ADVANCEMENTS IN DIGITAL HEALTH: CURRENT LANDSCAPE & EVALUATION PROCESSES FOR US, UK & EU4 MARKETS

Hope Sheppard[1] & David Alderson[1]

[1]Cogentia Healthcare Consulting Ltd, Cambridge, CB1 2JD, UK. Author for correspondence: hope.sheppard@cogentia.co.uk

SCAN ME FOR MORE CONTENT

Cogentia®

WWW.COGENTIA.CO.UK

INTRODUCTION

- Over the past year, there has been a shift in how individual countries approach the reimbursement of digital health products (DHPs).
- The European Federation of Pharmaceutical Industries and Associations (EFPIA) defines digital health broadly as the integration of information technology, big data, artificial intelligence, and machine learning into healthcare systems to optimise care and improve patient outcomes[1].
- DHPs encompass a wide range of technologies, such as electronic patient records, telemedicine, remote monitoring devices, and digital therapeutics.
- In 2021, the World Health Organisation (WHO) developed a global strategy report for the advancement of DHPs between 2020-2025, acknowledging that countries must individually decide and commit to integrating DHPs into their national health system[2].
- This acknowledgement correlates to a current lack of standardisation between reimbursement processes for DHPs across US, UK, and EU4 markets.
- Whilst the UK, Germany and France have established evaluation frameworks for DHPs, Italy, Spain and the US remain hesitant to adopt dedicated assessment pathways, resulting in limited reimbursement, access and adoption for digital technologies.
- Discussions surrounding a harmonised market access framework for DHPs in Europe are ongoing with the European Institute for Innovation & Technology Health (EIT Health).

OBJECTIVE

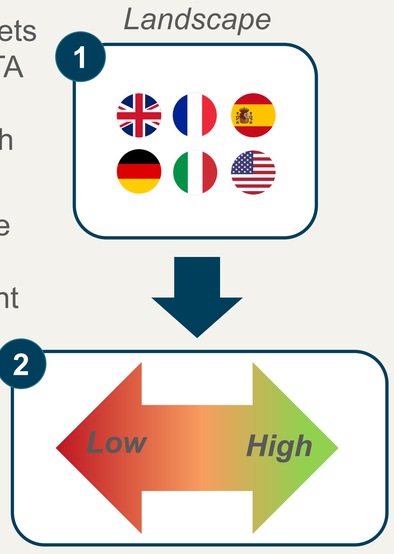
- This analysis aims to explore the digital health landscape over the past year for US, UK and EU4 markets, focusing on existing market access evaluation processes and latest product reimbursements.

METHODS

- The current digital health landscape in US, UK, and EU4 markets was examined through a targeted literature review (TLR) of HTA agency websites, relevant policies, and recent news articles between 2023-2024 to identify the latest advancements in each market.
- This review focused on the reimbursement processes available for DHPs including: the presence or absence of a dedicated evaluation pathway, evidence requirements, examples of recent product reimbursements, and latest landscape developments (**Table 1**).
- Extracted data enabled a comparative analysis of the digital health landscape between scope markets.
- A ranking of low, moderate or high was given to each market based on the maturity of their reimbursement landscape.

**High maturity ranking relates to markets with well-established evaluation processes for DHPs, and evidence of successful utilisation i.e., recent DHP reimbursement. Low maturity ranking relates to markets lacking a dedicated evaluation process for DHPs, with no products reimbursed via a specified route.*

TLR of Digital Health Landscape



*Ranking of Landscape Maturity**

RESULTS

- Across markets, the digital health reimbursement landscape varies in its maturity level.
- Only two markets (UK and Germany) were considered highly mature, having dedicated evaluation process for DHP reimbursement, with associated evidence requirements, alongside recent DHP reimbursement(s) (**Table 1**).
- The UK continues to utilise multiple assessment processes for DHPs, including NICE's Early Value Assessment (EVA) and Medical Technologies Guidance (MTG) routes, which offer three levels of guidance depending on the level of evidence submitted. DHPs recommended by NICE via EVA receive funding to support a proposed evidence generation plan (i.e., real-world evidence generation).
- Germany's DiHA process is still used for the 'fast-track' reimbursement of DHPs following introduction of the Digital Healthcare Act in 2019. As of October 2024, Germany has permanently and provisionally reimbursed 54 DiHA across various diseases, a ~15% increase from 47 in June 2023.
- France and the US show moderate levels of maturity in the digital health landscape.
- In France, the PEC-AN early access scheme offers temporary reimbursement for DHPs. However, to secure permanent coverage, approved applicants must undergo the standard HAS process, which has stringent evidence requirements, and it is arguably challenging to quantify the DHP's impact to the healthcare system.
- The US lacks a centralised evaluation process for DHPs, leading to reimbursement decisions on a case-by-case basis. Recent progress includes FDA approval of Rejoyn for depression and new Medicare billing codes for digital mental health treatments, despite previous reimbursement setbacks with reSET and reSET-O. For this reason, the maturity of the US digital health landscape is ranked as 'moderate'.
- Italy and Spain show low maturity across the digital health landscape, with no dedicated evaluation process for DHPs, leading to fragmented, local-level reimbursement decisions.
- Although reimbursement is possible for digital health solutions classified as medical devices, neither Italy or Spain has any recent DHP reimbursements through a centralised process, supporting their low maturity rankings.

Table 1 Summary of digital health reimbursement landscape per scope market

Country	Dedicated Evaluation Process?	Process Overview?	Level of Evidence Required?	Recent Product Reimbursements**?	Recent Developments/ News?	Level of Maturity?
UK	Y	NICE EVA or MTG appraisal	Flexible depending on product	Y – 7x DHPs recommended via NICE MTG or DG	**Jan 2024:** Funding to support EVA-recommended DHPs with RWE generation.	High
Germany	Y	DiHA 'fast-track' reimbursement	Mandatory performance monitoring to be introduced	Y – 7x DiHA recorded (provisionally or permanently since Jun 2023)	**Sept 2023:** Mandatory performance monitoring to be used as basis for price negotiations.	High
France	Y	PEC-AN early access scheme or HAS medical device assessment	Limited evidence for PEC-AN temporary reimbursement vs high evidence requirements for HAS	Y – first PEC-AN reimbursement in Oct 2023	**Jun 2024:** Approximately 30% of digital companies abandon product launch in France due to lack of clinical data to obtain reimbursement.	Moderate
Italy	N	No specific process currently available*	Minimum of two clinical trials with 'high quality' evidence	N	**May 2023:** 'Provisions on digital therapies' bill submitted providing principles for reimbursement inclusion.	Low
Spain	N	No specific process currently available*	Flexible depending on product	N	Currently developing regulations for addressing digital medical device reimbursement.	Low
US	N	No specific process currently available*	Flexible depending on product	N	**Apr 2024:** First digital therapeutic Rejoyn FDA-approved for depression. **Aug 2024:** Introduction of new Medicare billing codes for digital mental health treatment.	Moderate

Abbreviations: DG: Diagnostic Guidance; DiHA: Digital Health Application; EVA: Early Value Assessment; FDA: Food and Drug Administration; HAS: French National Authority for Health; MTG: Medical Technology Guidance; NICE: National Institute for Health and Care Excellence; PEC-AN: Early Access Process; RWE: Real-World Evidence. **Notes:** *May be reimbursed on a case-by-case basis. Telemedicine is automatically reimbursed by the National Health System in Spain. **via dedicated evaluation process (between Jan 2023-Oct 2024).

DISCUSSION

- Arguably, the most mature markets are Germany and the UK, with specific evaluation processes implemented for DHPs, and evidence of recent reimbursements via these dedicated pathways.
- However, there is no standardised pathway for the reimbursement of DHPs across US, UK and EU4 markets.
- Lack of a harmonised reimbursement framework results in fragmented product launches, limiting widespread adoption and patient access to DHPs.
- Reports have estimated that approximately 30% of digital companies have abandoned their product launches in France due to lack of clinical data for reimbursement[3].
- EIT Health are currently focusing on discussions surrounding a joint assessment framework for DHPs, aiming to enhance harmonisation in Europe by drawing on learnings from the German DiHA process.

CONCLUSIONS

- This analysis concludes that the DHP landscapes differs in maturity across the US, UK and EU4 markets, ranging from centralised to decentralised evaluation processes to decide upon reimbursement.
- Without clear, standardised reimbursement routes, DHPs face challenges in achieving widespread adoption, which ultimately impacts patient access to these potentially beneficial technologies.
- Development of a standardised approach to DHP reimbursement would provide an opportunity to facilitate faster, more uniform access to DHPs.
- Prioritisation of DHP integration within a market's national health system is also expected to provide further alignment across current pathways for digital health reimbursement.

REFERENCES

1 EFPIA website: https://www.efpia.eu/about-medicines/development-of-medicines/digital-health
2 WHO Global Strategy report: https://iris.who.int/bitstream/handle/10665/344249/9789240020924-eng.pdf?sequence=1
3 National Union of the Medical Technology Industry study reported in https://www.ticpharma.com/story?ID=2637