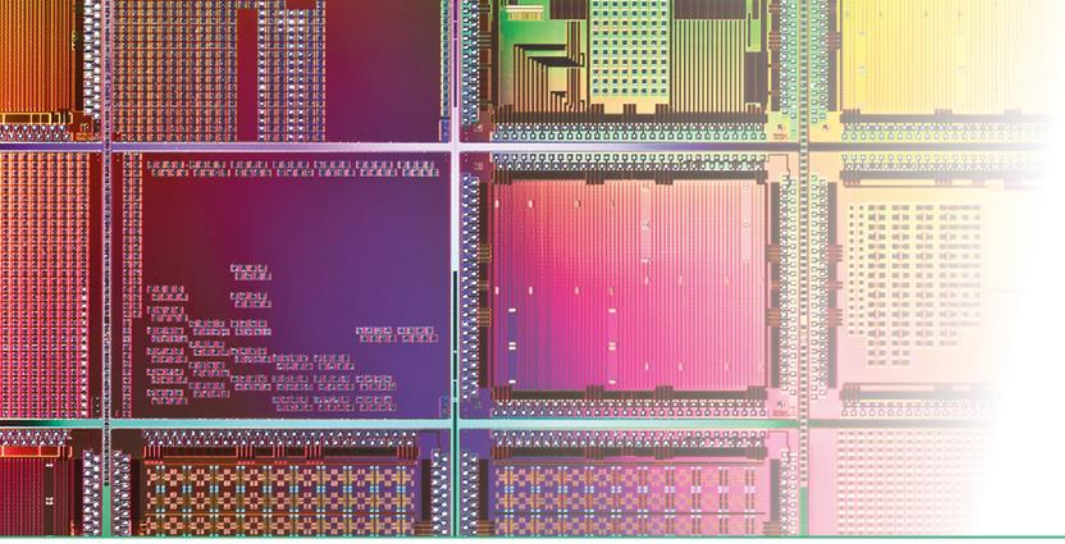

TaylorWessing

DVG

FAQs on the Digital Healthcare Act (DVG)

As at: 21.10.2020

Keyword	Question	Answer
DVG	What is the DVG and what are its most important provisions?	The Digital Healthcare Act ("DVG") largely came into force on 09.12.2019 and aims to improve healthcare provision for patients through digitalisation and innovation. **Apps on Prescription**: Since 06.10.2020, the first health apps have found their way into statutory health insurance provision, initially for testing purposes. The Federal Institute for Drugs and Medical Devices (BfArM) has included the first "apps on prescription" in the new directory for digital health applications (DiGA directory). Health apps are used, for example, to monitor the taking of medicines or to record vital parameters. The first apps that can be prescribed are kalmeda from the manufacturer mynoise GmbH, which offers patients with chronic tinnitus a guideline-based, behaviour-therapeutic therapy. And the web application velibra from the manufacturer GAIA AG, which is used to support patients with symptoms of certain anxiety disorders. Such health apps can now be prescribed by a doctor. The costs for the use of the app are borne by the statutory health insurance. This works as follows: • In the first year the apps are reimbursed at the manufacturer's prices. • In the long term, prices will be negotiated between manufacturers and the central association for statutory health insurance. Medical and psychotherapeutic services associated with the use of digital health apps should also be paid for. Up to now, payment has not yet been

regulated, but doctors and psychotherapists can still prescribe them (the prescription (Form 16) should be used for this purpose, stating the DiGA directory number and the prescription period in days), patients can then make use of them by way of reimbursement.

Financing and Capital: Health insurance funds can now specifically promote the development of digital innovations and cooperate more easily with manufacturers of health apps, providers of telemedical procedures or IT companies. They can also acquire shares in investment funds to promote the development of digital innovations. Funds specialising in health technologies are particularly suitable for this.

Digital Network: The DVG makes it compulsory for service providers to be integrated into a digital network. For doctors who still do not wish to be connected to the telematics infrastructure, an increased fee deduction of 2.5 percent instead of the current 1 percent will be provided for from 1 March 2020. Pharmacies will be obliged to connect to the telematics infrastructure by the end of September and hospitals by 1 January 2021. Midwives and physiotherapists as well as nursing and rehabilitation facilities can participate voluntarily, and the costs of the connection will be reimbursed.

Online Medicine: Doctors have been allowed to offer online consultations since mid-2018, but were not allowed to advertise them. If they did do so, they had to expect warnings, injunctions or fines. Doctors are now allowed to inform about their video consultation hours, e.g. on their websites, and are also allowed to provide information about the video consultation hours online.

Conclusion: The obligatory networking of health service providers will finally open up the possibility of a meaningful use of individual health data. This will hopefully lead to faster and more accurate diagnoses in the future and make treatment more efficient. For the digital health industry, the innovations open up previously unavailable financing possibilities for its developments and ideas. Uncertainties and problems will certainly arise in the initial implementation and conversion of many structures. However, it is better to start imperfectly than to hesitate perfectly.

DiGAV	What is the DiGAV?	The Digital Health Applications Ordinance, DiGAV for short, supplements the Digital Healthcare Act. The DiGAV is a legal ordinance and, together with guidelines of the Federal Institute for Drugs and Medical Devices (BfArM), standardises additional requirements and procedural specifications. This means that high-quality digital health applications become part of patient care as quickly as possible (in the sense of a so-called “fast-track procedure” within three months of receipt of the complete application documents) and can be prescribed. The DiGAV and the BfArM guidelines primarily regulate the following aspects: • the requirements to be met by digital health applications (“DiGA”), in particular as regards security, quality, privacy and data protection; • an upstream consultation of digital health application manufacturers; • the procedure for inclusion in the DiGA directory, which is necessary for reimbursement in the statutory health insurance sector; • guidelines for proving positive healthcare effects; • a permanent review procedure concerning these requirements for a DiGA; • the notification of substantial changes and the fees incurred in connection with the administrative procedure.
Application	Where must the application be made?	The application for inclusion in the directory must be submitted by the manufacturer of the digital health application to the Federal Institute for Drugs and Medical Devices (BfArM). The DiGAV explains how the application for a listing in the DiGA directory works and what it should include.
Costs	What costs are incurred for the application procedure at BfArM?	The decision to be included in the DiGA directory is subject to costs (estimated between 3000 and 10,000 Euros). Further costs may be incurred for subsequent change notifications after inclusion in the directory. Also for a possible rejection or withdrawal of the application, cost items are listed, so that the application is well prepared.

Advice from the BfArM	Where can I get help with completing the application?	BfArM advises manufacturers on the procedure and the information and evidence to be submitted with the application. However, this is subject to a fee.
Requirements	What requirements must the app meet in order to be prescribed?	In addition to criteria such as **robustness** (applications must be designed to be robust against disruptions and false conditions) or **user-friendliness** (easy and intuitive to operate), the focus is particularly on the **positive healthcare effects** defined in section 14 DiGAV. The core questions "what healthcare effect does the app bring?" and "which patient group will benefit from it?" must be answered conclusively in the application and, in principle, must also be proven by trials. In addition, the manufacturer of a health app must continuously ensure that the medical content used by the digital health application reflects the generally accepted **state of medical knowledge**. Overview: • Requirements for safety and suitability for operation • Data protection and data security requirements • Interoperability requirements • Requirements for robustness • Consumer protection requirements • User-friendliness requirements: easy and intuitive to use • Requirements for the support of service providers • Requirements on the quality of medical content • Patient safety requirements
CE-marking and medical device law		Health apps intended for the detection, prevention, monitoring, treatment or alleviation of diseases are medical devices within risk class I, for which the manufacturer has to carry out a conformity assessment procedure and which must be provided with the CE mark after successful completion. The risk class may increase if the EU Medical Devices Regulation 2017/745 applies (which is not expected to be the case until 26 May 2021 due to the

		postponement of the start of application recommended by the EU Commission). In case of an increase of the risk class, the conformity assessment procedure must be carried out by a Notified Body.
Data Protection		Data protection law can be a hurdle not just for the manufacturer, but also for the provider and possibly the doctor. In addition to the GDPR, which sets out special requirements for the processing of health data, certain special regulations apply. Medical professional secrecy must also be observed. The supervisory authorities have set specific requirements for health apps. In order to overcome these hurdles and make a product successful, all applicable regulations must be complied with. In addition, special care should be taken when drafting the consent of the insured person, tracking of health data should be the exception and ideally, the processing should take place in an EU Member State.
Overview	How do I maintain an overview?	The DiGAV contains a 19-page checklist.
Prescription for a health application	How can I prescribe a health application? And how does reimbursement by the health insurance company work?	In the DiGA directory, which is continuously updated, digital health applications are listed which were previously CE-certified as medical products and then tested by the BfArM in a fast-track procedure. Doctors and psychotherapists can then prescribe them. For this purpose, the prescription units provided for each DiGA in the directory on the information page, including the respective characteristics and the corresponding pharmacy central number (PZN), are indicated. This information must then be entered on Form 16 of the usual cash register prescription. The patient can submit the prescription to his health insurance company and ask for an activation code for the DiGA. Once the DiGA has been activated, it can be used for the prescribed period and the DiGA manufacturer settles the costs directly with the health insurance company with reference to the activation code used.

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