Germany focuses on data protection, data security and positive care effects for digital health applications
Publisher
Published by Global Regulatory Press
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Introduction

When the Digital Healthcare Act (Digitales Versorgungsgesetz, DVG) entered into force in December 2019, a dedicated pathway enabling reimbursement of digital health offerings was introduced to the German healthcare system. This enabled patients in the Statutory Health Insurance (SHI) system to be reimbursed for digital health applications (digitale Gesundheitsanwendungen, DiGAs) on prescription by doctors or psychotherapists.

Digital health applications offer a wide range of possibilities for providing support in the diagnosis and treatment of diseases and on the path to a self-determined, health-promoting lifestyle. Numerous patients already use healthcare applications that support them, for example, to take their medications regularly or to document their blood glucose levels.

A DiGA is a CE-marked medical device that needs to meet the following characteristics and criteria:

- It must be classified as a low-risk medical device (Class I or IIa) under Regulation (EU) 2017/745 on medical devices (MDR).
- Its function must be based primarily on digital technology.
- Its medical purpose must be achieved by the main digital function.
- It must be used by the patient alone or shared by the service provider and patient.
- It must demonstrate a positive effect on care, either a medical benefit or a procedural/structural improvement in healthcare.
- It must support the diagnosis, monitoring, treatment, or alleviation of diseases or the diagnosis, treatment, alleviation of, or compensating for, an injury or disability.

If a re-classification to risk Class IIb or higher becomes necessary, the digital application would no longer meet the basic requirements of a DiGA according to the DVG. In this case, an already listed DiGA would immediately be removed from the DiGA Register. Primary prevention digital applications cannot be included in the Register: preventing a disease is not covered by the legal definition of a DiGA.
The procedure for inclusion of a DiGA in the DiGA Register, and therefore eligible for reimbursement by the SHI, is designed as a ‘fast-track’ evaluation procedure by the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). The evaluation time for BfArM is three months from receiving a complete application. Introducing this fast-track evaluation process was considered necessary to ensure a rapid introduction of innovative medical technology into standard healthcare.

Data protection and security
All DiGAs process and analyse data from users. High data protection and data security requirements are therefore mandatory for an application to be included in the DiGA Register. In particular, the implementation of an Information Security Management System in accordance with the ISO/IEC 27000 series2 or BSI-Standard 200-23, published by the German Federal Office for Information Security (Bundesamt für Sicherheit in der Informationstechnik, BSI), is one of the basic requirements for data security.

Approximately 150 DiGAs have been submitted to BfArM for review to date. As of September 2022, 33 of these DiGAs had been included in the DiGA Register4. These include DiGAs that provide, for example, support for anxiety disorders, tinnitus or sleep problems. Around 10% of applications submitted have been rejected by BfArM. In contrast, more than 50% of applications have been withdrawn by the applicants themselves as it became apparent during the review process that, for example, essential data protection requirements had not been met and the manufacturers were also unable to resolve this within the timeframe of the review process.

According to BfArM, the five most common deficiencies in the implementation of data protection and data security requirements relate to the following:

- patient consent;
- the data privacy policy statement;
- data processing not permitted in the USA;
- protection against data theft – information security;
- authentication.

With the First Regulation amending the Digital Health Applications Regulation5 the legislature has created even tighter regulations, which will lead to more intensive audits and the presentation of a data protection certificate. BfArM has also published new test criteria for data protection requirements for digital health applications6. In the future, these criteria will form the basis for new
certificates with which manufacturers of health applications can prove that their applications are data protection compliant. These include both the requirements of the European General Data Protection Regulation\(^7\), and the extended requirements for DiGAs. Since 1 April 2022, BfArM can request the submission of a suitable certificate or proof of information security management to demonstrate compliance with information security requirements. From 1 January 2023, compliance with data security requirements must be demonstrated by a certificate issued by the BSI. This also applies to manufacturers with applications already listed in the Register. Thus, the integration of information security into the Quality Management System for medical devices is of particular importance.

The positive care effect

In an application for inclusion in the DiGA Register, a manufacturer must provide information on the planned studies or existing evidence of positive care effects for the relevant patient groups. Positive care effects are either a medical benefit or patient-relevant structural and procedural improvements in care. The medical benefit is the patientrelevant effect, in particular for improving health status, shortening the duration of illness, prolonging survival, or improving quality of life. Patient-relevant structural and procedural improvements in care are designed to assist patients in the context of diagnosis, monitoring, treatment, or alleviation of disease or diagnosis, treatment, alleviation of, or compensating for injury or disability. This specifically includes the areas of:

- coordination of treatment processes;
- alignment of treatment with guidelines and recognised standards;
- adherence to a therapy;
- facilitating access to care;
- patient safety;
- health literacy;
- patient confidence;
- overcoming disease-related difficulties in daily life;
- reducing therapy-related effort and burden on patients and their families.

To demonstrate the positive healthcare effects, a retrospective or prospective comparative study in compliance with relevant international applicable standards is required. The study must show that the use of the DiGA is significantly better compared to non-use. The legal framework for clinical investigations in humans is defined by the MDR. In addition, the manufacturer must provide evidence
of transferability to the German healthcare context if studies were completely or partially conducted in other countries.

Alternatively, there is the possibility to prove a positive care effect within a provisional listing with a plausible justification. For this, the manufacturer must submit, as a minimum, the results of a systematic data evaluation on the use of the DiGA with a corresponding evaluation concept. The manufacturer may request a one-time extension of the provisional listing by up to 12 months. The key goal of the evaluation concept is to show a common thread from systematic literature research to systematic data evaluation to expected positive care effects in scope of the study for a provisional listing.

In principle, a DiGA is a digital medical device. Services such as consulting, coaching or private medical services can additionally be offered from the DiGA or in connection with the use of the DiGA, but they are not taken into account for SHI reimbursement. Accordingly, evidence for positive care effects must be provided without the use of such additional services. The extent to which accompanying services may be permissible should be clarified by the manufacturer during a consultation with BfArM.

Outlook

Digital health applications, DiGAs, enable patients to receive up-to-date treatment, regardless of location, finances and availability of medical staff. DiGAs are therefore making a significant contribution to digitising the healthcare system. Digital health applications, electronic patient records and video consultations create new diagnostic and treatment options and simplify communications between doctors and patients. Patients can be empowered to actively shape their care and contribute to treatment successes themselves. At the same time, a great deal of effort must be paid to protect sensitive patient data. DiGA users must be able to rely on the manufacturer handling their data with care and implementing measures to protect confidentiality, availability and integrity. For this, the Digital Health Applications Ordinance (Digitale Gesundheitsanwendungen-Verordnung, DiGAV) specifies and supplements the requirements from the European General Data Protection Regulation and other data protection requirements for the manufacturer’s company, for the DiGA itself, and for all systems in connection with the DiGA, including third parties such as cloud providers. Manufacturers should address the question of how to expand their management system in accordance with ISO 13485 to include the components of information security management at an early stage. Depending on the type of DiGA, data processing can be very complex and there are many different aspects to consider.
When it comes to proving the actual benefit of the DiGA for patients, there is a fundamental criticism of the rules by the National Association of SHI Funds (GKV-Spitzenverband). With respect to the current design of the fast-track evaluation procedure by BfArM, the GKV-Spitzenverband sees a discrepancy in relation to other areas of SHI standard care: on the one hand the comparatively low access requirements for DiGAs in terms of proof of benefit, and on the other hand with regard to cost effectiveness. According to the GKV-Spitzenverband, the goal in the coming years should be to guarantee a considerable positive effect on care for all DiGAs. An appropriate cost/benefit ratio should be maintained in comparison to analogous SHI services offered by medical and non-medical service providers. Therefore, in the future, the requirements regarding the demonstration of positive care effects and the procedure for provisional inclusion in the DiGA Register may change.

In the run up to submitting an application, a manufacturer should urgently address the question of which medical device regulations must be followed as a prerequisite for the start of the planned study to prove the positive care effects. For the proof of a positive care effect, adequate study planning with appropriate endpoints must be ensured.

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Alexander Reck, MSc is an experienced consultant in the medical devices industry for NSF and is based in Hamburg, Germany. He supports medical device manufacturers in the field of state-of-the-art regulatory affairs. Besides his core competences in the clinical aspects of medical devices, he brings together risk management and usability considerations to build solid foundations for safe and effective medical devices.