BRIDGING THE GAP: WHAT SPAIN CAN LEARN FROM EUROPEAN LEADERS IN DIGITAL THERAPY REIMBURSEMENT

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Introduction and Objective

Digital therapeutics (DTx) are a reality. After reviewing the European database on medical devices, 607 software products were registered as of June 23, 2025[1]. Countries like Germany, Belgium, and France are pioneers in the integration of these therapies into their healthcare systems. In contrast, Spain does not have specific regulations for the inclusion of these therapies in the national healthcare system.

The aim of this study is to compare the regulatory frameworks for the reimbursement of DTx in Germany, France, Belgium, and Spain, and to identify opportunities for improvement within the Spanish National Healthcare System.

Methods

(1) **Review** the official documents from the Federal Institute for Drugs and Medical Devices in Germany[2]; the High Authority of Health and the National Gateway for Innovation and Digital Health in France[3]; the National Institute for Health and Disability Insurance and the Federal Centre for Healthcare Expertise in Belgium[4], and the Spanish Agency for Medicines and Health Products and the Ministry of Health[5].

(2) **The study examined six key dimensions:** legal frameworks, evaluation procedures, requirements for clinical and economic evidence, cybersecurity standards, interoperability with healthcare institutions, and institutional support mechanisms.

Results

Germany, France, and Belgium have implemented structured and transparent pathways for the evaluation and reimbursement of DTx. **Table 1** outlines the six key dimensions highlighted in this study. As shown, Spain's lack of a dedicated regulatory framework, a public directory of reimbursed DTx, and other essential elements limit the adoption of DTx in the country.

Table 1. Comparative Framework for the Evaluation and Reimbursement of Digital Therapeutics in Germany, France, Belgium, and Spain

Key dimensions	Germany[2]	France[3]	Belgium[4]	Spain[5]
Legal frameworks	DiGA Fast track	PECAN	INAMI	No legal frameworks available
Evaluation procedures	BfArM (Fast track)	HAS	INAMI	?
Requirements for clinical and economic evidence	Clinical benefit	Clinical and economic evaluation	Economic and organizational evaluation	?
Cybersecurity standards	Mandatory certificate	Compliance with GDPR	Requirements for data privacy and confidentiality	Compliance with GDPR
Interoperability with healthcare institutions	Mandatory	Mandatory	Mandatory	?
Institutional support mechanisms	✓	✓	✓	?

Conclusions

- **Spain faces significant challenges** in aligning with European best practices for DTx reimbursement.
- Essential steps to enhance **transparency, efficiency, and innovation** in the Spanish National Healthcare System:
  - To stablish a **dedicated regulatory pathway.**
  - To adopt **recognized cybersecurity certification standards.**
  - **To create a national directory** of reimbursed digital tools.

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ABBREVIATIONS: BfArM, Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices); DiGA, Digitale Gesundheitsanwendungen (Digital Health Applications); DTx, digital therapies; GDPR, General Data Protection Regulation; HAS, Haute Autorité de Santé (French National Authority for Health); INAMI, Institut national d'assurance maladie-invalidité (National Institute for Health and Disability Insurance); PECAN, Prise en charge anticipée numérique (Digital advance care).

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