THE PROMISING FUTURE OF DIGITAL HEALTH: A ROAD TO REIMBURSEMENT IN EU5 & US MARKETS?

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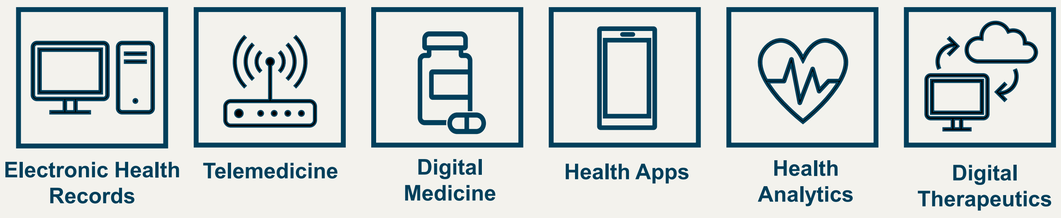
INTRODUCTION

- Digital health solutions encompass a wide range of technologies with the aim of promoting, improving or supporting health care systems and the delivery of health care (Figure 1).
- In recent years, the digital health landscape has rapidly evolved presenting new opportunities for the healthcare industry.
- However, many countries still lack comprehensive reimbursement frameworks for digital health products, hindering widespread adoption and accessibility.

Figure 1 Examples of digital health solutions[1]



OBJECTIVE

- This analysis aims to explore the digital health landscape across the EU5 and US markets, examining current market access strategies and future reimbursement opportunities for digital products.

METHODS

- Targeted review of policy documents, journal articles and news articles between the years of 2020-2023 to understand the current digital health landscape for EU5 and US markets.
- The digital health landscape involved a review of the following topics: digital health product (DHP) classification, reimbursement pathways, key stakeholders, alternative pathway options and recent developments.
- Identification of a range of DHP case studies across scope markets based on a review of published Health Technology Assessments (HTAs), journal articles and news articles.
- Selection of two DHP case studies according to their varying reimbursement status across scope markets: Deprexis and Velibra. To further explore the US landscape and challenges experienced with DHP reimbursement, an additional DHP case study was explored: reSET and reSET-O.
- Extracted data and performed analysis on case studies: including information such as reimbursement status, evidence types submitted for evaluation, rationale for final reimbursement decision and list price information to assist comparison across scope markets.

Key: AETS: Health Technology Assessment Agency; AIFA: The Italian Medicines Agency; BfArM: The Federal Institute for Drugs and Medical Devices; DHP: Digital Health Product; FDA: Food and Drug Administration; HAS: Haute Autorité de santé; NHS: National Health Service; NICE: National Institute for Health and Care Excellence.

RESULTS

- The classification of digital health products (DHPs) varies per market. Two of the six markets analysed consider DHPs under the remit of medical devices rather than a single entity.
- Only three markets (UK, France and Germany) conduct a centralised evaluation of DHPs, and mechanisms of reimbursement vary between markets. Despite this, all markets have shown recent progression in the digital space, either through the introduction of pilot schemes or publication of new legislation for digital products.
- Spain, Italy and the US lack a standardised evaluation framework and reimbursement decisions occur at a regional or local level (Table 1). To date, no digital products have been reimbursed in Spain or Italy.

Table 1 Digital health reimbursement landscape in scope markets

Country	DHP Classification	Centralised Evaluation?	Centralised Decision?	Main Stakeholders?	Alternative Pathway?	Recent Developments?
UK	Digital health products	Yes	No	NICE, ICBs	Yes	IDAP pilot scheme for innovative medical devices (2023).
France	Medical devices	Yes	Yes	HAS	Yes	PEC-AN fast-track reimbursement scheme for digital health solutions (2023).
Germany	DiGA products	Yes	Yes	BfArM	Yes	Draft Digital Act (DigiG) containing new pricing and reimbursement rules for DiGAs published by German Federal Ministry of Health (2023).
Italy	Digital health products	No	No	Varies*	Yes	Parliamentary Intergroup Digital Health and Digital Therapeutics introduced an initial bill on digital therapeutics (DTx) (2023).
Spain	Medical devices	No	No	Varies*	No	Launch of the F^{3}T framework for fast-track of DHPs in Barcelona (2023).
US	Digital health products	No	No	Varies*	Yes	Introduction of Medicare benefit category for prescription DTx (2022).

Key: BfArM: The Federal Institute for Drugs and Medical Devices; DiGA: Digital Health Applications, DTx: Digital Therapeutics; HAS: Haute Autorité de santé; ICB: Integrated Care Board; IDAP; Innovative Devices Access Pathway; NICE: National Institute for Health and Care Excellence; PEC-AN: Prise en Charge Anticipée.
Notes: *Reimbursement decision is decentralised therefore decisions are made by multiple stakeholders at a regional or local level.

- As of June 2023, Germany had successfully reimbursed 47 DiGA products in over 20 disease areas, including Deprexis and Velibra.
- In 2018, Deprexis was assessed and recommended in the UK via the NICE Improving Access to Psychological Therapies (IAPT) programme, although Velibra was not following evaluation one year later.
- Deprexis was also recommended in France, with a notably similar evidence base to Germany and the UK, which included two randomised controlled trials (RCTs). Velibra has not been assessed (Table 2).

Table 2 Case studies: Deprexis and Velibra

Country	Reimbursed?		Evidence Submitted	Key Rationale/ Decision	List Price
UK	Deprexis	Yes*	2x RCTs	Further evidence required; conditional approval	£324 (incl. VAT)**
	Velibra	No	1x RCT	NICE IAPT evaluation criteria not met	£343 (incl. VAT)
France	Deprexis	Yes	2x RCTs	SA: Insufficient, ASA level: V	€300 (incl. VAT)
	Velibra	NA	-	-	-
Germany	Deprexis	Yes	2x RCTs	Permanent DiGA listing	€210 (incl. VAT)
	Velibra	Yes	1x RCT	Permanent DiGA listing	€230 (incl. VAT)
US	Deprexis	Yes	2x RCTs & RWE	VA FFS contract granted until 2032	$399 (incl. VAT)
	Velibra	NA	-	-	-

Key: ASA: Added Medical Benefit; Improving Access to Psychological Therapies (IAPT); NA: Not Assessed; RWE: Real-World Evidence; SA: Medical Benefit; VA FFS: Veteran Affairs Federal Supply Schedule.
Notes: *NICE conditional recommendation published May 2023. **Price for a period of 90 days.

Reimbursement Challenges: reSET and reSET-O in the US

- Prescription digital therapeutic products reSET and reSET-O included a large evidence base of over 40 studies including RCTs.
- Despite this, both products surprisingly failed to secure a widespread reimbursement contract in the US. Coverage was provided for the products under the Medicaid plan, MassHealth.
- An ICER report (2020) highlighted that reSET-O failed to demonstrate significant value stating: '*[the product] represents low long-term value for money at its current price*.'

DISCUSSION

- This analysis has provided some interesting insights helping to explore and characterise the digital health landscape across EU5 and US markets.
- Differences exist between markets in terms of the mechanisms of reimbursement for digital health products, with a split of centralised and decentralised evaluation and decision-making processes.
- The above suggests there is no uniform way for digital health products to enter the core markets at present, although the constant evolution of the landscape is likely to change this in future years.

CONCLUSIONS

- Based on our analysis the UK, France and Germany appear to be leading in digital health product reimbursement, with standardised evaluation frameworks. Most markets also have alternative pathway options for digital products highlighting that variation exists between country-specific reimbursement pathways.
- Despite this, a centralised evaluation framework does not appear essential as highlighted in the US, where Deprexis, reSET and reSET-O are all reimbursed.
- However, challenges with a decentralised evaluation and decision-making process include not achieving widespread adoption which restricts the extent of accessibility.
- Assessment of digital health products is easier in some markets (i.e., Germany) than others, and ultimately access depends on a multitude of factors ranging from the strength of the clinical evidence submitted through to the market's evaluation criteria.
- It remains crucial that developers understand the importance of selecting the correct evidence generation method and remain aware of recent market developments to minimise negative recommendations and adoption difficulties across markets.

REFERENCES

1 Adapted from: https://dtxalliance.org/wp-content/uploads/2023/06/Guidance-to-Industry-Classification-of-Digital-Health-Technologies-2023Jun05.pdf