DiGA-Report 2024

Market Development of Digital Health Applications

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Spitzenverband Digitale Gesundheitsversorgung

Authors

Diana Meskendahl
Advisor to management board at SVDGV

Tobias Bachmann
Head of Market Access at Selfapy

Editorial Team:
Susanne Moser
Mareike Schröder

Graphics:
Leo Radloff

Publisher

Spitzenverband Digitale Gesundheitsversorgung e.V. (SVDGV)
Pappelallee 78/79, 10437 Berlin

Chairperson: Dr. Paul Hadrossek
1st Deputy Chair: Dr. Anna Haas
2nd Deputy Chair: Henrik Emmert

Registered in the association register: Registernummer VR 37693 B
Vereinsregister Berlin, Amtsgericht Charlottenburg

Email: kontakt@digitalversorgt.de
Phone: +49 30 62 93 84 94
Fax: +49 30 62 93 84 96

About the German Digital Healthcare Association (Spitzenverband Digitale Gesundheitsversorgung: 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 170 e-health companies. All DiGA providers listed in the BfArM directory are members of the association. For more information, please visit digitalversorgt.de or LinkedIn.

Dear readers,

In the fourth year after its introduction, the successful model of Digital Health Applications (DiGA) has become further established in German healthcare. DiGA stand for an evidence-based form of therapy that is available independent of location and time. This form of therapy bridges gaps in the provision of healthcare and strengthens the sovereignty of patients. Moreover, DiGAs reduce the burden on the healthcare system and contribute to cost savings. They enable the early treatment of illnesses and the expansion of the range of treatment options for patients and practitioners.

As this second DiGA-Report shows, at the time of publication, patients have benefited almost one million times from the advantages of a DiGA. At the same time, the DiGA offering has become even broader and more diverse.

Furthermore, DiGAs set global standards as "Innovation Made in Germany" as Germany was the first country to include digital treatment methods in standard care. Other countries such as France and Belgium have since emulated this example.

On the one hand, the legal framework for DiGA gives doctors and psychotherapists the certainty that they can prescribe certified medical devices with proven health care benefits and a review by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte: BfArM). On the other hand, it regulates the unconditional reimbursement of costs for DiGA by the statutory health insurances.

Contrary to the positive developments over the past four years, the DiGA concept also faces several obstacles that are difficult to overcome. Thus, a bureaucratic and outdated process for activation is blocking broader DiGA use. In addition, the investments required to fulfill regulatory obligations are continuously increasing. As a result, fewer innovative products are reaching the healthcare system.

In its second DiGA-Report, the German Digital Health Association (Spitzenverband Digitale Gesundheitsversorgung: SVDGV) provides a quantitative assessment of DiGA development, evaluates key developments of the last year, and takes a look at necessary future steps for digital healthcare:

1. **The Digital Health Act brings some changes for DiGA.**

   With the Digital Health Act of March 2024, various regulations came into force that change the framework conditions for DiGA. For example, the statutory health insurances are obliged to issue activation codes more quickly, which the SVDGV has been demanding for a long time. In addition, the linking of ongoing outcome measurement (anwendungsbegleitende Erfolgsmessung: AbEM) to part of the DiGA remuneration marks a first step in Germany towards a concept of mandatory variable price components. However, SVDGV's analysis shows how bureaucratic roadblocks significantly hinder the practical implementation of these in principle progressive approaches.

2. **The DiGA market continues to grow sustainably.**

   As of December 31, 2024 the number of redeemed activation codes continued to rise with significant double-digit growth rates. At the same time, the offering has expanded by 20 percent compared to the previous year, with 59 listed DiGA. The current data also confirms the success of the DiGA Fast Track procedure as more than two thirds of DiGA initially provisionally included in the BfArM directory are now permanently listed. Thus, in the fourth year, there are more

permanently than provisionally included DiGA available in the directory. At the same time, it is clear that it was a difficult year, there were hardly any new listings, the leading position is in risk of being lost — there is need for action.

3. **DiGA are becoming an international model for success.**

   DiGA are now considered a "role model" for healthcare systems in other countries - in particular the unique DiGA Fast Track procedure. Patients in France and Belgium can now also benefit from digital therapies as part of standard care. However, there is still a lack of harmonized standards for the reimbursement of digital medical devices across Europe. The SVDGV is therefore committed to the harmonization of the regulatory framework.

4. **Now is the right time to set the political course.**

   In the final chapter of this DiGA-Report, the SVDGV provides specific proposals on how the overall conditions for DiGA can be improved in the next legislative period. Such measures include simplified access for patients as well as the removal of bureaucratic hurdles that place a disproportionately strong burden especially on young and innovative DiGA companies. It is also important to more firmly anchor the possibilities of DiGA among patients and practitioners. Finally, the concept of DiGA should be further developed and established as a third sector of care.

The new legislative period offers the opportunity to readjust the framework conditions for DiGA and thus have a lasting influence on their further development until the end of this decade. The SVDGV calls on the responsible parties to seize this opportunity and improve the regulatory conditions for DiGA. Only then can DiGA develop their full potential and make an even greater contribution to sustainable and patient-centered healthcare.

We wish you an insightful read.

Dr. Anna Haas
Chairwoman of
SVDGV

Henrik Emmert
Chairman of
SVDGV

Dr. Anne Geier
Managing Director

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Executive Summary

With its second DiGA-Report, the SVDGV presents a comprehensive overview of the framework conditions and development of the DiGA market in Germany. It is based on the reporting period of the first DiGA-Report from October 1, 2020 to September 30, 2023 and extends it to December 31, 2024. The latest data shows that the innovative and successful DiGA model has now become an export hit.

The year 2024 was marked by the "Act to Accelerate the Digitization of Healthcare" (Digital Health Act - DigiG), which came into force in March. This law was passed with the aim of advancing the digitalization of German healthcare and thus also DiGA. The Digital Health Act actually fulfilled some of the SVDGV's demands, including the obligation for health insurance companies to issue DiGA activation codes more quickly and the extension of the legal claim for reimbursement to DiGA in risk class IIb.

Moreover, a glance at the latest key figures offers grounds for optimism: the DiGA market is growing sustainably. At the end of 2024, 59 DiGA were listed in the BfArM directory - two thirds (38 DiGA) of which were permanently included. The last four years have also shown that the vast majority of provisionally included DiGA are getting permanently listed in the BfArM directory. The one year trial phase thus remains important and contributes to the success of DiGA.

For the fourth year in a row, with the expanding DiGA offer the number of redeemed activation codes increased at a significant double-digit growth rate. At the time of publication, patients from all age groups benefitted from the low-threshold therapy options almost one million times. Furthermore, the 20 percent share of follow-up prescriptions confirms that DiGA is continuing to establish itself as a third sector of healthcare.

This success story is now considered a blueprint for other European countries. Consequently, France and Belgium have based their reimbursement processes for digital healthcare offerings on the German example - especially the DiGA Fast Track procedure. Other countries such as Austria and Switzerland are currently also taking steps towards more digital healthcare. However, there is a lack of cross-border harmonization of reimbursement regulations of digital medical devices (DMDs). The SVDGV has therefore been advocating for a long time for a European-wide harmonization of the regulatory framework for the reimbursement of DMDs. Amongst others, this is a field in which Germany, with its pioneering role in DiGA, can contribute valuable experience.

Nevertheless, the positive developments of the past year should not obscure the fact that the framework conditions for DiGA need to be significantly improved in order to fully exploit their potential. For the new legislative period, the SVDGV is calling, among other things, for easier and faster access to DiGA. There is also an urgent need to stop the proliferation of increasing bureaucracy, to critically question existing bureaucratic processes and, if possible, to streamline them. Another key aspect is to better inform patients and practitioners about the possibilities of healthcare through DiGA. This includes incorporating DiGA into the training and further education curricula of doctors, psychotherapists and other healthcare professionals. These and other changes are the prerequisite for realizing the many ideas for further developing the DiGA concept and thus integrating DiGA more closely into the healthcare processes.

1. Introduction

The healthcare system is facing immense challenges: The ongoing shortage of skilled labor is putting a strain on the healthcare system, demographic trends are progressing towards an aging population resulting in an increase in the number of chronic illnesses[1] and in the number of people requiring care[2]. In many rural regions, there is already a noticeable lack of medical care[3].

In order to ensure accessible, high-quality healthcare in the future, digital offerings such as DiGA are indispensable because they can close already existing gaps in healthcare provision.

Since the Digital Healthcare Act (Digitale-Versorgung-Gesetz: DVG) came into force in December 2019[4], so-called "apps on prescription" can be prescribed by a doctor or therapist and have since become an established pillar of standard healthcare. Patients can also apply to their health insurance companies for the use of a DiGA if they have the required proof of indication.

By the time of publication, patients have used this digital therapy option almost a million times, and DiGA have become an integral part of the routines of many doctors and therapists. They offer a quick and easily accessible form of everyday support for many indications, especially in a healthcare landscape characterized by waiting times and a shortage of therapy slots[5].

What is a DiGA?

- Smartphone-App or web-based application
- To support the detection, monitoring, treatment or alleviation of diseases or the detection, treatment, alleviation or compensation of injuries or disabilities
- Cost coverage by statutory health insurance
- Evidence of positive healthcare effects demonstrated
- High standards regarding safety, functionality and quality, as well as data protection and data security
- Digital medical device of risk class I, IIa or IIb, CE certification
- Ad-free
- Interoperability: integration with the electronic health record, integration of the health ID etc.

1 More than a third (34%) of people with chronic illnesses are 70 years old and older. Stiftung Gesundheitswissen. Faktenblatt Menschen mit chronischen Erkrankungen. 2022

2 According to the Federal Statistical Office of Germany, a further increase in care rates can be assumed by 2027, which means that 6.3 million people will be in need of care by 2035 and around 7.6 million by 2055. In 2021, the figure was 5.0 million. Federal Statistical Office of Germany (Destatis). Zahl der Pflegebedürftigen steigt bis 2070 deutlich an. 2025

3 A feasibility study by Bosch Health Campus shows that many rural regions in Baden-Württemberg do not have sufficient medical care: More than 300,000 people there have to accept travel times of more than 30 minutes for general internal medicine for example. Bosch Health Campus. Zusammenfassung Machbarkeitsstudie Telemedizin in Baden-Württemberg. June 2024

4 Gesetz für eine bessere Versorgung durch Digitalisierung und Innovation (Digitale Versorgung-Gesetz DVG). BGBl Jg. 2019 Teil I Nr. 49 as of 18.12.2019

5 The average waiting time for psychotherapy, for example, is more than four months between the initial consultation and the start of therapy. German Federal Chamber of Psychotherapists (Bundespsychotherapeutenkammer: BPtK), press release. Psychisch Kranke warten 142 Tage auf eine Psychotherapie. 09.12.2022

To be included in the DiGA directory, an intensive review process by BfArM is required. This includes the examination of criteria such as proof of a positive healthcare effect which can consist of a medical benefit or a patient-relevant structural and procedural improvement (e.g. better adherence or increased health literacy). DiGA can be listed as provisional or permanent in the directory. Provisional inclusion is based on a systematic data evaluation that provides an initial indication of a positive healthcare effect. If the positive healthcare effect has already been demonstrated in a clinical trial, the DiGA can be permanently included in the directory.[6] Manufacturers generally prove the efficacy of their DiGA in randomized controlled clinical trials. Chapter 1.1 of the SVDGV DiGA-Report of 2023 provides a detailed account of the legal and regulatory basis for DiGA.[7]

Nevertheless, the legal regulations for DiGA are constantly evolving. The Digital Health Act, which came into force in 2024, contains numerous new regulations regarding DiGA that will have an impact on future digital healthcare. These are addressed in more detail in the following chapter.

6 Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte: BfArM). DiGA-Leitfaden. version 3.5, as of 28.12.2023

7 SVDGV. Market Development of Digital Health Applications (DiGA Report 2023). October 01 2020 - September 30, 2023

2. Effects of the Digital Health Act on the care provided by DiGA

On 14 December 2023, the German Bundestag passed the "Act to Accelerate the Digitization of Healthcare" (Digital Health Act: Digital-Gesetz — DigiG), which came into force on 26 March 2024.[8,9] With this law, the Federal Minister of Health promised nothing less than a "turbo boost" for the digitization of the German healthcare system.[10] In fact, it brought with it changes for all areas of care - especially for the DiGA sector. However, it remains to be seen whether this is a step forward or a step backwards.

One of the key concerns of the Digital Health Act is **improved interoperability** and thus the interconnection of the various digital offerings, such as between the electronic health record and DiGA (§ 386 SGB V, right to interoperability). DiGA are to be given read and write access to the electronic health record, which will enable patients to enter more medical information into a DiGA or ePA in future and thus personalize its use to a greater extent.

The Digital Health Act is also intended to enhance **transparency** with regard to the care through DiGA, as the SVDGV has long been calling for. Among other things, DiGA manufacturers will be given the right to submit a statement before the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband: GKVSV) published its annual DiGA-Report in accordance with "§ 33a Absatz 6 SGB V". This change is a step in the right direction, as the DiGA-Report of the GKVSV should become more neutral overall. However, at the time of producing this DiGA-Report (January 2025), it was still unclear what the process for operational implementation of this right to comment would look like.

In addition to the DiGA manufacturers' right to comment on the report by the GKV-Spitzenverband, further provisions of the Digital Health Act are intended to contribute to greater transparency in DiGA care. This includes the adaptation of GKV-Spitzenverband's reporting period to the calendar year in "§ 33a Absatz 6 SGB V" (previously from October 1 to September 30 of a year) and the DiGA-Report must be submitted to the Federal Ministry of Health by April 01. In addition, the GKV-Spitzenverband was obliged by the new paragraph 7 of § 33a SGB V to provide the Federal Ministry of Health with the following data per quarter:

- For each DiGA, the number of DiGA prescribed and provided by doctors and psychotherapists
- The number of applications submitted to the health insurance funds for approval of a DiGA, including the number of approved and rejected applications
- The amount of expenditures for DiGA

The SVDGV welcomes these improvements in transparency. However, it is regrettable that no further aggregated data from the GKV-Spitzenverband's DiGA-Report is reported quarterly in addition to the legally required information. Since the health insurance funds have access to these - hopefully - automatically collected routine data anyway - including the age and gender of DiGA users as well as initial and follow-up prescriptions.

8 Gesetz zur Beschleunigung der Digitalisierung des Gesundheitswesens (Digital-Gesetz — DigiG). BGBl. 2024 I Nr. 101 vom 25.03.2024
9 Federal Ministry of Health. Gesetz zur Beschleunigung der Digitalisierung des Gesundheitswesens. as of 25.03.2024
10 Lau T. Digitalisierung: Lauterbachs Turboschub. Dtsch Arztebl 2023; 120(11): A-459 / B-395

Furthermore, the Digital Health Act contains other **changes that are relevant to the DiGA market**:

- Since March 26, 2024, health insurance funds have to issue activation codes for DiGA ”generally within two working days“ of receiving the prescription (“§ 67 Absatz 3 SGB V”).
- From January 1, 2025, the e-prescription obligation was also supposed to apply to DiGA, which currently can only be prescribed using a paper-based prescription (“§ 360 Absatz 4 SGB V”).
- From 2026, there ought to be a performance-related price component of at least 20 percent for the remuneration fee of DiGA, which will be based, among other things, on the results of the ongoing outcome measurement (“§ 134 Absatz 1 S. 3 SGB V”).
- The permitted product types for DiGA extend to services for pregnancy and maternity (“§§ 24c und 24e SGB V”) and to medical devices in risk class IIb (“§ 33a Absatz 2 SGB V”). The latter enables the use of DiGA for remote patient monitoring (RPM)/ telemonitoring and their integration into disease management programs (DMP) - for example into the planned digital diabetes DMP (“§ 137f Absatz 9 SGB V”).[11]

In the following chapters 2.1. to 2.3., this DiGA-Report goes into the details of some of these changes.

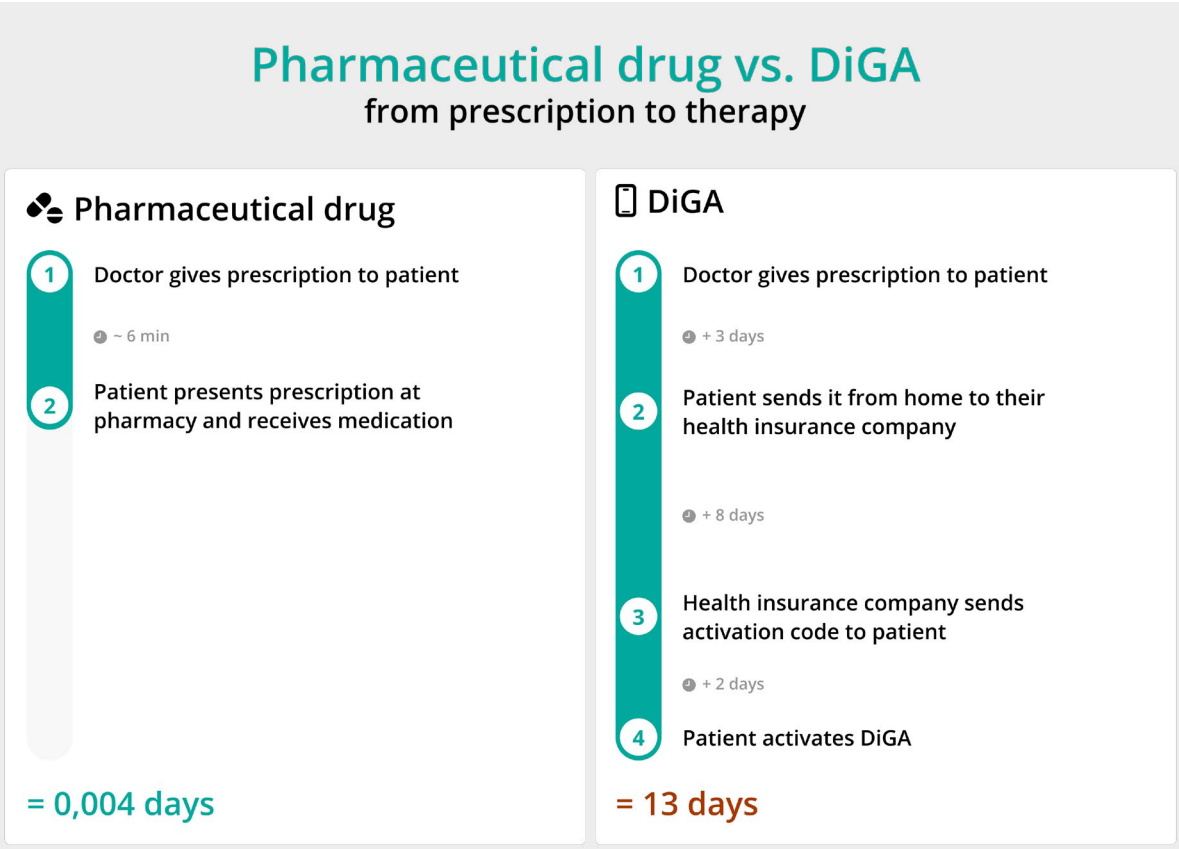
2.1. DiGA access: new law meets old hurdles

The ”process duration“ topic has already been discussed in detail in the DiGA-Report 2023 as a major hurdle for DiGA care. Too much time elapses between the prescription of the DiGA and the activation code being redeemed, as shown by a survey conducted by the SVDGV among its member companies in August 2023. It revealed that the average waiting time from the submission of a prescription for a DiGA until the code activation by the health insurance companies was around 13 days (Figure 1).[12]

11 Draft law of the Federal Government. Entwurf eines Gesetzes zur Beschleunigung der Digitalisierung des Gesundheitswesens (Digital-Gesetz – DigiG). Printed matter 20/9048, 01.11.2023

12 SVDGV. Market Development of Digital Health Applications (DiGA Report 2023). October 01 2020 - September 30, 2023

Figure 1: Comparison between processes filling prescriptions for a pharmaceutical drug and a DiGA based on a survey conducted by the SVDGV among DiGA manufacturers in August 2023, before the Digital Health Act came into force.[13]



The Digital Health Act has taken up the SVDGV's demand from the commentary on the draft bill for the Digital Health Act and with § 67 (3) SGB V requires health insurance companies from end of March 2024 onwards to enable insured persons to use a Digital Health Application "[...] **generally within two working days** from the time the health insurance company receives a prescription [...]". This is a desirable first step on the way to the demanded faster and more user-friendly prescription and activation processes in the interests of patients. After all, the paper-based prescription fulfillment process was only designed in 2020 as a transitional solution by the involved parties, even though it is still practiced today. At that time, it was agreed that "[...] a fully digital care process for the use of Digital Health Applications should be established in the long term [...]".[14]

Have processes actually changed for patients since the Digital Health Act came into force? The SVDGV conducted a survey among its member companies on this topic between the end of March and the end of June 2024. It turned out that with the process still being analog, it takes an average of 14 days from submission to the health insurance company to activation code redemption. On average, the health insurance companies are responsible for around seven days of this time (Figure 2). This means that the processing time for DiGA prescriptions at the health insurance companies takes on average

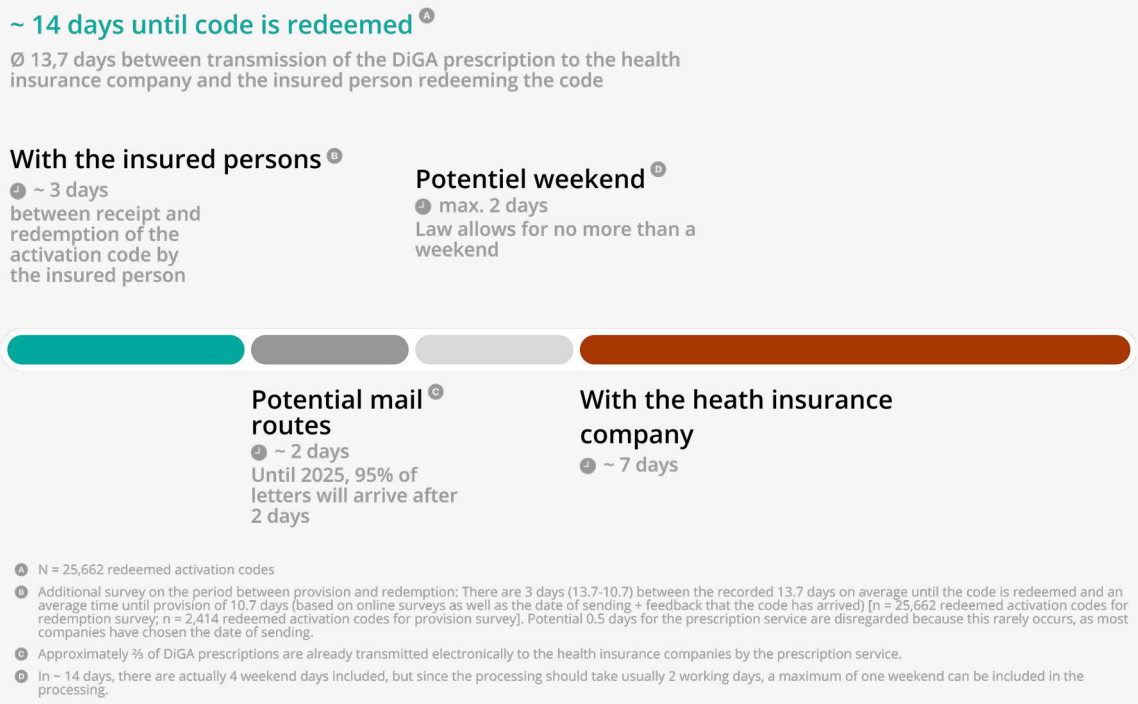
13 SVDGV. Survey among more than 20 DiGA manufacturers in August 2023

14 Health insurance associations and health insurance companies with the manufacturers' associations. Gemeinsame Erklärung zur inhaltlichen Ausgestaltung des DiGA-Versorgungsprozesses. 24.08.2020

more than three times as long as the legally prescribed two working days. The desired improvement for patients has therefore not yet materialized. However, the survey showed a large variance in the length of time taken to process prescriptions, ranging from 9.4 to 25.7 days[15], which suggests that faster processing times are possible. The SVDGV therefore urges that DiGA care for patients be accelerated and thus improved for patients. Therefore, the SVDGV advocates for an end to the transition process including activation codes and for a direct patient access to digital therapies - without manual checks by health insurance companies. The future care process should be based on the processes for pharmaceutical drugs. This would enable doctors and psychotherapists to issue DiGA prescriptions via the e-prescription server. Patients confirm their request for use directly in the prescribed DiGA, while the synchronization with the e-prescription server and billing processes run in the background. The advantages of this concept are, on the one hand, that patients receive immediate and easily accessible care and, on the other hand, that the process becomes less bureaucratic – without manual checks by the health insurance companies. Overall, this could lead to genuine process digitization.

The analog processes still take much longer than legally permitted and the necessary e-prescription for DiGA is still not available, although it should have become mandatory by January 1, 2025.[16]

Figure 2: Timeline of the activation process for DiGA after the Digital Health Act came into force based on a survey conducted by the SVDGV among DiGA manufacturers[17]



15 For n> 100 codes

16 Gesetz zur Beschleunigung der Digitalisierung des Gesundheitswesens (Digital-Gesetz — DigiG). BGBl. 2024 I Nr. 101 vom 25.03.2024

17 SVDGV. Survey among DiGA manufacturers in the period from March 26 to June 25, 2024

2.2. The e-prescription for DiGA is delayed

The Digital Health Act made e-prescriptions for pharmaceutical drugs mandatory for all parties from January 1, 2024 (§ 360 (2) SGB V) – two years later than planned. Because it was originally supposed to be introduced on January 1, 2022, in accordance with the Patient Data Protection Act of 2020.[18] The legal text also stipulates in § 360 (2) SGB V that "[...] From January 1, 2025 [...] the service providers referred to in paragraph 2 sentence 1 [...] are obliged to issue prescriptions for Digital Health Applications electronically in accordance with § 33a and to use services and components in accordance with paragraph 1 for their transmission". However, the legislator reserves the following right: "The obligation pursuant to sentence 1 shall not apply if the electronic issuance or transmission of prescriptions pursuant to sentence 1 is not possible for technical reasons in individual cases." As of December 31, 2024, it is clear that the e-prescription for DiGA will also be delayed. All parties involved, including the Federal Ministry of Health, gematik GmbH, the GKV-Spitzenverband and the SVDGV, are currently working on a concept for e-prescription implementation. The SVDGV is committed to making it as easy as possible for patients to redeem DiGA prescriptions. Therefore, the SVDGV demands that the provisional solution of the activation codes from the early days of the DiGA finally be replaced with a long-term solution. The aim is for patients to be able to redeem their DiGA prescriptions directly and immediately - without having to go through their health insurance companies.

However, the agreement process for the DiGA e-prescription had not yet been completed between the involved parties by December 31, 2024. Thus, it is not yet possible to prescribe DiGA via e-prescription (January 2025). One of the proposals continues to require that the health insurance companies should take on the task of checking the prescription and creating an activation code when e-prescriptions are filled. This would cement the process, which was designed as a transitional solution, for the future as well - at the expense of patients. Since an improvement would not be expected in a process designed in this way.

In the run-up to the 2025 federal elections, the SVDGV called for the course to be set for sustainable digital healthcare for the previously described transitional solution to be replaced with long-term sustainable processes.[19,20]

To achieve this, it is essential to design the e-prescription for DiGA in such a way that patients can start their digital therapy immediately after receiving their prescription. Patients should have the freedom of choice to use their DiGA flexibly, digitally and without manually entering an activation code - for example, directly in the DiGA, via the e-prescription app or the electronic health record. Moreover, it is important to prevent health insurance companies from exercising legally inadmissible control over DiGA activation in the future. DiGA manufacturers are willing to assume the resulting billing risks for the benefit of improved patient care.

18 Gesetz zum Schutz elektronischer Patientendaten in der Telematikinfrastruktur (Patient Data Protection Act: Patientendaten-Schutz-Gesetz - PDSG). BGBl. 2020 I Nr. 46 as of 14.10.2020

19 SVDGV. DiGA – Eine Erfolgsgeschichte mit Zukunftspotenzial. Forderungspapier Bundestagswahl 2025. December 2024

20 The editorial deadline for the DiGA-Report 2024 was 31.12.2024. It was published after the 2025 federal election.

2.3. DiGA as a pioneer for Value Based Healthcare

The Digital Health Act also brought a novelty for the German healthcare system: linking ongoing outcome measurement to a variable price share of 20 percent of DiGA remuneration, for the first time the legislator has legally implemented relevant aspects of Value Based Healthcare from 2026 onwards.

The SVDGV considers the introduction of the AbEM as an opportunity to fundamentally modernize the healthcare system. DiGA manufacturers are confident about a success-oriented remuneration model, as the efficacy of DiGA has already been proven in numerous clinical trials. At the same time, the question arises as to why the legislator chose DiGA of all things, as the youngest healthcare sector, for the introduction of a Value Based Healthcare approach. After all, this concept has been the subject of intense discussions since the mid-2000s.[21]

For the SVDGV, the decisive factor is how the AbEM is going to be implemented. The AbEM must not become the next bureaucratic monster. In its position paper from July 2024, the SVDGV therefore published constructive proposals for a sensible, practical design of the AbEM and defined five prerequisites to that end[22]:

1. The AbEM must not be at the expense of therapeutic efficacy.
2. The AbEM must take into account scientific and context-specific aspects.
3. The AbEM is a supplementary component and not a substitute for comprehensive quality assurance.
4. Preventive measures are needed to avoid drawing the wrong conclusions from the way the AbEM results are presented.
5. The AbEM should be designed to entail as little bureaucracy as possible.

These requirements have not yet been taken into account in the Federal Ministry of Health's latest draft bill for a second ordinance amending the Digital Health Applications Ordinance (Digitale Gesundheitsanwendungen-Verordnung: DiGAV).[23] The current DiGAV-draft threatens to worsen both healthcare provision and the framework conditions for DiGA manufacturers, most of which are start-ups and SMEs. Among other things, the SVDGV views the following planned contents of the DiGAV as critical:

- **The AbEM regulations lead to unscientific pseudo-transparency.** Thus, the duration and frequency of DiGA use, for instance, is erroneously equated with the success of the therapy. In addition, results are published that are based on a statistically unreliable small sample size. Finally, questionnaires are utilized that do not meet the generally recognized scientific standards.

21 Porter, Michael E. & Olmsted Teisberg, Elizabeth: Redefining Health Care: Creating Value-based Competition on Results, 1st ed. Harvard Business Review Press. USA: 2006

22 SVDGV. 5 Eckpunkte für eine praxistaugliche Umsetzung der Anwendungsbegleitenden Erfolgsmessung. 17.07.2024

23 Zweite Verordnung zur Änderung der Digitale Gesundheitsanwendungen-Verordnung. Draft bill of the Federal Ministry of Health. Status 03.01.2025

- **The AbEM regulations are a bureaucratic monster:** for example, patients are forced to interrupt their therapy in order to answer numerous questions about their state of health and satisfaction with their DiGA. The DiGA manufacturers must carry out the AbEM four times a year, report to the BfArM every six months and finally bear the costs of the BfArM audit.

The SVDGV calls on those responsible not to reduce the innovative approach of the AbEM to absurdity through unscientific and bureaucratic overregulation.

3. Four years of DiGA care in figures

3.1. Data baseline of this report

As of December 31, 2024, 59 digital health applications were permanently or provisionally included in the BfArM directory.[24] The manufacturers of 58 listed DiGA are members of the SVDGV at this time. The SVDGV requested the data contained in this report from the respective manufacturers of the individual DiGA.

Only the SVDGV office and the respective manufacturing company had access to the data sheet used to collect the number of redeemed activation codes for the respective DiGA. This is the second publication of the SVDGV DiGA-Report, which builds continuously on the first DiGA-Report and its methodology.

This DiGA-Report covers the period from to October 1, 2020 December 31, 2024 and is divided into four "DiGA years":

- DiGA year 1 (Oct '20 - Sep '21): October 01, 2020 to September 30, 2021
- DiGA year 2 (Oct '21 - Sep '22): October 01, 2021 to September 30, 2022
- DiGA year 3 (Oct '22 - Sep '23): October 01, 2022 to September 30, 2023
- DiGA year 4 (Oct '23 - Dec '24): October 01, 2023 to December 31, 2024 NEW

With a total of 15 months, DiGA year 4 deviates from the previous twelve-month reporting periods. This is due to a legal change via the Digital Health Act, according to which the DiGA reporting of the GKV-Spitzenverband (§ 33a (6) SGB V) has been switched to the calendar year since 2024.[25]

Key figures

- Total number of redeemed DiGA activation codes
- Distribution of reedemed activation codes by months
- Distribution of reedemed activation codes by initial & follow-up prescriptions
- Distribution of reedemed activation codes by gender (female, male, diverse, gender not specified)
- Distribution of reedemed activation codes by age (18 - 29 years, 30 - 39 years, 40 - 49 years, 50 - 64 years, 65 + years, age not specified)[1]

1 The age group ‚under 18 years' was not included in the age breakdown because there were only two DiGA listed for minors in the reporting period and the redeemed activation codes could therefore be traced back to these two.

The SVGDV received aggregated data on the number of redeemed activation codes for 49 DiGA. It is not possible to draw conclusions about individual patients or practitioners. The DiGA manufacturers collect different key figures for their therapies - some according to company-specific methods, such

24 Federal Institute for Drugs and Medical Devices. DiGA-Verzeichnis
25 Gesetz zur Beschleunigung der Digitalisierung des Gesundheitswesens (Digital-Gesetz — DigiG). BGBl. 2024 I No. 101 as of 25.03.2024

as for initial and follow-up prescriptions.[26] Therefore, for each key figure the underlying sample size (n) of the respective redeemed activation codes is indicated in the footnotes. The data on the gender and age of users is self-reported.[27] The data provided in the current and last year's DiGA-Report by the SVDGV differs due to a larger sample size and thus a broader data basis.

In order to determine the total number of redeemed activation codes, all 68 DiGA ever listed in the BfArM directory were taken into account, including those that have since been removed from the directory.

For DiGA years 1 through 3, the respective total number of all redeemed activation codes was available from the 2023 DiGA-Report by the GKV-Spitzenverband.[28] The total number for the most recent reporting year, DiGA year 4, was estimated using the following methodology: The SVDGV's survey for DiGA year 3 captured 98 percent - almost 100 percent - of the total number of redeemed activation codes according to the DiGA-report by the GKVSV.[29] Given this high level of consistency, the SVDGV also calculated the total number of redeemed activation codes for the 15 months of DiGA year 4 with a coverage rate of 98 percent.

3.2. DiGA data 2024: Sustainable growth in the youngest care sector

3.2.1. DiGA overview: the number and variety of DiGA is increasing

With 68 Digital Health Applications from twelve categories, the number of DiGA ever listed in the BfArM directory since 2020 reached a new high. Of these, 38 DiGA are permanently included and 21 DiGA are provisionally included. It also shows that the one year trial phase is a crucial factor for the success of DiGA. As with 26 out of 38 permanently listed DiGA, 68.4 percent of these applications were initially provisionally included in the directory. Only nine out of a total of 35 DiGA that were initially provisionally listed were removed from the directory. Around three quarters of these DiGA (26 out of 35) have successfully made the leap from provisional to permanent listing (Figure 3).

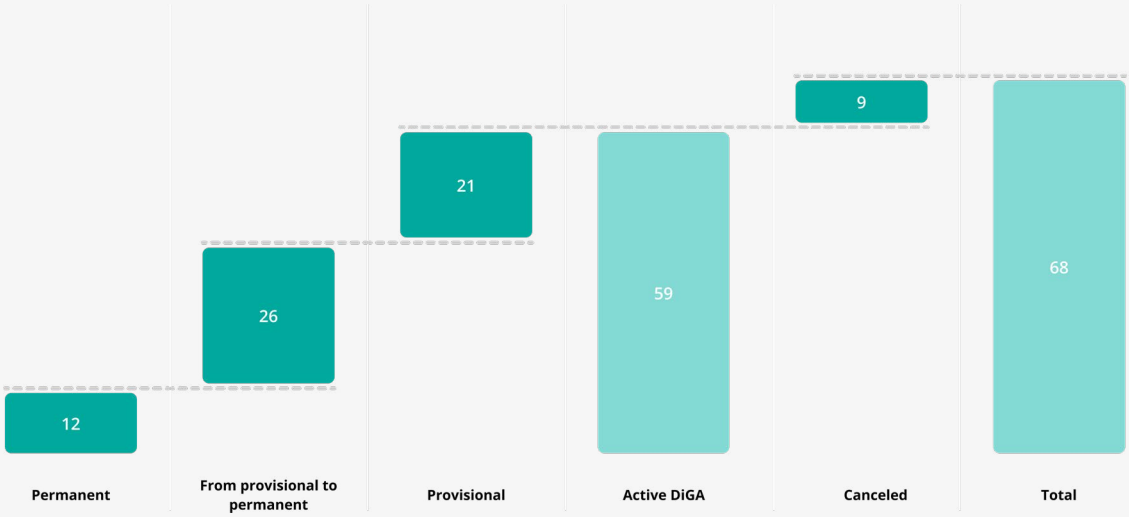
26 For example, there are individual DiGA that have different pharmaceutical central numbers for initial and follow-up prescriptions, as the initial prescription may include hardware. For most manufacturers, a follow-up prescription can only be identified if patients associate it with their already registered account.

27 DiGA users may provide age or gender information for example because the respective DiGA because the respective DiGA only covers certain age or gender groups.

28 GKV-Spitzenverband. Bericht des GKV-Spitzenverbandes über die Inanspruchnahme und Entwicklung der Versorgung mit Digitalen Gesundheitsanwendungen (DiGA-Bericht) in accordance with § 33a (6) SGB V. Reporting period: 01.09.2020–30.09.2023

29 The calculations for the third DiGA year with 209,192 redeemed activation codes were based on the information in the DiGA-Report of the GKV-Spitzenverband for the period 01.09.2020-30.09.2023: "In the first year after DiGA introduction, 41 thousand DiGA were utilized. In the second year, from October 2021 up to September 2022, there were already 124 thousand DiGA (...) In the third year, i.e. the current reporting year, 209 thousand DiGA (...)". In its calculations, the SVDGV therefore assumes 41,000 redeemed activation codes for the first DiGA year (01.09.2020-30.09.2021). Based on the information from previous DiGA-Reports of the GKV-Spitzenverband, the respective number of redeemed activation codes for the individual DiGA years was calculated as the difference amounts.

Figure 3: DiGA overview as of 31.12.2024[30]



As the number of listed DiGA increases, so do the indications addressed by them (DiGA categories): As of December 31, 2024, among the listed DiGA, the largest DiGA category "Psyche" included 27 applications, followed by the categories "Muscles, bones and joints" with nine DiGA and "Hormones and metabolism" with eight DiGA. Thanks to the growing range of DiGA-based treatments for an increasingly wide range of conditions, more and more patients and their doctors and psychotherapists can benefit from the possibilities of digital therapy (Table 1).

30 Federal Institute for Drugs and Medical Devices. DiGA-Verzeichnis

Table 1: Overview of DiGA listed and deleted from the BfArM directory as of December 31, 2024[31]

DiGA	Kategorie	Initial inclusion	Status as of 31.12.2024
Kalmeda	Ears	25.09.2020	Permanently included
velibra	Psyche	01.10.2020	Permanently included
somnio	Nervous system; Psyche	22.10.2020	Permanently included
Vivira	Muscles, bones and joints	22.10.2020	Permanently included
zanadio	Hormones and metabolism	22.10.2020	Permanently included
Invirto - Die Therapie gegen Angst	Psyche	03.12.2020	Permanently included
elevida	Nervous system	15.12.2020	Permanently included
Selfapys Online-Kurs bei Depression	Psyche	16.12.2020	Permanently included
deprexis	Psyche	20.02.2021	Permanently included
Mindable: Panikstörung und Agoraphobie	Psyche	29.04.2021	Permanently included
vorvida	Psyche	06.05.2021	Permanently included
Selfapys Online-Kurs bei Generalisierter Angststörung	Psyche	19.06.2021	Permanently included
NichtraucherHelden-App	Psyche	03.07.2021	Permanently included
Mawendo	Muscles, bones and joints	09.08.2021	Permanently included
Oviva Direkt für Adipositas	Hormones and metabolism	03.10.2021	Permanently included
companion patella powered by medi - proved by Dt. Kniegesellschaft	Muscles, bones and joints; injuries	04.10.2021	Permanently included
Novego: Depressionen bewältigen	Psyche	10.10.2021	Permanently included
HelloBetter Stress und Burnout	Other	18.10.2021	Permanently included
HelloBetter Diabetes	Hormones and metabolism	11.12.2021	Permanently included
HelloBetter Chronische Schmerzen	Muscles, bones and joints; Psyche	18.12.2021	Permanently included
Kranus Edera	Genitals, kidneys and urinary tract	18.12.2021	Permanently included
Cara Care für Reizdarm	Digestion	26.12.2021	Permanently included
HelloBetter Vaginismus Plus	Psyche	04.02.2022	Permanently included
neolexon Aphasie	Other	06.02.2022	Permanently included
Meine Tinnitus App - Das digitale Tinnitus Counseling	Ears	06.03.2022	Permanently included
HelloBetter Panik	Psyche	03.04.2022	Permanently included
Vitadio	Hormones and metabolism	15.04.2022	Permanently included
PINK! Coach	Cancer	27.06.2022	Permanently included
Endo-App	Genitals, kidneys and urinary tract	09.10.2022	Permanently included
HelloBetter Schlafen	Nervous system; Psyche	18.12.2022	Permanently included
edupression.com®	Psyche	26.12.2022	Permanently included
elona therapy Depression	Psyche	26.12.2022	Permanently included
Selfapys Online-Kurs bei Binge-Eating-Störung	Psyche	05.01.2023	Permanently included

31 Federal Institute for Drugs and Medical Devices. DiGA-Verzeichnis

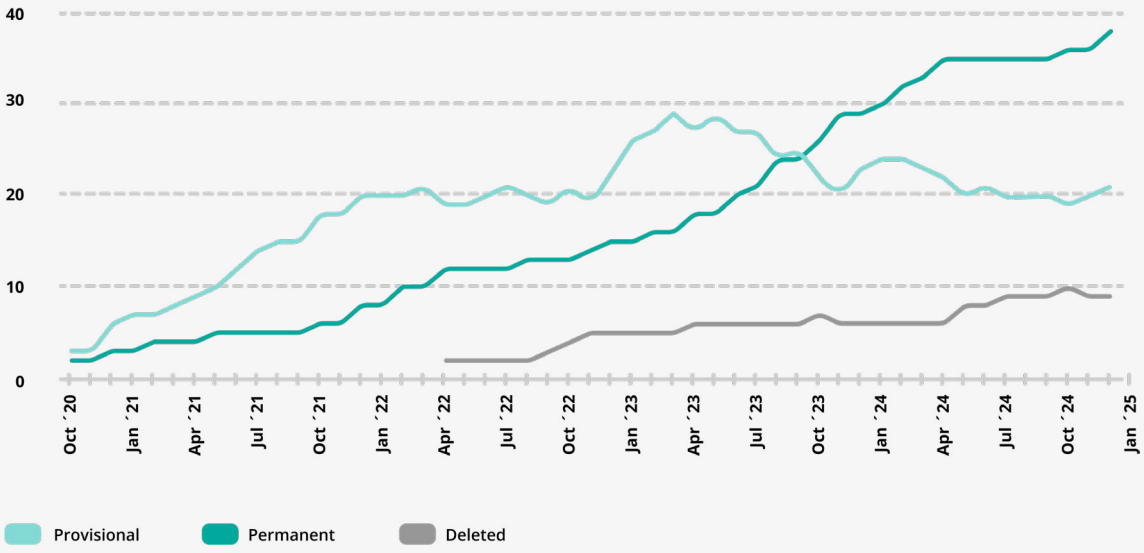
DiGA	Kategorie	Initial inclusion	Status as of 31.12.2024
Selfapys Online-Kurs bei Bulimia Nervosa	Psyche	05.01.2023	Permanently included
Kaia Rückenschmerzen - Rückentraining für Zuhause	Muscles, bones and joints	03.02.2023	Permanently included
priovi - digitale Unterstützung der Borderline-Behandlung	Psyche	05.03.2023	Permanently included
Kranus Lutera	Genitals, kidneys and urinary tract	15.04.2024	Permanently included
somnovia	Psyche	28.10.2024	Permanently included
sinCephalea - Migräneprophylaxe	Nervous system	10.10.2022	Provisionally included
levidex	Nervous system	07.01.2023	Provisionally included
Smoke Free - Rauchen aufhören	Psyche	29.01.2023	Provisionally included
My7steps App	Psyche	17.02.2023	Provisionally included
Novego: Ängste überwinden	Psyche	24.03.2023	Provisionally included
Selfapys Online-Kurs bei chronischen Schmerzen	Muscles, bones and joints; Psyche	21.04.2023	Provisionally included
NeuroNation MED	Psyche	13.05.2023	Provisionally included
ProHerz	Heart and circulation	15.05.2023	Provisionally included
mebix	Hormones and metabolism	14.07.2023	Provisionally included
Orthopy bei Knieverletzungen	Muscles, bones and joints; injuries	09.09.2023	Provisionally included
Mindable: Soziale Phobie	Psyche	11.12.2023	Provisionally included
Untire®	Cancer	25.12.2023	Provisionally included
actensio	Heart and circulation	30.12.2023	Provisionally included
glucura Diabetestherapie	Hormones and metabolism	11.01.2024	Provisionally included
Vantis | KHK und Herzinfarkt	Heart and circulation	19.01.2024	Provisionally included
MindDoc Auf Rezept	Psyche	08.02.2024	Provisionally included
unaHealth für Diabetes	Hormones and metabolism	09.02.2024	Provisionally included
My Dose Coach	Hormones and metabolism	16.06.2024	Provisionally included
Uroletics	Cancer	14.12.2024	Provisionally included
companion® shoulder	Muscles, bones and joints	27.12.2024	Provisionally included
eCovery - Therapie bei Schmerzen im unteren Rücken	Muscles, bones and joints	27.12.2024	Provisionally included
M-sense Migräne	Nervous system	16.12.2020	Deleted
Rehappy	Heart and circulation; Nervous system	29.12.2020	Deleted
Mika	Cancer	25.03.2021	Deleted
CANKADO PRO-React Onco	Cancer	03.05.2021	Deleted
Selfapys Online-Kurs bei Panikstörung	Psyche	19.06.2021	Deleted
ESYSTA App & Portal – Digitales Diabetesmanagement	Hormones and metabolism	04.07.2021	Deleted
optimune	Cancer	14.07.2022	Deleted
re.flex	Muscles, bones and joints	29.09.2022	Deleted
Kaia COPD: Meine aktive COPD Therapie	Respiratory system	26.12.2022	Deleted

Figure 4 shows the number of DiGA provisionally and permanently included in the BfArM directory, as well as those deleted, from the beginning of the directory in fall 2020 to the cut-off date of December 31, 2024. This illustration of the development over time confirms the importance of the one year trial phase for the success of DiGA. As since October 2023, the directory has contains more permanently than provisionally included DiGA. This positive development was only possible because many DiGA manufacturers were able to use the one year trial phase with provisional inclusion in order to create the conditions for permanent listing.

Inversely, without the possibility of provisional listing, start-up companies in particular would hardly be able to shoulder the high investments of all the underlying obligations of an application for permanent inclusion. As a result, the level of innovation in the DiGA sector would be considerably lower, as only twelve DiGA have immediately been permanently included in the directory to date.

Another aspect becomes clear from the timeline in Figure 4: in the first twelve months of the most recent DiGA year, the number of new listings declined compared to the three previous years. Some of the reasons include the increasing regulatory requirements that are making it more difficult to bring further DiGA into the market.

Figure 4: Number of DiGA throughout time[32]



32 Federal Institute for Drugs and Medical Devices. DiGA-Verzeichnis

3.2.2. More and more patients are benefiting from DiGA

Since the first inclusion of DiGA in the BfArM directory in the fall of 2020, this digital offering have become established in healthcare: From October 2020 to December 2024, c. 870,000 DiGA activation codes were redeemed. Thus, in the 15 months of the most recent reporting period, the number of redeemed activation codes more than doubled compared to the total period of the three previous DiGA years (374,377 activation codes redeemed in total).[33] Excluding the one-time effect of the additional fourth quarter of 2024, a total of c. 750,000 activation codes were redeemed within four years. This means that at the time of publication of this report, digital therapy options could be provided to patients almost a million times. DiGAs are thus gradually becoming the third relevant sector - alongside outpatient and inpatient care.

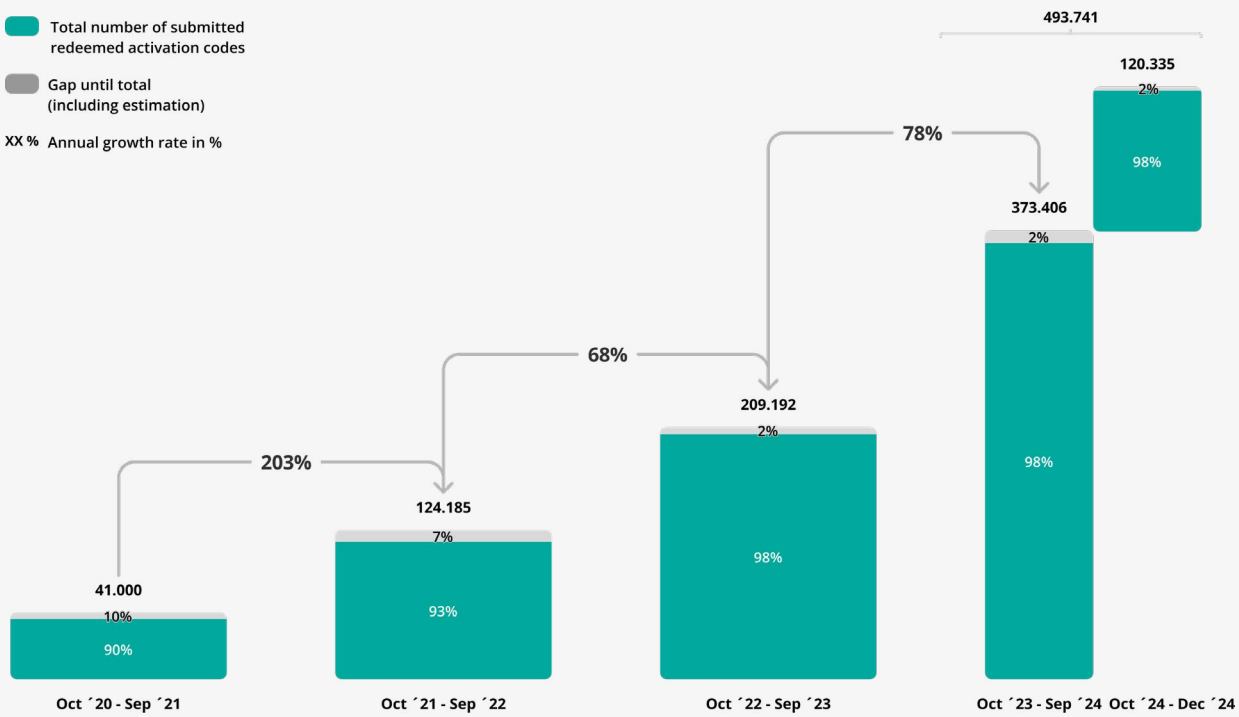
This dynamic growth can be clearly seen in a comparison of the individual reporting years (Figure 5). The total number of redeemed activation codes tripled from DiGA year 1 (Oct ‘20 - Sep ‘21) to DiGA year 2 (Oct ‘21 - Sep ‘22), which corresponds to a growth rate of 203 percent. Between DiGA year 2 (Oct ‘22 21 - Sep ‘22) and DiGA year 3 (Oct ‘22 - Sep ‘23), the growth rate was 68 percent.[34]

According to feedback from DiGA manufacturers to the SVDGV, 500,000 activation codes were redeemed in DiGA year 4 (Oct ‘23 - Dec ,24), of which around 375,000 in the period October 01, 2023 to to September 30, 2024. Based on this data and the trends of previous years, the SVDGV estimates a considerable growth rate of c. 80 percent compared to the same period of the previous year (Oct ‘22 - Sep ‘23 compared to the period Oct ‘23 - Sep ‘24). Which means that the substantial growth of the DiGA market is continuing for the fourth year in a row.

33 GKV-Spitzenverband. Bericht des GKV-Spitzenverbandes über die Inanspruchnahme und Entwicklung der Versorgung mit Digitalen Gesundheitsanwendungen (DiGA-Bericht) in accordance with § 33a (6) SGB V. Reporting period: 01.09.2020–30.09.2023

34 The calculations for the third DiGA year with 209,192 redeemed activation codes were based on the information in the DiGA-Report of the GKV-Spitzenverband for the period 01.09.2020-30.09.2023: “In the first year after DiGA introduction, 41 thousand DiGA were utilized. In the second year, from October 2021 up to September 2022, there were already 124 thousand DiGA (...) In the third year, i.e. the current reporting year, 209 thousand DiGA (...)“. In its calculations, the SVDGV therefore assumes 41,000 redeemed activation codes for the first DiGA year (01.09.2020-30.09.2021). Based on the information from previous DiGA-Reports of the GKV-Spitzenverband, the respective number of redeemed activation codes for the individual DiGA years was calculated as the difference amounts.

Figure 5: Total redeemed activation codes: 870,000[35]



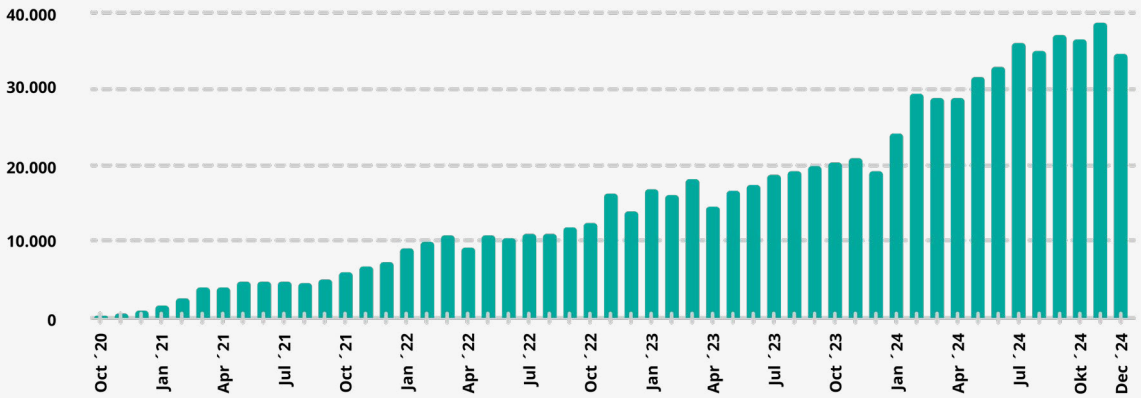
Although the monthly analysis of the number of redeemed activation codes over the past four DiGA years shows seasonal fluctuations, such as the recurring decline in December 2022, 2023 and 2024 (Figure 6), overall there is a steady upward trend with an average monthly growth rate (CMGR) of around 14% over the total period of 51 months.

The SVDGV already explained the decline from March 2023 to April 2023 in the last DiGA-Report: due to a cyber attack on the IT service provider Bitmarck, many health insurance companies were neither able to generate DiGA activation codes nor were they able to validate DiGA activation codes that had already been generated.

In addition, further server outages were reported to the SVDGV by health insurance companies. In the fourth DiGA year (Oct ‘23 - Dec ‘24), there were 19 outages alone, three of which affected Bitmarck and thus the vast majority of health insurance companies. These outages lasted several hours or days - in some cases there were even multiple outages over a week. These figures only describe technical outages. In addition, there are many other sources of error in such a manual process. Once again, it becomes clear that a direct path for activation code redemption, as described in Chapter 2, would improve care for patients.

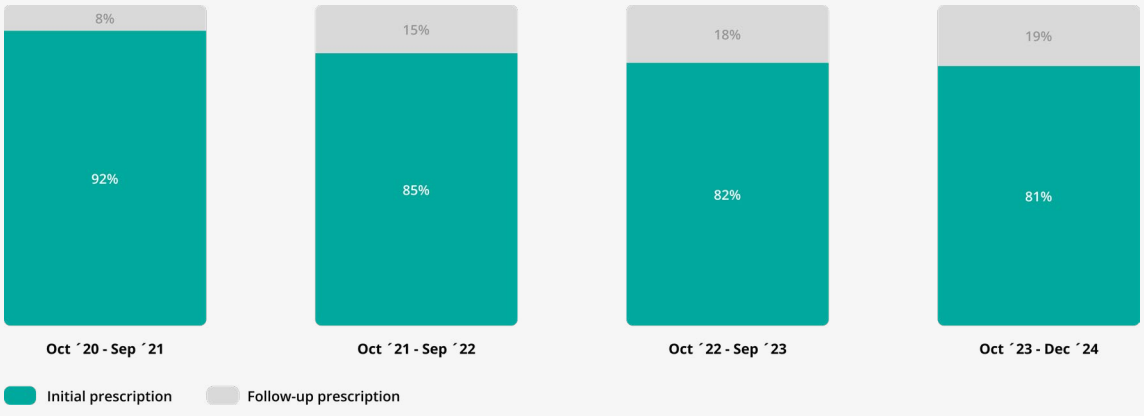
35 GKV-Spitzenverband and SVDGV. Note: The totals of redeemed activation codes reported back to the SVDGV in all DiGA years differ from the figures in the DiGA-Report 2023, as the SVDGV’s membership structure has changed.

Figure 6: Redeemed activation codes by month[36]



As in the first three DiGA years, in the most recent reporting period most of the redeemed activation codes were initial prescriptions. In DiGA year 1 (Oct ‘20 - Sep ‘21), around 92 percent of the activation codes reported to the SVDGV were initial prescriptions (Figure 7). This share decreased to c. 82 percent in DiGA year 3 (Oct ‘22 - Sep ‘23) and to 81 percent in DiGA year 4 (Oct ‘23 - Dec ‘24). The proportion of follow-up prescriptions thus increased slightly. This development shows that DiGA are becoming increasingly established in care and that patients want to continue using their DiGA for more than one prescription period, for example if they are affected by chronic diseases. It should be noted that the therapeutic objectives can be achieved within one quarter with some DiGAs, which is why follow-up prescriptions are not always necessary or possible.

Figure 7: Redeemed activation codes by initial & follow-up prescription[37]



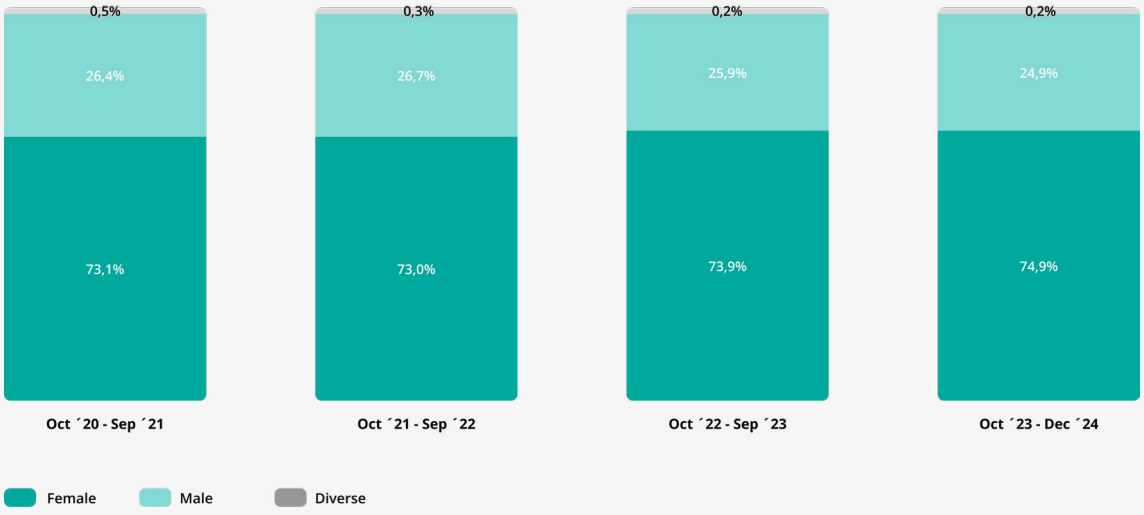
36 SVDGV. Sample size: Oct ,20 to Sep ,21: 36,572; Oct ,21 to Sep ,22: 113,883; Oct ,22 to Sep ,23: 200,389; Oct ,23 to Dec ,24: 455,299
37 SVDGV. Sample size: Oct ,20 to Sep ,21: 23,633; Oct ,21 to Sep ,22: 82,409; Oct ,22 to Sep ,23: 153,716; Oct ,23 to Dec ,24: 378,545

3.2.3. DiGA know no age and gender

DiGAs are used by adults of all gender identities and ages. The SVDGV data shows that the proportion of women remains constant between 73 and 75 percent (Figure 8). As already explained in the previous DiGA-report, there may be various reasons for the high proportion of women: On the one hand, some of the DiGA are aimed exclusively at women. These include “HelloBetter Vaginismus Plus” or “EndoApp”, which was developed for the treatment of women with endometriosis. On the other hand, some of the indications addressed by DiGA are diagnosed significantly more frequently in women than in men. For example, at the cut-off date, the BfArM directory contains seven DiGA for the treatment of depressive disorders, which are diagnosed twice as often in women as in men, depending on the age group.[38] Differences in health behavior between women and men may also play a role in DiGA use.

For example, men are less likely than women to utilize early detection offerings for illnesses.[39]

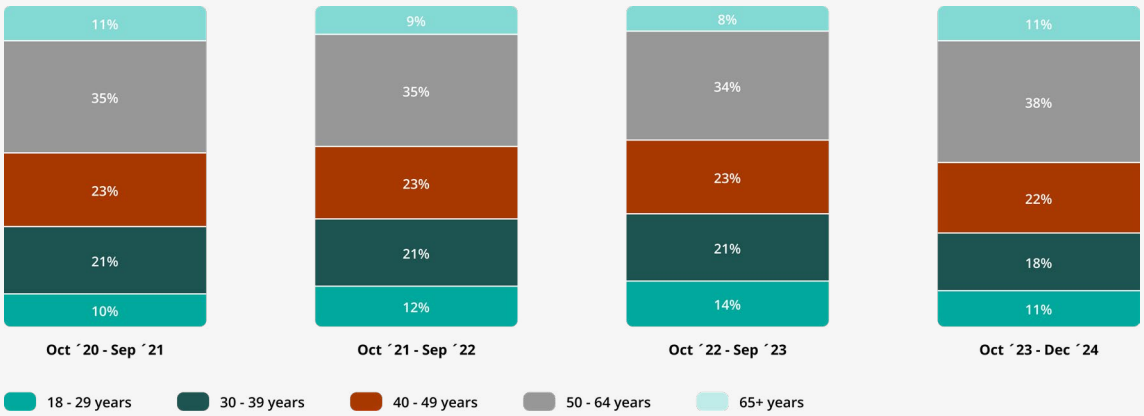
Figure 8: Redeemed activation codes by gender[40]



The data also confirms once again that adults of all age groups use DiGA, with the respective shares increasing with age up to the group of 50- to 64-year-olds (Fig. 9.). In all four DiGA years, they make up the largest proportion of DiGA users - most recently 38%. Possible reasons for this age distribution include demographic effects (”baby boomer generation“) and increasing morbidity with age.[41] At the same time, these data refute the common hypothesis that digital products are a phenomenon of the ”digital native generation“ (those born after 2000). Instead, DiGA are proving to be an inclusive and scientifically proven form of therapy for all age groups.

38 Scientific Institute of the AOK (Wissenschaftliches Institut der AOK: WIdO). Gesundheitsatlas Deutschland, Depressionen. October 2024
39 Bundeszentrale für gesundheitliche Aufklärung. Daten und Fakten zur Männergesundheit in Deutschland. December 2023
40 SVDGV. Sample size: Oct ,20 to Sep ,21: 18,088; Oct ,21 to Sep ,22: 71,141; Oct ,22 to Sep ,23: 125,050; Oct ,23 to Dec ,24: 339,611
41 Federal Statistical Office of Germany (Destatis). Bevölkerung nach Altersgruppen 2011 bis 2023 in percent Germany. as of 14.06.2024

Figure 9: Redeemed activation codes by age[42]



42 SVDGV. Sample size: Oct ,20 to Sep ,21: 17,931; Oct ,21 to Sep ,22: 64,473; Oct ,22 to Sep ,23: 114,078; Oct ,23 to Dec ,24: 290,310

4. DiGA: From Germany to Europe and to the world

With the introduction of the DiGA Fast Track procedure, Germany has taken on a pioneering role internationally: The procedure, which enabled rapid listing of digital medical devices as DiGA within three months, was unique and attracted a great deal of international interest. In addition to Germany, France, Belgium and Austria have now also developed models to bring digital therapeutics into standard care based on the German model. In France, the so-called Prise en Charge Anticipée Numérique des Dispositifs Médicaux (PECAN) procedure is already enabling the reimbursement of telemonitoring products. In a pilot phase, authorities, payers, manufacturers and associations developed a set of rules for the future reimbursement of DiGA for Austria. The implementation is to be completed by 2026. In Switzerland, applications can already be submitted for the MiGeL* list (Mittel- und Gegenstände-Liste: list of means and objects). England and Italy are also working on comparable concepts to standardized regulations for the reimbursement of digital therapeutics. The DiGA model thus serves as a blueprint for digital therapeutic innovations and sets international standards.

The desire for a swift process to integrate digital offerings into care provision quickly is widespread and extends far beyond national borders. Many stakeholders are therefore in favour of harmonized EU-wide approval and regulatory requirements in order to integrate innovative healthcare services across national borders. The developments to date in these countries and efforts towards harmonization are discussed in more detail below.

4.1. France and Belgium

For some time now, France has been offering several options for the reimbursement of digital medical devices, for example via registration as therapeutic software or as an application for remote medical monitoring.

Moreover, since March 2023, there has also been the faster PECAN procedure, which is largely based on the German DiGA Fast Track procedure. The PECAN procedure allows for the covering of costs for innovative DMDs for a period of 12 months, for which ongoing studies are being completed. Upon admission, the clinical or organizational benefit must be conclusively demonstrated by the end of the year.[43] However, in contrast to the German DiGA Fast Track procedure, an extension of the period is not possible.

Unlike the DiGA model, medical devices in risk class III can also be listed according to the PECAN procedure. In addition, digital medical devices in France must meet specific interoperability requirements, including embedding in the "French National eHealth ID" (Identité Nationale de Santé: INS).[44]

As of 31 December 2024, three applications are already eligible for reimbursement via the PECAN procedure: "Cureety"[45], a digital product for telemonitoring in oncology, "Axomove"[46], a digital application for rehabilitation and physiotherapy, and "Continuum+ Connect"[47], which is also used for telemonitoring in cancer. The German DiGA company HelloBetter has also already submitted an application for inclusion under the PECAN procedure, but received a rejection notice. The product applied for, "HelloBetter Insomnia", is listed as a DiGA in Germany and has demonstrated a positive

43 Tarricone, R., Petracca, F. & Weller, HM. Towards harmonizing assessment and reimbursement of digital medical devices in the EU through mutual learning. npj Digit. Med. 7, 268. 2024

44 Agence du Numérique en Santé. Interoperability and Security standards for Digital Medical Devices (DMDs)

45 Haute Autorité de Santé. Cureety TechCare. 31.07.2023

46 Haute Autorité de Santé. Axomove Therapy. 22.10.2024

47 Haute Autorité de Santé. Continuum+ Connect. 15.07.2024

healthcare effect in a clinical trial with more than 200 tudy participants. This example illustrates the importance of harmonizing evidence requirements across the EU in order to provide patients with a variety of digital therapeutics while creating efficient processes that enable fair and swift decisions on market access in different countries.

Although France has already developed its own complete process for inclusion into reimbursement, there are also challenges in implementing the services in day-to-day care. For example, there is currently no clear path for patients to gain access to a PECAN application. In addition, knowledge about digital care options among professionals is rather low: As a survey of almost 400 doctors in France from May 2024 showed, the majority of respondents (>60%) do not know which digital therapeutics are currently on the market and can be reimbursed.[48] Educating and informing patients and healthcare professionals therefore remains one of the major tasks associated with the digital transformation of healthcare and is essential to its success.

Belgium, as well as France, has also established its own process for reimbursing Digital Health Applications based on the German model. Preparations for it began in 2015 with the development of a framework concept for the integration of DMDs into healthcare. Detailed requirements for quality and reimbursement were defined in 2018 with the introduction of the mHealth validation pyramid, which stipulates three different certification levels. The associated assessment procedure was introduced as early as 2021. In practice, however, the planned process proved to be too bureaucratic, so the entire procedure was redesigned in summer 2023. Since then, provisionally reimbursing a digital application based on the German model has also been possible.[49] As of December 31, 2024, two applications had been included in the reimbursement in Belgium: The “moveUP” application, which supports rehabilitation after knee or hip surgery, and “CardioCare@Home”, which is used for remote monitoring of patients with chronic heart failure. Both applications are permanently reimbursable (“CardioCare@Home” since 01.01.2025 and therefore after the cut-off date of this DiGA-report).[50]

Both countries, France and Belgium, have thus developed their own processes at an early stage for the rapid inclusion of digital therapeutics into reimbursement, based on the German model. So far, however, the number of reimbursable applications in both countries is considerably lower (five DMDs) than in Germany, where four years after the launch of the DiGA Fast Track procedure, almost 60 Digital Health Applications can be prescribed by a doctor or applied for.

4.2. Austria and Switzerland

In addition to France and Belgium, efforts are also underway in the German-speaking countries of Austria and Switzerland to implement a standardized way of reimbursing digital therapeutics. As part of its national e-health strategy, Austria is planning to introduce a similar procedure to the DiGA Fast Track procedure. The goal is to introduce such a process for evaluating DiGA and DiPA by 2026.[51] A pilot phase was therefore carried out from October to December 2024 to develop the corresponding framework conditions and requirements. This pilot also served to develop legal aspects and drafts

48 VIDAL. ”Observatoire des DTx 2024: Quel niveau d’adoption par les médecins français“. Quantitative survey conducted by VIDAL on the use of DTx among 388 practicing physicians in France from May 14 - 31, 2024

49 Tarricone, R., Petracca, F. & Weller, HM. Towards harmonizing assessment and reimbursement of digital medical devices in the EU through mutual learning. npj Digit. Med. 7, 268. 2024

50 Quickbird Medical. DiGA in Belgien - Zulassung digitaler Gesundheitsanwendungen. as of January 2025

51 Federal Ministry Republic of Austria Social Affairs, Health, Care and Consumer Protection. eHealth-Strategie Österreich V 1.0. June 2024, p. 34

for legislative amendments.[52] Five applications were examined as part of the pilot phase: Four digital medical devices and one further digital application, which was included in particular due to telemedicine and the connection to the electronic health record ELGA.[53] These included applications that are already listed as DiGA in Germany. At present, it can be assumed that DiGA will be included in healthcare provision in Austria from 2026 following the completion and evaluation of the pilot phase and the implementation of a reimbursement process.

It remains to be seen exactly what the Austrian process will ultimately look like. It is likely that it will be designed to be interoperable from the beginning on and to work without media discontinuities. Which is why a solution using a printed activation code as in Germany is out of the question. Instead, the aim is to connect to other digital solutions and the ELGA patient file at an early stage.[54]

In Switzerland, the concrete implementation of the digital transformation of the healthcare system has so far focused primarily on the introduction of the electronic health record (EPD). A separate remuneration model for DiGA with faster processing procedures does not yet exist. Instead, the plan is to include DiGA-related services in the existing remuneration lists. This is still difficult in practice, as DiGA are hardly integrated into existing processes and the highly fragmented reimbursement structure makes a uniform assessment difficult.[55] In principle, DiGA are reimbursable in the following ways: as a medical service via the open service catalog, as a non-medical service via the closed service catalog or as self-application by patients via inclusion in the list of means and objects (MiGeL).[56]

Due to the large number of remuneration options and the lack of standardized structures, choosing the right model is a challenge for many manufacturers. So far only a few digital applications have been included in the existing service catalogs, but none in the nationally applicable MiGeL. Various organizations are therefore calling for a uniform set of rules to simplify and accelerate market access and use of these digital innovations.[57] The Federal Office of Public Health (FOPH - Bundesamt für Gesundheit:BAG) in Switzerland has already recognized this need to create a uniform framework for the reimbursement of Digital Health Applications and has designated the examination and development of the possibilities in its digital program ”DigiSanté“.[58]

4.3. Further countries

Within Europe and beyond, numerous countries have recognized the standardized reimbursement of digital healthcare solutions as a potential for their future healthcare provision and are discussing the introduction of their own regulations. Similarly, in Italy, digital health solutions can be reimbursed in principle. However, the reimbursement procedure is not clearly defined and so far there is no application that has been included in the price list of all medical devices of the primary healthcare of the National Health System (SSN).[59]

52 Herzig, A., Mandlz, G. Pilotprojekt Digitale Gesundheitsanwendungen in Österreich. 17.10.2024
53 Das Medizinprodukt. App auf Rezept - Erstattung 2026 möglich?. 05.11.2024
54 Das Medizinprodukt. App auf Rezept - Erstattung 2026 möglich?. 05.11.2024
55 Jörn, B. et al. Vergütung von digitalen Gesundheitsanwendungen in der Schweiz - ein Leitfaden. 09.12.2024
56 Federal Office of Public Health FOPH. Faktenblatt Vergütung von digitalen Gesundheitsanwendungen im Rahmen der OKP. November 2024
57 Allianz Digitale Transformation im Gesundheitswesen. Positionspapier Vergütung digitaler Gesundheitsanwendungen in der Schweiz. 27.05.2024
58 Swiss Confederation. Botschaft zum Verpflichtungskredit für ein Programm zur Förderung der digitalen Transformation im Gesundheitswesen für die Jahre 2025–2034. 22.11.2023
59 Quickbird Medical. DiGA in Italien - Leitfaden für Hersteller. 2024

In England, there is also no separate process for reimbursing digital therapeutics (DTx) in the same way as other medicines. Nevertheless, there is a large number of digital therapeutics that can be prescribed by the National Health Service (NHS) doctors as a single intervention or as part of a hybrid care package. Once again, several initiatives are working to develop a dedicated process to simplify the prescription and reimbursement of DTx.[60]

Meanwhile, efforts are also being made in the USA, Japan, Australia and South Korea, for example, to develop a consistent approach and corresponding legal framework for reimbursement structures.[61]

While plans in South Korea are still at a relatively early stage, they are already more advanced in the USA and Japan: In Japan, DTx products that have been validated as Software as a Medical Device (SaMD) can be included in the reimbursement by health insurance companies. The processes are partly similar to those in Germany, but there is no specific time frame from application to decision as in the German DiGA Fast Track procedure.[62] In the USA, the first coordinated cornerstones of a separate regulatory system for the reimbursement of DTx are already in place. However, a centrally developed path that digital applications can follow from application to reimburseability is still lacking.

These international developments highlight the need and interest in digital healthcare approaches worldwide, which require an effective regulatory framework for healthcare provision. With its DiGA Fast Track procedure, Germany has therefore made an important contribution to digital progress in the healthcare system of the future, which many nations can follow and from whose experiences they can benefit.

4.4. The call for European cooperation

Various European countries are facing similar challenges with regard to future healthcare: the increase in chronic diseases, the demographic trend towards an ageing population and the shortage of skilled workers are causing high costs. In this context, digital therapeutics and remote patient monitoring applications can offer personalized and evidence-based approaches to improve healthcare. They can facilitate access to guideline-based care, empower patients and improve their quality of life. Therefore, digital therapeutics should be firmly integrated and promoted in national healthcare systems in the future in order to better meet future challenges in healthcare. The DiGA Fast Track procedure established in Germany or the French PECAN procedure, which is based on it, are good examples of what such an approach could look like. However, they also highlight the need for European cooperation. Until now, each country has had to develop its own, separate pathway. This reduces the possibilities for patients to benefit from different digital offerings, as it is more difficult for the providers of such offerings to reach new markets.

In order to strengthen the European digital health market in the future and consistently promote innovation, there is a need for Europe-wide harmonized reimbursement requirements for DiGA and comparable DTx. These include requirements for clinical evidence (including mutual recognition of clinical trials) as well as for data and patient safety. The harmonized requirements must offer manufacturers planning security and be implemented in such a way that no duplications arise. SVDGV has

60 Digital Therapeutics Alliance. England, DTx Regulatory & Reimbursement Pathways
61 Digital Medicine Society DiMe. International Digital Health Regulatory Pathways
62 Digital Therapeutics Alliance, Japan. DTx Regulatory & Reimbursement Pathways

already pointed out several times in the past the need for such harmonization.[63]

As a pioneer, Germany can play a central role in this situation: It can share with other countries the wealth of experience gained and contribute important impetus to the development of a harmonized procedure.

In addition to the Europe-wide harmonization of the inclusion of digital healthcare solutions in reimbursement, which was already called for in the aforementioned political statement on the 2025 federal elections, the SVDGV considers further topics to be essential.

These are crucial to ensuring a reliable healthcare provision in Germany in the future, as can be read in the following chapter.

63 SVDGV. press release. Advancing Digital Health in Europe: Regulatory and Policy Perspectives on Digital Medical Devices. 25.11.2024

5. DiGA 2030: What the new government must change

In recent years, important political steps have been taken in Germany to make healthcare more digital. Particularly in the area of DiGA, Germany has set a good example, as the international comparison in Chapter 4 shows. At the same time, there is still a great need for action to ensure high-quality and equitable care in the future. In the run-up to the 2025 federal elections, the SVDGV has already politically addressed key aspects that will be crucial for digital healthcare in the coming years.[64,65] The following points are particularly crucial to ensure that the availability of DiGA can be further expanded and that more people have access to these digital care offerings.

5.1. Access to DiGA must be direct and digital

Patients have to invest a lot of time and effort before they can use the DiGA prescribed to them. The procedure to redeem activation codes practiced to date has already been described in Chapter 2 (Fig. 2): Four years after the introduction of DiGA, it is still only possible to obtain a paper-based prescription, which in turn must be sent to the health insurance company for verification, which only then sends the insured person the required activation code. The code must then be entered manually into the DiGA before it can be used. This procedure is cumbersome, counter-intuitive and error-prone. It represents a significant hurdle when using DiGA and therefore urgently needs to be simplified. The SVDGV has already called several times for the introduction of a more direct, simpler and faster process.[66] As described in Chapter 2, the first steps in this direction have been taken with the Digital Health Act. Since the end of March 2024, health insurance companies have been obliged to provide access to a DiGA within two working days. However, the situation has hardly changed so far: In practice, it still takes around 14 days on average for patients to be able to use DiGA.[67]

This unsatisfactory situation should change with the e-prescription for DiGA, the introduction of which has been delayed. In order for there to be real improvement for patients, the SVDGV's perspective is tha the future e-prescription must enable the direct activation of a DiGA after it has been prescribed. Patients should have the choice of activating it directly in the DiGA, via the e-prescription app or the electronic health record. As outlined in Chapter 2, the SVDGV has already presented a well thought-out organizational and technical concept for this. The transitional solution currently in use, whereby an activation code created and issued by the health insurance companies, must be abolished. Not only is it error-prone and cumbersome, it also contradicts the digital user experience.

In addition to the hurdles caused by delays in the provision of activation codes and the cumbersome process to redeem activation codes, DiGA-impeding interventions by health insurance companies have also been reported. This is documented by two circulars from the Federal Office for Social Security (Bundesamts für Soziale Sicherung: BAS) based on specific incidents: In those circulars, the BAS made it perfectly clear that health insurance companies are not allowed to intervene in the prescription decisions and thus the therapeutic freedom of doctors and psychotherapists. They are also not allowed to "switch" to a DiGA other than the one prescribed for cost reasons. In addition, health insurance companies no material right to review DiGA prescriptions.

64 SVDGV. position paper. Gesundheitsversorgung mit Zukunft - Voraussetzungen für eine bessere, gerechtere Versorgung und einen wettbewerbsfähigen E-Health-Standort Deutschland. 06.12.2024

65 SVDGV. DiGA – Eine Erfolgsgeschichte mit Zukunftspotenzial. Forderungspapier Bundestagswahl 2025. December 2024

66 SVDGV. Market Development of Digital Health Applications (DiGA Report 2023). October 01 2020 - September 30, 2023

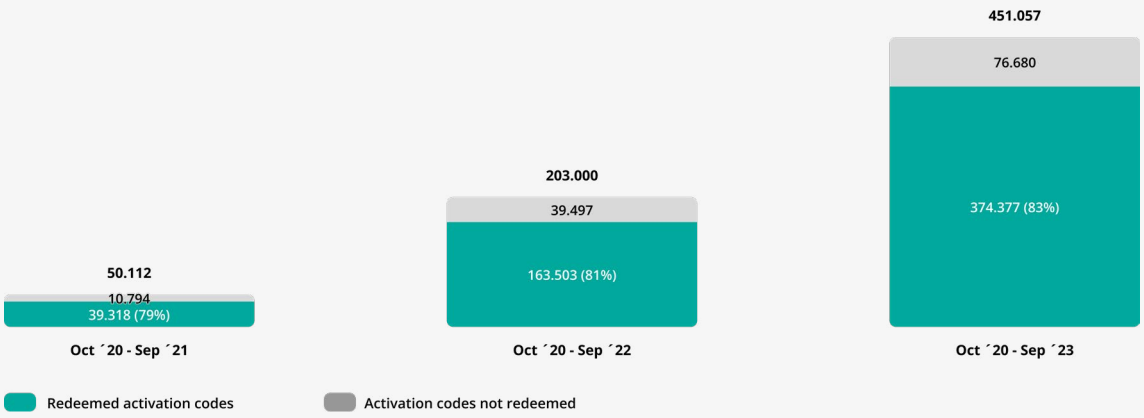
67 SVDGV. Survey among DiGA manufacturers in the period from March 26 to June 25, 2024

They can only verify the necessity of a DiGA prescription by the Medical Service (Medizinischer Dienst: MD) in individual cases where there are justified doubts. A regular review of follow-up prescriptions, for example, is not permitted. Another point of criticism from the BAS in the context of DiGA is the unauthorized inspection of medical records by health insurance companies. The SVDGV calls for an end to this obviously unlawful interference by health insurance companies in the healthcare provision of DiGA.[68,69]

Frustrating processes: Every 5th DiGA prescription is not filled

What are the effects of these multiple restrictions on access to DiGA? The utilization data from the DiGA-Reports of the GKV-Spitzenverband provide some indications. It shows that in the first DiGA year, around one in five prescriptions (21%) were not filled. This rate has slowly improved in the following years (Fig. 10). However, it was still only 83% for the period October 1, 2020 to September 30, 2023 (374,377 redeemed activation codes). Conversely, this means that 17 percent - almost 77,000 times - patients did not redeem their DiGA activation codes and thus did not start their digital therapy.[70,71,72]

Figure 10: Share of redeemed activation codes in total prescriptions and and proofs of indications[73,74,75]



68 Federal Office for Social Security. Prüfpflichten und -rechte der Krankenkassen bei der Abgabe von Digitalen Gesundheitsanwendungen (DiGA) nach § 33a SGB V. 13.06.2023

69 Federal Office for Social Security. Rundschreiben an bundesunmittelbare Krankenkassen. Prüfung der Notwendigkeit von verordneten Digitalen Gesundheitsanwendungen (DiGA) nach § 33a SGB V. 21.11.2023

70 GKV-Spitzenverband. Bericht des GKV-Spitzenverbandes über die Inanspruchnahme und Entwicklung der Versorgung mit Digitalen Gesundheitsanwendungen (DiGA-Bericht) gemäß § 33a (6) SGB V. Reporting period: 01.09.2020–30.09.2023

71 GKV-Spitzenverband. Bericht des GKV-Spitzenverbandes über die Inanspruchnahme und Entwicklung der Versorgung mit digitalen Gesundheitsanwendungen (DiGA-Bericht) gemäß § 33a (6) SGB V. Reporting period: 01.09.2020–30.09.2022

72 GKV-Spitzenverband. Bericht des GKV-Spitzenverbandes über die Inanspruchnahme und Entwicklung der Versorgung mit Digitalen Gesundheitsanwendungen gemäß § 33a (6) SGB V. Reporting period: 01.09.2020 – 30.09.2021

73 GKV-Spitzenverband. Bericht des GKV-Spitzenverbandes über die Inanspruchnahme und Entwicklung der Versorgung mit Digitalen Gesundheitsanwendungen (DiGA-Bericht) gemäß § 33a (6) SGB V. Reporting period: 01.09.2020–30.09.2023

74 GKV-Spitzenverband. Bericht des GKV-Spitzenverbandes über die Inanspruchnahme und Entwicklung der Versorgung mit digitalen Gesundheitsanwendungen (DiGA-Bericht) gemäß § 33a (6) SGB V. Reporting period: 01.09.2020–30.09.2022

75 GKV-Spitzenverband. Bericht des GKV-Spitzenverbandes über die Inanspruchnahme und Entwicklung der Versorgung mit Digitalen Gesundheitsanwendungen gemäß § 33a (6) SGB V. Reporting period: 01.09.2020 – 30.09.2021

By way of comparison, let's take a look at the situation with pharmaceutical drugs, where the prescription filling process is much simpler: For newly prescribed medicines, it is assumed that the non-filling rate is around 10 percent.[76] For DiGA, this rate is almost double.

This leads to the assumption that the cumbersome processes, media disruptions and unreasonably long waiting times between the prescription and the provision of the activation code are frustrating and demotivating many patients.

As a result, they refrain from seeking help via digital therapy. This conclusion is tragic because, for example, many DiGA are aimed at people with mental illnesses, whose stamina tends to be lower than that of mentally healthy people.[77]

Conversely, it seems likely that a digital, simple and direct redemption process would at least raise the utilization rate for DiGA to the level seen for prescription drugs. If only one in ten DiGA prescriptions - instead of one in five as is currently the case - were not redeemed, in the reporting period of the GKV-Spitzenverband, almost 32,000 times more, patients could have benefitted from digital therapy. This data underlines the SVDGV's urgent call to finally simplify processes for the provision of DiGA in the interest of patients and thus remove the patient-hostile access barriers. This is the only way to ensure that Digital Health Applications can fully unfold their benefits in healthcare.

5.2. Bureaucracy - less is more

The DiGA Fast Track procedure has become an international model for the rapid inclusion of digital services in standard care (chapter 4). Despite a concrete schedule, it often takes more time than the planned three months between application and decision. This is partly due to the high levels of bureaucracy and often overlapping requirements.

The sharp increase in DiGA from an initial five to almost 60 listed applications means significantly more work for the responsible BfArM. In order to be able to meet the requirement for an assessment within three months despite the increased workload, the authority needs additional personnel resources. The SVDGV already pointed this out in its DiGA-Report 2023. This is the only way to ensure that applications and changes are checked quickly, which in turn speeds up the entire process.[78]

If the listing and use of DiGA is not to be hampered by further administrative hurdles in the future, all new processes must also be designed to be as efficient and as free of bureaucracy as possible. This also applies to ongoing outcome measurement (see section 2.3.), in order for it to strengthen digital healthcare provision not to slow it down as an additional bureaucratic monster.

In addition, simplified administrative processes are needed for DiGA. In an internal survey conducted by the SVDGV, DiGA manufacturers rated the bureaucratic effort for the DiGA application process as high or extremely high. Three-quarters of respondents also stated that this effort has increased significantly compared to 2021. They also pointed out that the increasing regulatory requirements usually have a strong or very strong impact on the company's growth as a DiGA manufacturer. The requirements therefore represent a significant hurdle to growth or dominate the company's

76 Hüttemann D. Wenn der Patient das erste Rezept gar nicht einlöst. Pharmazeutische Zeitung. 27.07.2023
77 Stiftung Deutsche Depressionshilfe und Suizidprävention. Diagnose der Depression
78 SVDGV. Market Development of Digital Health Applications (DiGA Report 2023). October 01 2020 - September 30, 2023

resources and thus massively slow down growth.[79] These aspects are discussed in more detail in the following chapter.

5.2.1. Data protection and data security: Targeted requirements instead of additional costs

Sensitive handling of data as well as a high level of data security and protection form the basis of Digital Health Applications. However, there are now a large number of regulatory requirements and certifications for both areas, some of which overlap (e.g. pentests, ISO standards, BSI and BfArM certificates). This duplication of requirements is neither sensible nor useful. On the contrary, it leads to high additional personnel expenses and costs. Agile product development is also often restricted by the requirements, which in turn inhibits innovation.

Compliance with the current data protection and data security requirements causes additional costs for DiGA manufacturers of 160,000 - 270,000 Euro per DiGA.[80] These costs are incurred, for example, for compliance with the examinations by the BSI or BfArM, the performance of regular pentests or additional certificates, for example for software updates. In addition, there are not enough notified bodies for some of the required examinations or certifications, which means that examinations can sometimes only be carried out after months.

If DiGA manufacturers are to remain capable of acting and developing innovations in the future, the current administrative processes surrounding certification must be made less bureaucratic. Continuous further development of DiGA must be enabled without incurring high recertification costs with every update.

The existing data protection and data security requirements restrict both the user-friendliness of digital applications as well as the product development and economic viability of DiGA manufacturers: Often, less intuitive solutions have to be implemented, which makes usability more difficult. Complex evaluations cause partially unnecessary costs, which are ultimately shouldered by the community. In order to foster ease of use, self-determination rights and innovation, the requirements should be streamlined in a targeted manner and overlaps reduced. In doing so, an equally high level of data protection and data security will continue to be guaranteed.

5.2.2. Consistent interpretation of evidence requirements creates certainty

The high evidence requirements for DiGA, as set out in the DiGAV, ensure their medical efficacy and benefit.[81] At the same time, the current interpretation of the requirements by the BfArM is such that manufacturers can hardly plan complex studies with any certainty, and the requirements are not clear.

In addition, the unclear requirements have recently led to several temporary deletions from the DiGA directory (e.g. DiGA “PiNK” and “Sincephalea”). These deletions did not only cause uncertainty among patients and considerable effort on the part of the affected companies, they can also damage the

79 SVDGV. Responses from DiGA manufacturers representing 31 DiGA
80 SVDGV. survey of DiGA manufacturers in the period May 2024
81 Digitale Gesundheitsanwendungen-Verordnung DiGAV of April 8, 2020, BGBl. I p. 768. Status: 22.03.2024

reputation of the industry, which is still very young. This has a long-term impact on the success of DiGA and the perception of digital healthcare options.

The evidence requirements for DiGA must be based on scientific findings and interpreted both clearly as well as comprehensibly in future. When processing the applications, the legal deadlines must be adhered to. It must be easy for DiGA manufacturers to understand and plan what constitutes a ”significant change in accordance with the DiGA-Verordnung“ and the BfArM should consider the practical application of the DiGA during the review process. This is the only way to ensure the smooth inclusion of new DiGA and to favor the further development of digital products instead of being penalized by additional requirements, as has been the case so far.

Furthermore, it must be possible to continue to recognize DiGA as class I medical devices in the future. Germany should therefore refrain from taking special paths in the implementation of the European Medical Device Regulation in order to consistently foster innovative and digital healthcare options.[82]

5.3. Anchor and refine the DiGA concept

Digital Health Applications can enrich and improve the healthcare of tomorrow in many ways. In order to realize their full potential, it is important that they be even more closely integrated into healthcare practice. Informing and educating patients and professionals plays a central role here, as does close integration into hybrid models and the remuneration of medical services related to DiGA.

5.3.1. Education as key: anchoring DiGA in training and practice

The DiGA healthcare sector is comparatively young. Thus, the survey by strategy consultancy Deloitte in 2023, already cited in the previous DiGA-Report by SVDGV, showed that around 57 percent of patients are not yet familiar with DiGA.[83] Nevertheless, awareness of the apps on prescription is gradually increasing, as a survey conducted by the GET.ON Institut für Online Gesundheitstrainings in 2024 shows: 43 percent of respondents said they were already familiar with DiGA; In the previous year, an equally designed survey by the same institute showed that this figure was still at 33 percent.[84] According to a survey by the digital association bitkom, as many as 71 percent of respondents had heard of DiGA in 2024.[85]

Awareness of Digital Health Applications is continuing to grow among medical and nursing professionals as well: a survey conducted by Stiftung Gesundheit at the end of 2023 found that around 37 percent of doctors surveyed had already used DiGA with their patients, up from 33.6 percent the year before.[86] In its Arztreport 2024, BARMER Krankenkasse even comes to the conclusion that more than half of all doctors surveyed (56%) have already prescribed DiGA at least once. Of these, half (50.5%)

82 SVDGV. DiGA – Eine Erfolgsgeschichte mit Zukunftspotenzial. Forderungspapier Bundestagswahl 2025. December 2024

83 Deloitte. Gegenwind für die Digitalisierung im Gesundheitswesen. Representative survey on digitalization in the healthcare sector. 2023

84 Representative survey within the German population (N=2,000), conducted by the market research company IPSOS on behalf of GET.ON Institut für Online Gesundheitstrainings GmbH, survey period: September 3 to 6, 2024. Results: 57% (1) No, I've never heard of it, 32% (2) I have heard of it before, but I can't imagine what it is exactly, 8% (3) Yes, I'm familiar with DiGA, 3% (4) Yes, I've used a DiGA myself.

85 Bitkom. Umfrage Digital Health. July 16, 2024

86 Stiftung Gesundheit. Digitale Gesundheitsanwendungen gehören in der Patientenversorgung dazu, ad hoc survey ”Im Fokus“ among 1,913 physicians. December 4-11, 2023

want to do so more often or significantly more often in the future.[87]

Even though the figures vary slightly depending on the source, they show that awareness of DiGA continues to grow and that it is becoming part of everyday healthcare for more and more people - both professionals and patients.

Nevertheless the number of people who still know nothing or little about DiGA is still not negligible. In order to close gaps in healthcare provision and make DiGA accessible to a wide range of patients and healthcare practitioners, the digital programs need to be made more widely known. The aim should be for the general public to be just as aware of the healthcare options offered by DiGA as other established treatment options, such as physiotherapy. In order to achieve this, targeted investments in information and education are required.

It is worth taking a look at France, where important knowledge about digital therapies is already being taught in medical training and further education. In Germany too, the transfer of knowledge about DiGA and other digital care solutions should be integrated into the training, continuous education and further training of medical, therapeutic and nursing professionals at an early stage.

87 BARMER. BARMER Arztreport 2024 - Digitale Gesundheitsanwendungen. p. 197-200

In Germany and beyond, DiGA have already been included in some evidence-based guidelines[1]:

- S3-Leitlinie Nationale VersorgungsLeitlinie Unipolare Depression[2]
- NICE Guideline: Depression in adults: treatment and management[3]
- S3-Leitlinie Behandlung von Angststörungen[4]
- The European Insomnia Guideline: An update on the diagnosis and treatment of insomnia 2023[5]
- S3-Leitlinie Nationale VersorgungsLeitlinie Chronische KHK[6]
- 2024 ESC Guidelines for the management of chronic coronary syndromes[7]
- 2024 ESC Guidelines for the management of elevated blood pressure and hypertension[8]
- Praxisempfehlungen Digitalisierung in der Diabetologie der Deutschen Diabetes Gesellschaft 2024[9]
- S3-Leitlinie Prävention und Therapie der Adipositas[10]
- In addition, the Federal Joint Committee (Gemeinsamer Bundesausschuss) included two Digital Health Applications into the DMP Obesity[11]

1 The list of guidelines presented here was compiled on the basis of information provided by the manufacturers. There is no claim to completeness. The SVDGV would be pleased to receive information on further guidelines.

2 German Medical Association (BÄK), Kassenärztliche Bundesvereinigung (KBV), Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF). Nationale VersorgungsLeitlinie Unipolare Depression. Langfassung. Version 3.2. 2022. p. 63ff; p. 96ff; p. 112ff

3 NICE. NICE Guideline: Depression in adults: treatment and management. p. 28ff ; p. 47ff

4 Bandelow B. et al. Deutsche S3-Leitlinie Behandlung von Angststörungen. Version 2. 2021. p. 42-44

5 Riemann. D. et al. The European Insomnia Guideline: An update on the diagnosis and treatment of insomnia 2023. J Sleep Res. 2023;32(6):e14035. doi:10.1111/jsr.14035, Table 8; Table 9; Table 10

6 German Medical Association (BÄK), Kassenärztliche Bundesvereinigung (KBV), Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF). Nationale VersorgungsLeitlinie Chronische KHK. Langfassung. Version 7.0. 2024. p. 57; p. 133

7 European Society of Cardiology. 2024 ESC Guidelines for the management of chronic coronary syndromes. Table 15; Table 28

8 European Society of Cardiology. 2024 ESC Guidelines for the management of elevated blood pressure and hypertension. Table 35

9 Deutsche Diabetes Gesellschaft. Praxisempfehlungen Digitalisierung in der Diabetologie der Deutschen Diabetes Gesellschaft 2024. Tab. 2

10 Deutsche Adipositas-Gesellschaft (DAG) e.V. S3-Leitlinie Prävention und Therapie der Adipositas. Version 5.0. October 2024. p. 135, 185

11 Federal Joint Committee (Gemeinsamer Bundesausschuss). Beschluss des Gemeinsamen Bundesausschusses über die 34. Änderung der DMP-Anforderungen-Richtlinie (DMP-A-RL): Änderung der Anlage 2, Ergänzung der Anlage 23 (DMP Adipositas) und der Anlage 24 (Adipositas Dokumentation). p. 11, in conjunction with the Tragenden Gründen, p. 5ff

5.3.2. Integrating DiGA into healthcare – it doesn't work without practitioners

A comprehensive, close integration of Digital Health Applications into existing healthcare structures also requires that these solutions are treated the same as other services. Therefore, new medical services must be defined that are remunerated in connection with DiGA. To date, there has been a legal gap here that needs to be closed by clear regulations. Currently, only the follow-up for the use of a DiGA is remunerated for doctors at 7.93 Euro.[88] The prescription of the application is part of the basic and insured flat rate and is therefore not remunerated separately.

88 Kassenärztliche Bundesvereinigung (KBV). Digitale Gesundheitsanwendungen - Abrechnung und Vergütung. 13.01.2025

Additional solutions are therefore required to ensure that practitioners also receive remuneration for further medical services related to education and therapy support and that DiGA do not mean additional investment for practitioners, but are integrated into healthcare equally with other treatment approaches.

5.3.3. DiGA offer potential for data-based, hybrid care

Hybrid care approaches involving DiGA can make healthcare more patient-oriented and improve it. The large amount of data collected in a DiGA makes more individually tailored treatments possible or provides practitioners with a sound basis for decision-making. Supporting therapy with digital tools or direct digital interventions can also increase patient adherence to treatment, as many studies suggest.[89] This opens up new avenues, for example in the treatment of chronic and rare diseases or in rehabilitation. The use of DiGA in hybrid models should therefore be significantly expanded and fostered. The SVDGV has already issued a statement on this matter in 2023 and demands the approval of blended care models for DiGA of all risk classes, which should be anchored in law accordingly.[90]

The Digital Health Act has expanded the DiGA eligibility to include higher risk classes, paving the way for further innovative care options. One example is the integration of telemedical monitoring functions. To date, telemonitoring has only been used to a limited extent in Germany - although it can bring great benefits in terms of health economics as well as improving patient care: the potential benefit amounts to around 4.3 billion euros per year, as telemonitoring technologies can be used, among other things, to avoid hospital stays or shorten hospitalization times.[91] DiGA are ideally suited to integrating corresponding telemonitoring functions, as they continuously record and evaluate data. The prospective integration of the TI messenger into DiGA would also enable simple and secure communication between practitioners and patients via chats or video consultations.

These advantages of DiGA should be given more consideration in the future and their integration into hybrid models should be fostered: Through the interaction of DiGA, ePA, assistive devices and telemonitoring programs or other services, structured treatment programs can be developed that significantly simplify care, for example in rural regions or for certain high-needs diseases.

89 Pharmazeutische Zeitung. Steigern digitale Interventionen die Therapietreue? 21.07.2022
90 SVDGV. Stellungnahme des SVDGV zum Digital-Gesetz (DigiG). 01.08.2023
91 McKinsey. Press release, Studie: Apps auf Rezept werden häufiger verschrieben. 24.02.2024

6. Outlook

This DiGA-Report shows that the market and thus the importance of digital therapies are growing strongly and sustainably. DiGA offer a low-threshold, scalable and effective approach to solving the three major challenges that healthcare in Germany is facing: ageing society, increasing shortage of skilled workers and widening gap between urban and rural areas in terms of medical care.

However, regulatory and legislative interference threatens to slow down the promising development of the young DiGA market. Duplicate regulation and bureaucratic hurdles as well as the lack of planning certainty regarding evidence, can be a heavy burden, especially for young companies that have not yet been able to build up financial reserves.

In the new legislative period, those responsible in politics and self-administration have it in their hands to consistently and resolutely drive forward the digitalization of the German healthcare system. The Digital Health Act of 2024 has expanded the legal framework so that DiGA can be used in further areas of healthcare. In 2025, these new possibilities need to be designed in such a way that they can really be used. Only then will it be possible to have a broader and more diverse range of DiGA, while at the same time anchoring DiGA more firmly into healthcare.

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