Germany's "DiGA" Digital Health Fast Track Process Is Modeling A New Way To Regulate Market Access and Reimbursement

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The benefits of digitalization for the healthcare sector are now widely acknowledged, but the challenge is to bring these developments to market and into actual use. The European Commission is creating a common regulatory framework for digital transformation in all EU Member States, including regulations for data privacy, medical devices, artificial intelligence, and health technology assessment (see EU's digital strategy "A Europe fit for the digital age"). At the national level, numerous Northern European countries have made strides in electronic health records and e-prescribing, and the UK is already moving toward wide-scale COVID-19 pandemic-driven telehealth patient care and remote chronic disease management. Germany's DiGA Fast Track process has created a new model for enabling more rapid market access for digital health applications (apps).

Under the Digital Healthcare Act ("Gesetz für eine bessere Versorgung durch Digitalisierung und Innovation"), Germany introduced a Digitale Gesundheitsanwendungen ("DiGA", digital health app) fast track process (the DiGA Fast Track Process) for rapid approval, testing, and reimbursement of digital health apps. It aims to ease the path for innovative apps into regular care and thus statutory reimbursement in Germany. Medical apps classified as class I and IIa medical devices can apply for fast-track market access and, after a successful completion of a maximum three-month assessment period, can be listed in the DiGA, Digital Health Applications directory for reimbursable digital health apps. As "apps on prescription," they are immediately available to around 73 million patients with statutory health insurance in Germany, the largest European healthcare market.

To be listed in the directory, an app must, *inter alia*, meet privacy regulatory compliance, interoperability standards, and user friendliness requirements and demonstrate sufficient evidence for a positive healthcare effect (*cf.* the Ordinance on DiGAs (Verordnung über das Verfahren und die Anforderungen der Prüfung der Erstattungsfähigkeit digitaler Gesundheitsanwendungen in der gesetzlichen Krankenversicherung)). For a final listing in the directory, the app developer must prove a "positive healthcare effect" by means of a scientific comparative study conducted in Germany. It is possible, however, for an app to be provisionally listed for a one-year testing period, in which the developer can conduct this study and prove the "positive healthcare effect" while having its product on the market. Irrespective of the listing (provisional or final), a listed app is fully reimbursable in Germany.

For the moment, the DiGA Fast Track Process focuses on low to medium risk medical devices of Classes I and IIa. However, because many apps will be upgraded to higher risk classes under the stricter medical devices regime of the EU Medical Device Regulation (Regulation (EU) 2017/745) which has just recently become applicable, it is likely that the

DiGA Fast Track Process will need to be adapted to include higher risk DiGAs in the near future.

Digital health apps are considered one cornerstone of the wider digitalization of health and are likely going to play a significant role in healthcare (*cf.*, *inter alia*, comments of the former German health minister on the BfArM website and a position paper of the Federal Association of Drug Manufacturers (Bundesverband der Arzneimittelhersteller)).

In fact, recently, French President Emmanuel Macron announced plans to replicate the DiGA Fast Track Process for market access for innovative products in France, and the regulation is being considered as a model for further developments at the European level. The harmonization of healthcare systems regarding digitalization and digital health, in particular with comparable requirements for interoperability, could drive the development of a more aligned European healthcare sector.

Germany will see an uptick in DiGA Fast Track applications in 2022, and developers of apps are well advised to consider the DiGA Fast Track Process for their digital health apps. Furthermore, developers should monitor whether this kind of process will be replicated in other countries, at the European level, or for higher classified digital health apps in the near future.