DIGITAL THERAPEUTICS ALLIANCE

DTx Innovation in Europe: 2024 Milestones and a Vision for 2025

As we step into 2025, we carry forward the momentum of a year filled with progress, valuable lessons, and significant milestones for the DTx industry in Europe.

June 2024 was marked with the election of the European Parliament. All 27 EU countries elected the 720 members of the European Parliament for a five-year term, with the centre-right European People's Party (EPP) gaining the most seats and the Greens declining, while the overall composition suggests continuity in legislative trends, making health policy a continued priority.

In 2024, digital health policy has seen remarkable progress with the adoption of the AI Act and the European Health Data Space (EHDS). The AI Act seeks to regulate artificial intelligence, safeguarding the safety and fundamental rights of individuals in Europe while striving for a streamlined certification process. Likewise, the EHDS offers significant potential for enhanced data sharing and improved healthcare outcomes, emphasizing the importance of maintaining data integrity for all stakeholders involved.

Most critically, the need to reform the Medical Device Regulation (MDR) gained recognition across European institutions and Member States, highlighting its importance for public health, patient safety, and sustainable healthcare systems. DTA recommends that the European Commission implements immediate measures to streamline certification processes and long-term reforms to reduce bureaucracy, improve efficiency, and establish a unified governance model to support innovation and maintain safety standards.

Recently, the Medical Device Coordination Group (MDCG), the EU working group that deals with key issues for the medical devices sector, discussed how they wanted to update medical devices risk guidelines. They proposed a revision of Rule 11. While its intent is to enhance patient safety, the rule can lead to a significant up-classification of software, often assigning even low-risk applications to Class IIa or higher. Along with our partners, DTA is drafting a position paper that calls for revising MDR Rule 11 to prevent over-classification of low-risk medical device software, which currently stifles innovation by imposing disproportionate regulatory burdens. It highlights the low risk associated with self-management apps based on extensive safety data and proposes a more nuanced, risk-based classification system. This change would reduce costs and time-to-market for developers while ensuring patient safety and fostering innovation in digital health technologies.

In France, 2024 marked the start of the PECAN pathway implementation (fast track for Digital Therapeutics and Remote Patient Monitoring products). So far, the Haute Autorité de la Santé has received and evaluated 6 PECAN dossiers (5 RPM products and 1 DTx). Of these, only 3 RPM products were approved. Additionally, 6 RPM products directly applied to permanent listing, resulting in 4 approvals listed on the LATM. This is due to France's years of experience in

reimbursing and integrating RPM products, first through the experimental ETAPES program and now with the preliminary listing (PECAN) and permanent listings (LATM). Unfortunately, so far France has lacked the experience and expertise to evaluate DTx products.

In 2024, Germany steadily increased the number of DiGA that are reimbursed with a total number of 58 applications being listed (20 provisionally and 38 permanently).
In 4 years, Germany has done an incredible job evaluating, reimbursing and adopting diverse DTx products and staying the European leader in this field. However we need to stay vigilant on updates and modifications of the current regulation.

In October 2024, Victor Stephani, DTA's European task group co-chair, met with the German Ministry of Health and other digital medical device stakeholders about changes on the value-based pricing for DiGA. This was not about reimbursement pricing but how to measure and assess certain parameters such as duration and frequency of use of the DiGA, patient satisfaction and patient-reported outcome measures. With the legal framework acc. to §139e (13) SGB V, starting January 1st, 2026, BfArM will publish the results of the real world performance assessment of a DiGA. Following this meeting, a comment letter jointly signed by DTA and SVDGV, was sent to the MoH, outlining the most important demands that the data collection should entail. The letter had a positive impact: about a week ago, the MoH published a draft version of this regulation which is now open for comments until the end of January. While some of our raised points were considered in the draft, the final version will be determined after the consultation period. We will provide a detailed analysis and guidance on the implications of these regulatory changes once the final version is published, ensuring our members understand how the new requirements will affect their operations and compliance obligations

In terms of evaluation and reimbursement, each European country has its own rules and requirements. While Germany takes a process-driven approach, offering clear guidance for applications, France emphasizes a relationship-focused strategy that encourages and requires active engagement with authorities, the scientific community, and patient associations.
Over the years, DTA has developed and provided reliable resources to help policy makers, evaluators, payors, clinicians and patients understand the digital health technologies (DHT) ecosystem and where DTx fit in this broader industry, the definition of DTx, the DTx industry core principles, DTx' intended uses and mechanisms of action, DTx' regulatory and reimbursement pathways by country, and concrete examples of DTx that are on the market.

We are optimistic that 2025 will bring the positive changes we seek, as institutions and stakeholders collaborate to enhance lives across Europe. We remain dedicated to advancing access to medical technologies that improve health and quality of life for all.

Emilie Lopes-Fernandes, Head of European Policy