ISPOR Europe 2024, Barcelona

A Comparative Analysis of Requirements for Gaining Market Access of Digital Health Technologies in Germany, Spain, Poland, and Hungary

HPR128

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Background & Objective

- In the EU, digital health technologies (DHTs) classified as medical devices (MDs) must undergo a conformity assessment in accordance with the Medical Device Regulation (MDR) 2017/745. Upon successful assessment, the MD receives a CE marking.
- Reimbursement rules for DHT vary considerably across Europe. Understanding country-specific reimbursement requirements is essential for entering the international digital healthcare market.
- This analysis aims to identify the differences in DHT market access pathways in two Western (Germany, Spain) and two Central and Eastern (Poland, Hungary) European countries and to compare the resulting consequences for manufacturers.
- The reimbursement landscape for DHTs in these four countries presents several challenges, as country-specific frameworks for assessment apply.
- Consequently, incorporating DHTs into diverse European healthcare systems presents significant reimbursement challenges for manufacturers.

Methods

- A thorough search for health authority documents, and published literature was conducted.
- The focus was on identifying key decision-makers, regulatory frameworks, and reimbursement pathways specific to DHTs in each of the four countries.

Results

- The targeted search for publications on market access and reimbursement for DHTs in four European countries over 5 years yielded 54 sources.
  - Germany provided 22, Spain 18, Poland 8, and Hungary 7 sources. After evaluation, 15 main sources were used in this analysis.
  - Distinct challenges and opportunities confront manufacturers of DHTs as they enter these four healthcare markets (Table 1):
- Germany
  - Established one of the most advanced frameworks for DHTs in Europe
  - In 2019, the Digital Healthcare Act (DVG) introduced a "fast-track" process for Digital Health Applications (DiGA).
  - This process requires manufacturers to demonstrate safety, functionality, quality, data security, and positive healthcare effects for approval.
  - The Federal Institute for Drugs and Medical Devices (BfArM) oversees this approval process. Once approved, DiGAs are listed in a national directory and can be prescribed by doctors and reimbursed by statutory health insurance.
  - In 2024, a new Digital Health Act (DigiG) was approved to further expand the DiGA framework and integrate DHTs more comprehensively into healthcare processes.

Results (ctd)

- Spain
  - Agency for Quality and Assessment of Catalonia (AQuAS) has developed a specific HTA framework for DHTs.
  - Health Technology Assessments (HTAs) are performed at both national and regional levels.
  - Ministry of Health (MoH) provides guidance and ensures adherence to national laws and standards and is responsible for pricing and reimbursement decisions.
  - Interterritorial Council of the National Health System (CISNS) defines the package of benefits provided within the health system.
- Poland
  - Agency for Health Technology Assessment and Tariff System (AOTMiT) plays a crucial advisory role in the reimbursement process.
  - Differentiate between therapeutic and non-therapeutic DHTs, with only the former having a clear assessment pathway through the Polish Agency for Health Technology Assessment and Tariffication.
  - MoH is responsible for reimbursement decisions.
- Hungary
  - Hungary's evaluation process is less defined as in the other three countries, involving the Office of Health Technology Assessment (OHTA) and the National Health Insurance Fund (NHIF).
- Market access and reimbursement challenges:
  - Germany offers a centralized process for DHTs, but high clinical evidence requirements pose challenges for smaller manufacturers.
  - Spain's decentralized system with 17 regional decision-makers complicates reimbursement, requiring tailored strategies for each autonomous community.
  - Poland lacks reimbursement routes for non-therapeutic DHTs, while Hungary's market access involves a more complex, multi-entity system.

Conclusions

- The reimbursement landscape for DHTs in Europe is diverse and evolving.
- Germany's structured approach provides a clear pathway for manufacturers which may serve as a model for other countries seeking to streamline DHT integration,
- while Spain's decentralized system offers flexibility but increases complexity.
- Poland and Hungary are in transitional stages, with potential for significant developments in their DHT reimbursement processes.
- These differences underscore the importance of tailored market access strategies for DHT manufacturers. As digital health continues to evolve, further refinement of reimbursement processes across Europe can be expected, potentially leading to more harmonized approaches in the future.

Table 1: Overview Reimbursement Process

Country	Definition of DHTs	Assessment authority	Duration of assessment	Assessed aspects	Reimbursement decision	Pricing negotiation	Specifics
Germany	MD of class I or IIa according to MDR, with main function on assisting in detecting, monitoring, treating, or alleviating injuries and diseases (1)	BfArM (1)	3 or 12 months (subject to the fulfillment of the requirements for a fast-track procedure) (1)*	• Positive healthcare effect • Security, functionality, data protection, information security, and quality (1, 2)*	BfArM (1)	a) First 12 months: prices set by manufacturer within the boundaries of a framework contract between national associations of manufacturers and health insurance funds b) After 12 months: prices negotiated between the manufacturer and the federal association of health insurance funds (GKV-SV) (1)*	Fast-track, Trial period possible (1, 2)
Spain	Digital technologies used to improve people's health and well-being, as well as the smarter use of clinical and genetic data for patient healthcare (3)	RedETS (3)	Variable (3)	• DHTs considered as non-drug health technologies •Demonstrate clinical safety, effectiveness, and value • Fulfill data protection laws (4, 5)	MoH (6, 7)	•CIPM (outpatient, or public health service) •Negotiations with the Marketing Authorization Holder (MAH) are led by the MoH (6, 7) •Central decisions can be reviewed by local authorities	Regional pricing possible Spanish healthcare system currently undergoing changes
Poland	No specific definition Identified	AOTMiT is involved in HTA and provides recommendations to the MoH (8)	Variable (8)	• Clinical effectiveness • Cost-effectiveness •Budget impact • Relevance to current medical practice (8, 9, 10)	MoH / AOTMiT (8)	MoH / Supported by Economic commission (8)	DHT generally not reimbursable, except if there is a therapeutic effect (11)
Hungary	• No specific definition for DHTs • Software within digital health apps can be considered a MD if represented by the definition in Act CLIV of 1997 on Healthcare (12)	OHTA (OGYÉI) (13)	N/A	•Clinical effectiveness • Cost-effectiveness • Budget impact • Relevance to current medical practice (12, 13)	MoH/NEAK/NHIF (14, 15)	NHIF (13)	No established practices or guidelines for assessment of DHTs In the early stages of developing a framework for DHTs (13)

* Requirements to fulfill for fast-track application: 1) DiGA must be classified as a MD of class I or IIa; 2) main function of the DiGA must be based on digital technologies; 3) DiGA must assist in detecting, monitoring, treating, or alleviating injuries and diseases, or compensating for disabilities; 4) DiGA must be used either by the patient alone or jointly by the patient and healthcare provider; 5) developer must submit an application to the BfArM; 6) application must fulfill general requirements related to safety, quality, functionality, privacy, and data security; 7) developer must demonstrate positive care effects, which can include medical benefits or structural and procedural improvements: There are two pathways for the fast-track process: a) If the developer can already provide evidence of positive care effects, the process takes up to 3 months or b) if the developer cannot yet provide evidence, a 12-month trial period is conducted to collect data and demonstrate positive effects; 8) DiGA must be eligible for reimbursement by statutory health insurance (SHI) in Germany.

Legend

- AOTMiT: Agency for Health Technology Assessment and Tariff System
- AQuAS: Agency for Quality and Assessment of Catalonia
- BfArM: Federal Institute for Drugs and Medical devices
- CE: Conformité Européenne
- CISNS: Council of the National Health System
- CIPM: Interministerial Medicinal Products Pricing Commission
- DiGA: Digital Health Applications
- DigiG: New Digital Health Act
- DVG: Digital Healthcare Act
- GKV-SV: National Association of Statutory Health Insurances
- MD: Medical device
- MDR: Medical Device Regulation
- MoH: Ministry of Health
- NEAK: National Health Insurance Fund of Hungary
- NHIF : National Health Insurance Fund
- OGYÉI: National Institute of Pharmacy and Nutrition of Hungary
- OHTA: Office of Health Technology Assessment
- RedETS: Spanish Network of Agencies for Health Technology Assessment and Services of the National Health System
- SHI: Statutory health insurance

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