Spitzenverband Digitale Gesundheitsversorgung

Press Release

ADVANCING DIGITAL HEALTH IN EUROPE: REGULATORY AND POLICY PERSPECTIVES ON DIGITAL MEDICAL DEVICES

Berlin, November 25th 2024 – Digital Therapeutics (DTx) and digital monitoring applications (remote patient monitoring, RPM) offer significant advantages in the treatment of medical conditions, providing patients with personalized, **evidence-based** interventions that improve **health outcomes** and/or health procedures. These software-driven solutions not only improve access to guideline-adherent care but also empower patients to actively manage their symptoms, achieve better clinical results, and enhance their quality of life. As digital medical devices (DMD) become increasingly integral to healthcare, they promise to revolutionize the way medical care is delivered across Europe.

However, the integration of DMD into national healthcare systems requires a coordinated effort across the continent. Establishing **joint requirements for the transferability of DMD assessments** are crucial to ensuring consistent access to these innovations. Germany's DiGA Fast Track and France's PECAN process represent pioneering national approaches in this area. The DiGA Fast Track enables integration of digital health applications into the German statutory health insurance system, while the PECAN process in France seeks to streamline the evaluation and reimbursement of digital medical devices. These national initiatives highlight the **need for a broader European strategy** that supports **cross-border collaboration and standardization**.

This paper explores **four key requirements** essential for shaping the future of digital therapies and monitoring applications in Europe.

1. A Harmonised Taxonomy of DMDs

Harmonizing the nomenclature of Digital Medical Devices (DMDs) across Europe is an essential foundation for achieving consistency in regulatory and classification practices. While the EU Medical Device Regulation (MDR) provides guidelines for traditional Medical Devices (Classes I-III), the need for standardized nomenclature in the context of DMDs extends beyond the MDR. Establishing a shared understanding of the various categories of DMDs, such as digital therapies and monitoring solutions, is vital to ensuring uniformity in how these devices are classified and regulated across Europe. This alignment will support clearer communication, reduce regulatory fragmentation, and promote innovation in the DMD field.

2. Harmonization of Clinical Evidence Requirements

A key element in advancing the integration of DMD across Europe is the need for **harmonized clinical evidence standards**. The value and practicality of study designs that are genuinely integrated into real-world healthcare settings has been demonstrated in diverse DiGA listings in Germany.

Methodological guidelines concerning e.g. study duration, control groups, clinical relevance,

parallel treatments and endpoints must be consistent across borders. To achieve this alignment, the immediate installment **of mutual advice meetings** *with binding character* between national HTA agencies and manufacturers is necessary. To have a solid foundation for the automatic recognition of approval it also needs an upfront alignment on feasible and realistic criteria to guarantee the **transferability of study results** between countries, ensuring that DMD can be effectively integrated into healthcare systems throughout Europe.
Additionally, in novel policy fields like digital health regulation, it is critical to allow for structured interactions between manufacturers and authorities throughout the assessment process.

3. European Requirements for Patient and Data Safety

As a foundation, we should rely on the established European regulations. In the area of data protection, this is the GDPR (General Data Protection Regulation). To streamline efforts and reduce fragmentation, compliance requirements for Digital Medical Devices should align with **existing international standards**, such as ISO 27001 for information security and ISO 27701 for data privacy. Existing certificates in various countries should be mutually recognized.
Furthermore, the same requirements regarding **semantic interoperability** should apply. Patient access through various channels (e.g. e-prescriptions in different countries) and integration with each country's digital ecosystems (e.g. electronic health records) are unlikely to be harmonized and will probably require adaptation and corresponding resources from manufacturers during implementation.

4. Urgent Call for Harmonization and Collaborative Efforts

The development of joint requirements for the transferability of DMD assessments should be swiftly pursued, as there is still a historic opportunity to create unified access pathways. We now need greater speed and adequate resources to foster this collaboration. This requires commitment from the European Commission, national HTA bodies, research institutions, and companies. Lessons learned from the establishment of other European procedures, such as the EU HTA, should definitely be incorporated.
The challenges faced by healthcare systems and patients are similar across different countries. We now **need harmonized requirements** that provide planning security for companies and avoid duplicative efforts. By achieving this, we have a significant opportunity to create a decisive **push towards future-oriented, personalized and evidence-based therapies** to improve patient care across Europe.

About the German Digital Healthcare Association (SVDGV)
The German Digital Healthcare Association is the leading industry representative for e-health companies in Germany. It was founded in December 2019 and unites over 180 e-health companies. The aim of the association is to represent the interests of the young industry in the healthcare system at eye level with politicians, self-governing bodies and other institutions. For more information, visit digitalversorgt.de or follow us on LinkedIn.

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