domain 1: Research Team and Reflexivity		
Personal Characteristics		
1.Interviewer/ facilitator	Which author/s conducted the interview or focus group?	RA conducted the interviews.
2. Credentials	What were the researcher's credentials (eg, PhD, MD)?	At the time of undertaking the interviews, RA's credentials were BPharm, MRes and PhD.
3. Occupation	What was their occupation at the time of the study?	RA is a postdoctoral researcher and a pharmacist who is conducting a research project on the implementation of HTAR for high-risk devices and the implications of the regulation in the Irish context.
4. Sex	Was the researcher male or female?	Female
5. Experience and training	What experience or training did the researcher have?	RA has a PhD in Pharmaceutical Science with a background in pharmacy, public health, pharmacology, drug delivery and dosage form design. RA completed training in the utilisation of NVivo software and qualitative research methods.
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	The pilot interview was conducted with Irish stakeholders working with RA and also a co-author of the study; this interview was excluded from the analysis and results generation. There were no established relationships between any of the other 14 participants and the researcher. However, some participants were known professionally to other study team members through European HTA networks.
7. Participant knowledge of the interviewer	What did the participants know about the researcher (e.g., personal goals, reasons for doing the research)?	RA disclosed to all participants that she is a postdoctoral researcher and clarified the reason for doing the research as part of the participant information leaflet and invitation email prior to conducting the interviews.

8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? (e.g., bias, assumptions, reasons and interests in the research topic)	RA is a postdoctoral researcher and was conducting this study as a part of a project exploring the effect of HTAR implementation with regard to high-risk devices in the EU/EEA and its implications for the Irish context. In order to minimise the potential for RA's information bias, entering the analysis, KW was also involved in the analysis of coded transcripts.
Domain 2: Study Design		
Thematic analysis		
9.Methodological orientation and theory	What methodological orientation was stated to underpin the study? (e.g., grounded theory, discourse analysis, ethnography, phenomenology, content analysis)?	Reflexive thematic analysis as described by Braun & Clarke.
Participants selection		
10. Sampling	How were participants selected (e.g., purposive, convenience, consecutive, snowball)?	Potential interview participants were selected via purposive sampling using publicly available contact information or the authors' network. Initial invitations to participate were sent to representatives from all 30 EU/EEA Member States through official email. A total of 11 Member States agreed to participate in the interviews, and interviews were successfully completed with all 11. Representatives of 6 Member States declined to participate, and there was no response to the request for an interview from 13 Member States.
11. Method of approach	How were participants approached (e.g., face-to-face, telephone, mail, email)?	Potential interview participants were selected via purposive sampling using publicly available contact information or the authors' network. Invitations to participate in interviews were sent to institutional email addresses.
12. Sample size	How many participants were in the study?	A total of 15 participants from 11 EU/EEA Member States participated in the study (11 interviews), including one pilot interview.

13. Non-participation	How many people refused to participate or dropped out? Reasons?	Emails were sent to representatives from all 30 Member States; 11 Member States agreed to participate in the interview. Representatives of 6 Member States declined to participate, and there was no response to the request for an interview from 13 states.
Setting		
14. Setting of data collection	Where was the data collected (e.g., home, clinic, workplace)?	All interviews took place online using Microsoft Teams.
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample (e.g., demographic data, date)?	All demographic data are listed in Table 3.1. The interviews took place between January and April 2025.
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot-tested?	The topic guide (in supplementary section S1.1) was only circulated to participants upon request. The guide was pilot-tested by the participants from Ireland to ensure appropriate content and language. The topic guide was revised slightly after the pilot interview. Throughout the remainder of the study, the topic guides underwent iterative revision to ensure that emerging themes were captured in subsequent interviews.
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No repeat interviews were carried out.
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	All interviews were audio and or video recorded, based on participants' selection in the consent form.
20. Field notes	Were field notes made during and/or after the interview or focus group?	Field notes were recorded both during and immediately after each interview and were used to support data analysis and for topic guide refinement.

21. Duration	What was the duration of the interviews or focus group?	The median interview length was 38 minutes, and the range was 13 and 47 minutes.
22. Data saturation	Was data saturation discussed?	Data saturation was not formally considered as part of this analysis as it does not align with the methodological approach undertaken, however it was noted that the last three interviews conducted did not present new ideas, themes or patterns.
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Transcripts were only returned if requested by participants. Participants from one interview requested to review the transcript. No significant changes were made.
Domain 3: Analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	Two (RA, KW)
25. Description of the coding tree	Did the authors provide a description of the coding tree?	Thematic analysis was used as the basis for coding. The resulting, domains, themes and subthemes are presented in Figure 3.2.
26. Derivation of themes	Were themes identified in advance or derived from the data?	The reflexive thematic analysis described by Braun and Clarke was performed in a combined deductive-inductive manner. An initial coding framework was built around key topics identified in the interview guide and was refined iteratively as new themes were identified from the analysis.
27. Software	What software, if applicable, was used to manage the data?	NVivo 20
28. Participant checking	Did participants provide feedback on the findings?	No

Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g., participant number	Yes, each quotation was identified by interview number.
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Major explanatory themes (domains) are presented in the results section.
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	The predominant minor themes that feed into the major domains are explored in detail in the results section.

Table S10. Interview topic guide

Knowledge and general thoughts:
• Can you outline how HTA currently feeds into the reimbursement decision-making for high-risk medical devices and in vitro diagnostics in your country?
• How familiar are you with the new HTA Regulation (HTAR) 2021/2282 and the preparation your country is taking for its implementation? Can you describe these preparations if available?
HTAR implementation processes:
• Can you describe how your agency has implemented or plans to implement the JCA within HTA processes for high-risk medical devices and in vitro diagnostics in your national context?
• Based on your experience, how do you think the HTAR implementation will change the reimbursement processes for high-risk medical devices and in-vitro diagnostics in your national context?
• Do you believe that HTAR will improve, complicate, or otherwise alter the HTA process?
Challenges and barriers:
• What challenges has your agency faced or is currently facing in implementing the HTAR in the context of high-risk medical devices and in vitro diagnostics?
• What is needed to overcome these challenges?
• What do you see as the potential short-, medium- and long-term impacts of HTAR on HTA processes for high-risk medical devices and in vitro diagnostics in your country?
Optimism and future outlook:
• How optimistic are you about the HTAR's potential to harmonise HTA processes across the EU/EEA?
• What are you hoping HTAR implementation and associated changes will achieve for medical devices *(prompt if needed: bring more safety, resources, or governance for medical devices).*
• Is there anything else you would like to share about your experiences with HTAR

Published by the Health Information and Quality Authority (HIQA).

For further information please contact:

Health Information and Quality Authority

George's Court

George's Lane

Smithfield

Dublin 7

D07 E98Y

+353 (0)1 8147400

info@hiqa.ie

www.hiqa.ie

© Health Information and Quality Authority 2026