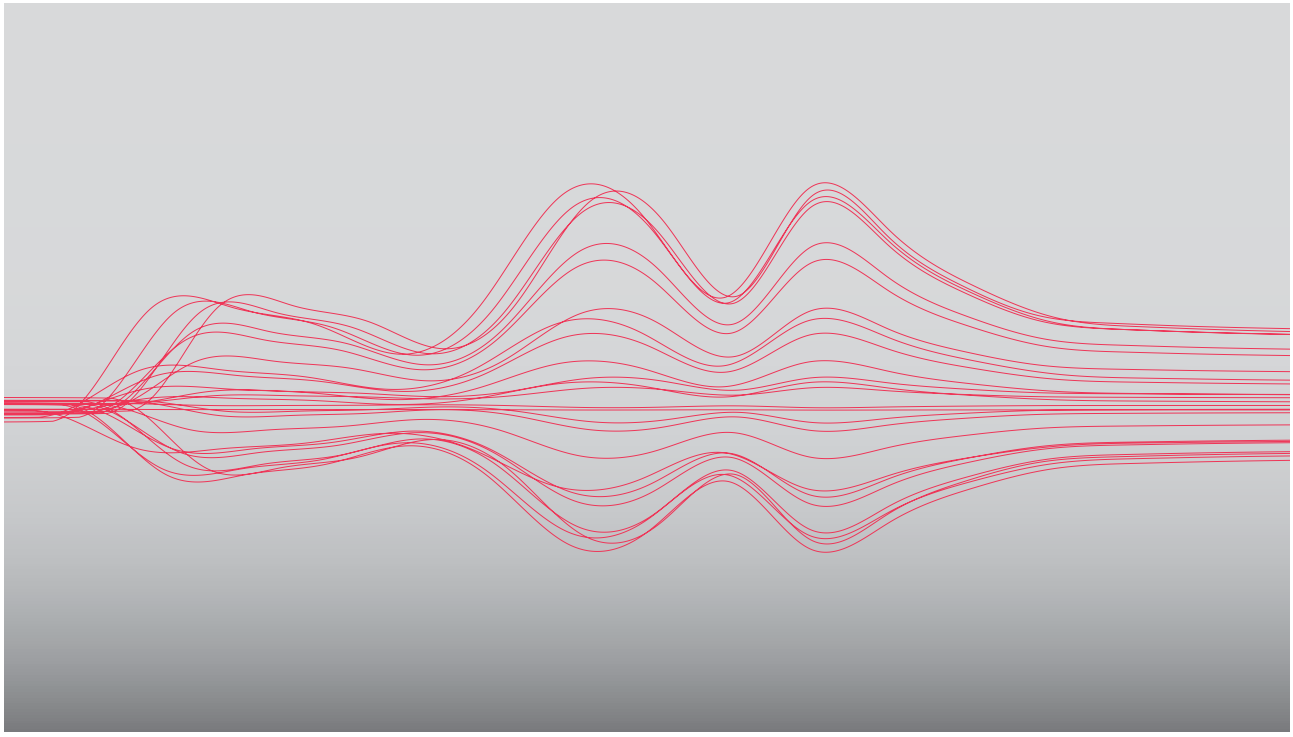


Germany's push towards Healthcare 4.0

A guide to the new fast-track pathway to reimbursement for digital health apps

The Internet of Medical Things (IoMT) continues to be one of the hottest topics in the global life sciences and healthcare industry. The new German Digital Healthcare Act (*DHA – Digitale-Versorgung-Gesetz/DVG*) entered into force on December 19, 2019. This legislation massively pushes Germany towards Healthcare 4.0 and may usher in an era of great opportunities: not only for traditional players in the life sciences and healthcare market, but also for newcomers to this sector, including tech giants, tech startups and data-driven enterprises. Among many other groundbreaking initiatives to accelerate the digital transformation, innovation and agility of the German healthcare system, the DHA enables any physician or psychotherapist in Germany to prescribe Digital Health Applications (*DH-Apps – digitale Gesundheitsanwendungen*) to the approximately 90% of the population who are covered by the country's Statutory Health Insurance (*SHI – gesetzliche Krankenversicherung/GKV*). Makers of DH-Apps are being given superfast access to the highly lucrative German healthcare reimbursement system.

Most notably, for a period of up to 12 months the makers of DH-Apps have the chance to additionally test their products and gather real-world scientific data on their benefits. Provisionally, the SHIs will also be required to fully reimburse the selling price of DH-Apps, which their makers may freely set at the start, of course provided that the products already fulfill the other key criteria, such as safety, functionality, quality, data privacy and data security. Based on the scientific evidence gathered, after the 12-month testing period, the German Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte/BfArM*) will take the decision to list a specific DH-App for permanent reimbursement. In this context, the final fixed price will also be negotiated with its maker. With this strategy, according to the German Federal Ministry of Health

DLA PIPER

(*Bundesministerium für Gesundheit*), Germany will become the first country in the world to put an end to the "Wild West" that now exists in some parts of the digital health industry, with the actual health benefits of such applications for patients and whether or not they comply with data protection standards often being unclear.

Background of the present reimbursement system for DH-Apps

Up until now, there has not been any specific regulation as regards the reimbursement for DH-Apps under German laws. Apart from certain exceptions, the reimbursement for such products was generally based either on the pricing and reimbursement framework pertinent to so-called "medical aids" (*Hilfsmittel*), i.e. products the purpose of which is to ensure the success of a medical treatment or to compensate for the consequences of a disability, according to Secs. 33, 139 of the German Social Code Book V (*SCB V – Sozialgesetzbuch V/SGB V*) or, alternatively, to so-called "new diagnostic and treatment methods" (*neue Untersuchungs– und Behandlungsmethoden*) according to Sec. 135 para. 1 of the SCB V.

In practice, however, the classification of DH-Apps either as medical aids or new diagnostic or treatment methods under the aforesaid regulations can often be very difficult to achieve for various reasons, in particular, due to the strict requirements as regards the proof of medical (diagnostic/therapeutic) benefits and/or cost-effectiveness of such products. And, the conduct of complex clinical trials regularly represents a great challenge and often leads to massive additional costs for makers of DH-Apps, which are in many cases small and medium business start-ups. Due to these and many other hurdles, a new and stand-alone reimbursement system for DH-Apps has now been introduced by the DHA into the German social laws.

In the following, we will provide an overview of the key aspects of the new regulatory framework and address a number of questions which makers of DH-Apps may have as regards the fast-track pathway to reimbursement for their products under the new regulation.

What are the key changes under the new DHA?

According to the new Sec. 33a para. 1 of the SCB V which has been introduced by the DHA into the German social laws, SHI-accredited physicians (*Vertragsärzte*) and psychotherapists *(Vertragspsychotherapeuten)* may prescribe DH-Apps to SHI patients at the expenses of the SHIs. Based on this regulation, SHI patients have an additional and independent right to the reimbursement for DH-Apps (cf. Sec. 33a para. 4 of the SCB V). Importantly, unlike the aforementioned reimbursement regulations which continue to be applicable to medical aids or new diagnostic or treatment methods and which may also include DH-Apps, under the new legal framework, makers of DH-Apps are granted provisional access to the reimbursement system for an initial period of 12 months without having to provide any evidence with regard to the claimed benefits of the product yet. During this testing period, makers have the chance to further gather real-world data on the basis of which a decision on permanent reimbursement will be made by BfArM. In addition to this, taking the circumstances of the individual case into consideration, the level of evidence required for the demonstration of the claimed benefits may be lower for DH-Apps.

Which types of DH-Apps fall under the DHA?

Essentially, the new Sec. 33a para. 1 of the SCB V applies to DH-Apps that are classified as low-risk medical devices and are intended for the aid of SHI patients or healthcare providers in the provision of services related to diagnosis, monitoring, treatment or alleviation of disease or the diagnosis, treatment, alleviation of or compensation for an injury or disability. Furthermore, the main function of these devices must essentially be based on digital technologies.

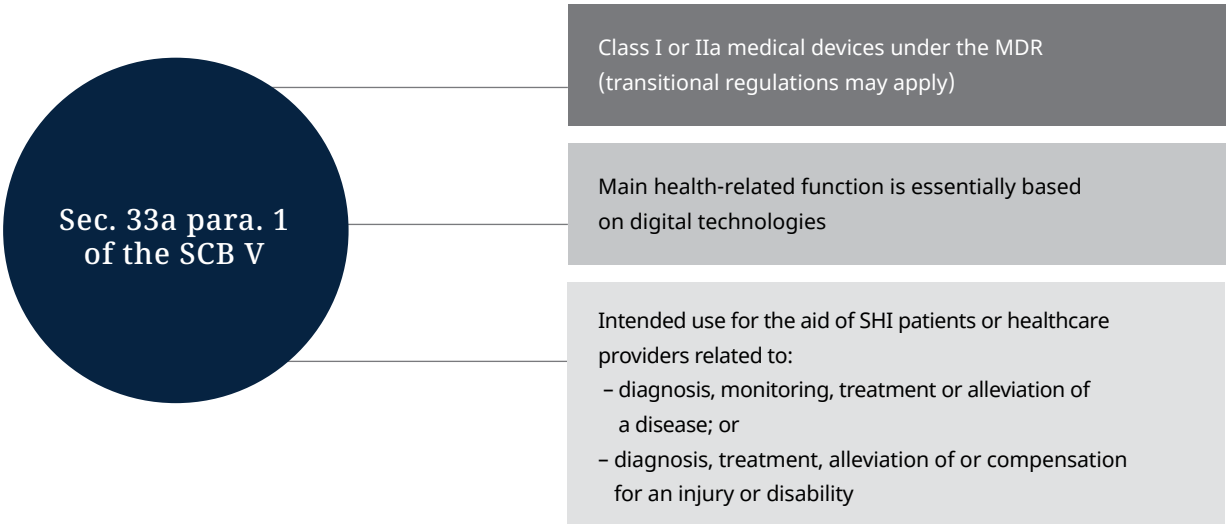
Low-risk medical devices are further specified in Sec. 33a para. 2 of the SCB V as follows:

- Class I or IIa products under Art. 51 of the (Medical Devices) Regulation (EU) 2017/745 that are, as such, already on the market;
- Class IIa products that were placed on the market on the basis of the transitional provisions under Art. 120 paras. 3 or 4 of the Regulation (EU) 2017/745; or
- Class I products that are on the market and remain marketable for the time being based on EU laws.

According to Annex III, Rule 11 of the Regulation (EU) 2017/745, software intended to provide information which is used to make decisions for diagnostic or therapeutic purposes is generally classified as Class IIa. The classification may be different if such decisions have an impact that may cause death or an irreversible deterioration of a person's state of health (Class III) or a serious deterioration of a person's state of health or a surgical intervention (Class IIb). Furthermore, software intended to monitor physiological processes is classified as Class IIa. However, this does not apply if the software is intended for monitoring vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient. In this case, it is classified as Class IIb. All other software is classified as Class I.

In addition, the main health-related function of the product must essentially be based on digital technologies. According to the explanatory memorandum of the German lawmaker, this would

Definition of DH-Apps



not be the case if, e. g., the DH-App only served the purposes to supplement or control another medical device. Furthermore, DH-Apps will not be reimbursable under the new regulation if they are related to a specific healthcare item or service which is generally not covered by the SHI, such as certain preventive medical checkups due to age limits.

Apart from the aforesaid restrictions, the scope of the application of the new Sec. 33a para. 1 of the SCB V is not limited to specific types or functions of DH-Apps. This may lead to a wide scope of application of this regulation to numerous innovative digital solutions in the life sciences, healthcare and digital technology sectors, including AI health apps, disease management apps, connected virtual assistants, biometric sensors or telemonitoring systems, not only from traditional players in this market, but also from newcomers, of course provided that such products are mainly intended to assist with patient healthcare.

Do DH-Apps have to be registered to be eligible for reimbursement?

Yes, according to Sec. 33a para. 1 sentence 2 no. 1 of the SCB V, SHI-accredited physicians and psychotherapists may generally only prescribe DH-Apps at the expenses of SHIs which are explicitly included in the so-called "list for DH-Apps" (*Verzeichnis für digitale Gesundheitsanwendungen*). The requirements for the (provisional or permanent) inclusion in this list are further specified in the newly introduced Sec. 139e of the SCB V. The BfArM is responsible for the binding decision as to whether a specific DH-App will be included in this list and for which specific medical use or indication it may be prescribed by physicians and psychotherapists at the expenses of the SHIs. Furthermore, only such DH-Apps are eligible for reimbursement which had been placed on the market before the maker filed the application for the inclusion of the product in the BfArM list.

What specific requirements apply to the inclusion of DH-Apps in the BfArM list?

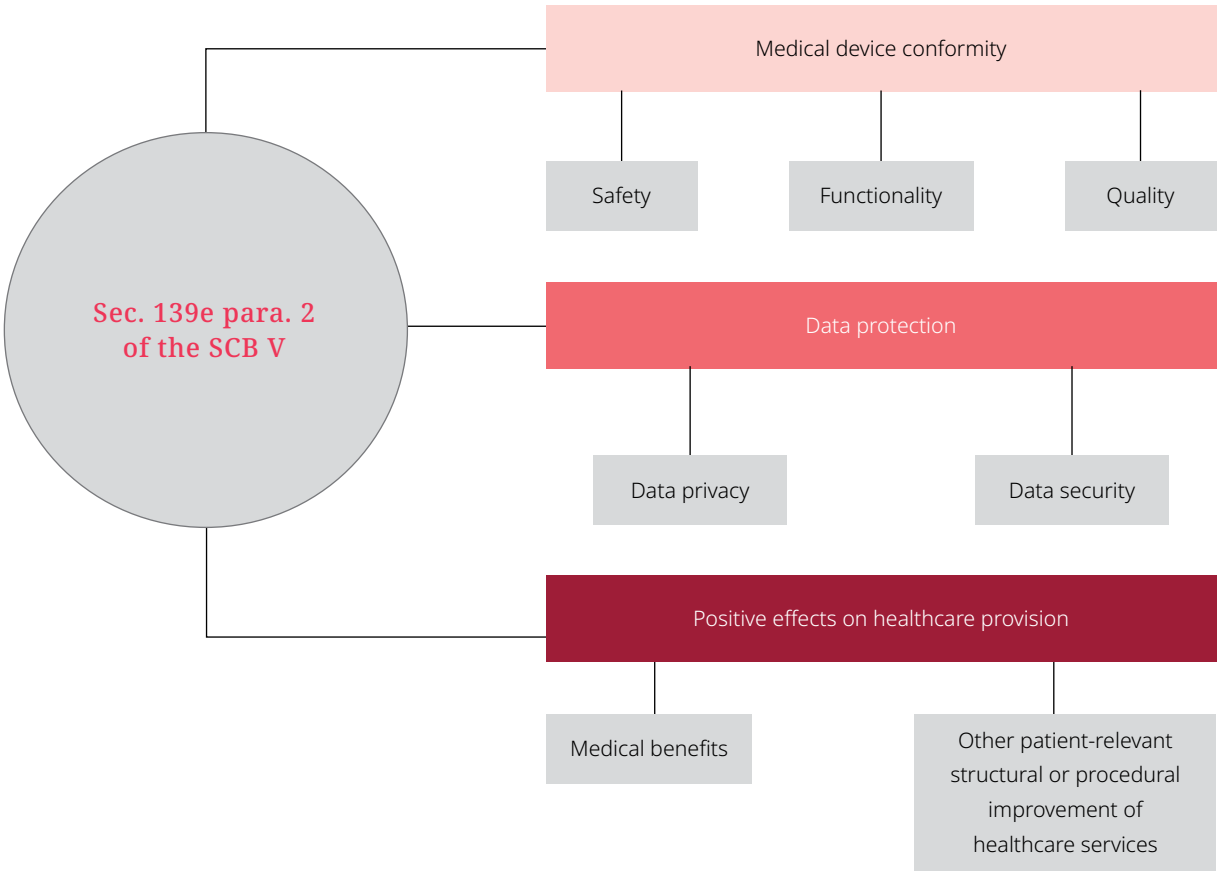
For the inclusion of a DH-App in the BfArM list, according to the new Sec. 139e para. 2 sentence 2 of the SCB V, the maker has to provide evidence that the product:

- meets the requirements for safety, functionality and quality of medical devices;
- complies with data protection requirements and guarantees data security in accordance with the state of the art; and
- has positive effects on healthcare provision (i. e. "benefits").

Since the CE marking of a medical device according to Art. 20 of Regulation (EU) 2017/745 generally already implies that the product complies with applicable safety, functionality and quality standards, these requirements will generally not be re-examined by BfArM. In particular, BfArM will assess the compliance with data privacy and data security requirements, the accessibility to the product by SHI patients and the product's relevance for the German healthcare system in terms of benefits (i. e. positive effects on healthcare provision). The BfArM has to make the decision whether all requirements are fulfilled for the inclusion of a DH-App in the BfArM list within a three-month time limit.

If the maker is not yet in a position to demonstrate the claimed benefits of its DH-App for healthcare provision at the time of its registration, it may apply for the DH-App to be provisionally included in the BfArM list for testing and evaluation purposes for up to 12 months (cf. Sec. 139e para. 4 of the SCB V). During this period, there will also be a provisional reimbursement for the product by the SHIs according to the selling price freely set by the maker. Furthermore, the BfArM may extend the testing period for another 12 months, if at least

Requirements for the inclusion of DH-Apps in the BfArM list



a predominant probability based on the data gathered during the initial 12-month period exists that the benefits claimed can be subsequently verified (cf. Sec. 139e para. 4 of the SCB V).

A positive feature of the new regulation is that the demonstration of positive effects on healthcare provision does not necessarily have to be limited to medical benefits (*medizinischer Nutzen*) in the strict sense, e.g. diagnostic or therapeutic effects, but may also be related to other patient-relevant structural and procedural improvement of healthcare (*patientenrelevante Struktur– und Verfahrensverbesserung in der Versorgung*) according to Sec. 139e para. 2 sentence 3 of the SCB V. The latter may include the promotion of patient education, improvement of the ability to cope with disease-related practical difficulties, the appropriate use of healthcare service providers, better coordination of healthcare processes or the reduction of healthcare-related costs.

Which level of evidence applies to the demonstration of benefits?

As mentioned above, positive effects on healthcare provision may be related either to medical benefits or to patient-relevant structural and procedural improvement of healthcare (cf. Sec. 139e para. 2 sentence 3 of the SCB V). And, in case the existing data is not sufficient to demonstrate the claimed benefits the maker may apply for a provisional reimbursement and inclusion of the product in the BfArM list for testing purposes. For that, however, the maker must submit a plausible explanation of the claimed benefits of the DH-App for healthcare provision, as well as a scientific evaluation concept by an independent institution to demonstrate these benefits. Furthermore, the maker must bear all evaluation costs himself.

As regards the definitive proof of the claimed benefits of the DH-App, the principles of evidence-based medicine (*EBM*) apply (cf. Sec. 139e para. 9 of the SCB V) which describes different levels of evidence, e. g. systematic reviews, randomized clinical trials, cohort studies, case-control studies or expert opinions.

As emphasized in the explanatory memorandum of the German lawmaker, in view of the only low-risk classification and the comparatively low costs of DH-Apps, high-level evidence which can regularly only be provided through expensive clinical studies shall not be mandatory for the proof of benefits.

Which patients are eligible for reimbursable DH-Apps?

In Germany, all SHI patients have equal access to the healthcare benefits of the SHIs. There are essentially two pathways for them to obtain reimbursable DH-Apps under the new regulation: either upon prescription by an SHI-accredited physician or psychotherapist or with the prior permission of the SHI (cf. Sec. 33a para. 1 sentence 2 no. 2 of the SCB V). However, for the permission of the SHI, patients have to demonstrate that they suffer from the same condition for the treatment of which the DH-App of interest has been included in the BfArM list. In practice, this will have to be confirmed by the attending physician to the SHI.

How should DH-Apps be made available to SHI patients?

Generally, DH-Apps are made available to SHI patients as benefits in kind and the makers are then reimbursed by the SHI. The makers have to ensure the existence of a valid physician's or psychotherapist's prescription or the permission of the SHI prior to making a DH-App available to patients.

Furthermore, makers are required to make available DH-Apps to patients by means of electronic transmission via publicly accessible networks or on machine-readable data carriers, for example via SHI portals. If this is not possible, DH-Apps may also be made available via publicly accessible digital distribution platforms (cf. Sec. 33a para. 3 of the SCB V). However, the making available of DH-Apps through a digital platform of third parties, e. g. for download from the App Store, is generally only permitted if the maker is not capable of dispensing the product by himself for factual or legal reasons or, if it entails unreasonable costs. In case DH-Apps are distributed through third-party digital platforms, any additional costs incurred will only be reimbursed by the SHIs to a limited extent which is still to be determined.

Can makers freely determine the selling price for their DH-Apps?

In the initial 12 months, a DH-App is generally reimbursed by the SHIs on the basis of the selling price freely set by the maker. This applies regardless of whether a DH-App already fulfills all requirements for its permanent inclusion in the BfArM list at the time of its registration or provisionally needs to go through a 12-month testing period in which the real-world testing and evaluation of the DH-App takes place.

In case a DH-App is permanently included in the BfArM list right away, which is decided by the BfArM within a three-month time limit from the registration, a fixed reimbursement price has to be negotiated uniformly for all SHIs by the GKV-SV and the maker (cf. new Sec. 134 paras. 1 and 2 of the SCB V). If a fixed price is not agreed upon within 12 months from the permanent inclusion of the respective DH-App in the BfArM list, an arbitration board will fix the reimbursement price within a further three-month period (cf. Sec. 134 para. 2 of the SCB V). The negotiated fixed price applies 12 months after the inclusion of the DH-App in the BfArM list at the earliest and, until a fixed price is agreed upon, the selling price freely determined by the maker continues to apply (cf. Sec. 134 para. 1 sentence 2 and para. 5 sentence 1 of the SCB V).

Similarly, a DH-App is also reimbursed by the SHIs on the basis of the free selling price of the maker during its 12-month provisional inclusion in the BfArM list for testing purposes. After this 12-month period and provided that BfArM decides, again, within a three-month time limit, to permanently include the DH-App in the BfArM list based on the benefits demonstrated by the maker, a fixed reimbursement price has to be negotiated by the GKV-SV and the maker within a further 12-month time limit from the permanent inclusion in the BfArM list. Again, in case the parties are not able to agree upon a fixed price within this period, an arbitration board will fix the reimbursement price within a further three-month period.

To already limit the overall financial burden on SHIs during the first 12 months, the GKV-SV and the German Federal Association of DH-Apps Makers may agree on a framework that determines thresholds below which a permanent remuneration is paid without further negotiations, as well as maximum amounts for the provisional remuneration for groups of comparable DH-Apps. In this context, criteria such as the scope of use of the DH-App by SHI patients, the type and/or the degree of demonstration of benefits may be taken into account, too (cf. e.g. Sec. 134 para. 5 of the SCB V).

This pricing procedure, however, does not completely restrict the free pricing by the makers of DH-Apps. They are still free to demand a higher selling price than the negotiated fixed price. In this case, the SHI patients have to bear the costs that exceed the fixed price themselves. Similarly, patients generally have to pay the full selling price set by the makers themselves, in cases where the functions or areas of indication for which they want to use a specific DH-App go beyond its specifications according to the BfArM list (cf. Sec. 33a para. 1 sentence 4 of the SCB V).

Conclusions

The IoMT continues to disrupt not only the boundaries of healthcare and life sciences, but also demands fundamental changes in the regulations dictating the access to the German healthcare and reimbursement system. With the new German DHA, the legislator has broken new ground to making the pathway to reimbursement more structured, simpler and faster for innovative DH-Apps that are market-ready but lack the full scientific evidence as regards their benefits so far. Of course, some issues remain unclear, such as the procedure for the registration of DH-Apps with the BfArM, the specific criteria for the inclusion of DH-Apps in the BfArM list or, the questions as to which potential consequences any modifications or updates of DH-Apps may have once the products have been registered and whether and to which extend physicians and psychotherapists are required to include DH-Apps in their treatment strategy and medical practice. It is expected that, at least, some of these questions will be further clarified in a supplementary ordinance in early 2020.

Practically, makers of innovative DH-Apps interested in a fast-track access to the German reimbursement system should, first, assess whether their products fall under the low-risk Classes I or IIa of the Medical Devices Regulation (EU) 2017/745. Secondly, they should carefully assess the claim strategy, the probability of gathering real-world data on positive effects on healthcare provision within the 12-month testing and provisional reimbursement period, as well as the right timing for the registration of the product. A wrong registration strategy might lead to substantial delays in the (permanent) reimbursement for the product or even its exclusion from the reimbursement system for at least a 12-month period.

Your contacts

Dr. Philipp Cepl
Rechtsanwalt | Partner
Fachanwalt für Gewerblichen Rechtsschutz
+49 221 277 277 397
philipp.cepl@dlapiper.com

Dr. med. Kokularajah Paheenthararajah
Rechtsanwalt | Senior Associate
+49 221 277 277 307
kokularajah.paheenthararajah@dlapiper.com

Fast-track pathway to reimbursement for DH-Apps

Application for the inclusion of DH-Apps in the BfArM list

BfArM decides about inclusion in the list within a three-month period

Registration

Provisional inclusion of DH-Apps in BfArM list

12-month testing of DH-Apps in real-world setting *(BfArM may extend the testing period for another 12 months, if a predominant probability exists that the positive effects claimed can be subsequently verified).*

Provisional Inclusion

Permanent inclusion of DH-Apps in BfArM list, provided that positive effects on healthcare provision are demonstrated (decision-making process may take up to a further three-month period)

Negotiation of fixed reimbursement price with GKV-SV *(determination of price by arbitration board within a three-month period if there is no agreement within 12 months)*

Permanent Inclusion

Requirements for the inclusion of DH-Apps in the BfArM list

Provisional inclusion and 12-month testing period

Medical device conformity | Data protection | Positive effects on healthcare provision

Permanent inclusion of DH-Apps in BfArM list

Makers freely set provisional selling prices of DH-Apps to be paid by SHIs

Maximum reimbursement amount for the testing period may be determined by the GKV-SV and the German Federal Association of DH-Apps Makers for groups of comparable DH-Apps

Gatekeeping in the use of reimbursable DH-Apps:

- prescription by physicians or psychotherapists; or
- permission of the SHIs

Provision of DH-Apps to patients by means of electronic transmission via publicly accessible networks or on machine-readable data carriers

Gathering of real-world data on positive effects on healthcare provision

Possible criteria for the determination of the fixed reimbursement price:

- type of positive effects
- degree of demonstration of positive effects
- scope of use of DH-Apps by SHI patients

SHI patients are entitled to full reimbursement up to the amount of the fixed reimbursement price

SHI patients have to bear any additional selling prices that exceed the fixed reimbursement price themselves

SHI patients have to pay the full selling price set by the makers themselves in case the functions or indications for which they intend to use a specific DH-App go beyond its specifications included in the BfArM list