

The New Reimbursement Route for Digital Health Applications (DiGA) in Germany: Critical Appraisal and First Evaluation of the Possible Effect on the German Healthcare System

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BACKGROUND



Figure 1: Consequences of the Digital Supply Act in Germany

- + In Germany, 73 million citizens are insured under the statutory health insurance scheme.
- + Digital health applications (“Digitale Gesundheitsanwendungen”, DiGA) are medical devices of low risk classes (I to IIa) for detecting, monitoring, treating or alleviating diseases.
- + The Digital Supply Act (“Digitale-Versorgung-Gesetz”, DVG) can be seen as an adaptation of the German early benefit assessment for pharmaceuticals (“Arzneimittelmarktneuordnungsgesetz”, AMNOG) which was introduced in 2011.

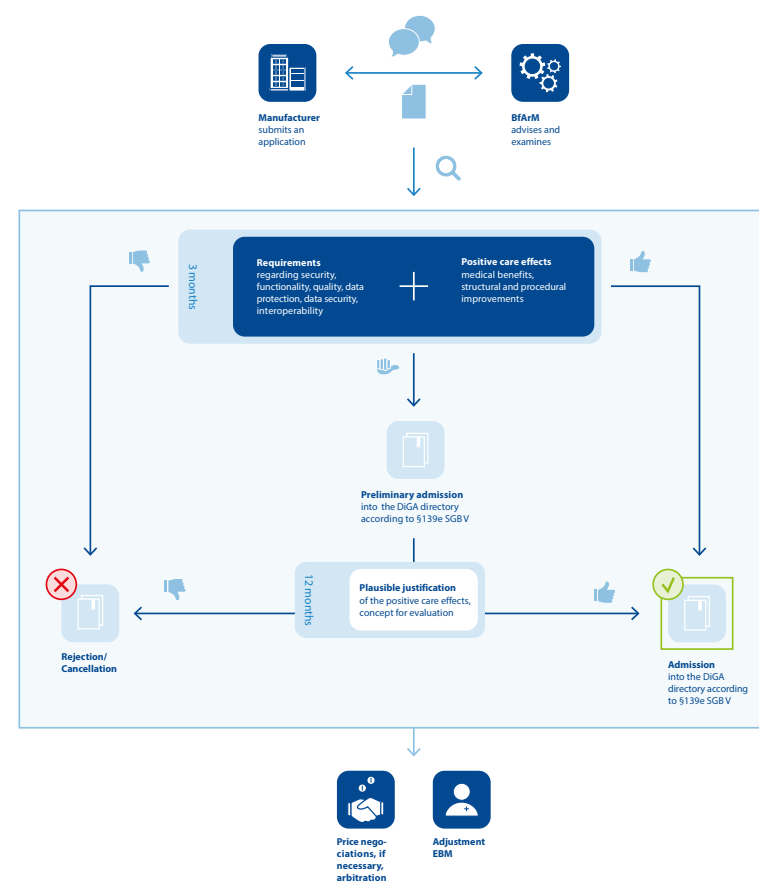


Figure 2: The fast track process for DiGA approval in Germany

OBJECTIVE

The DVG has the potential to tremendously influence the digitalization of healthcare in Germany. To gain first insights into this new reimbursement route before a broader data basis will be available, we analyzed the process and the first outcomes.

METHODS

We critically assessed the DiGA procedure using our extensive experience from consulting pharmaceutical companies regarding market access in the related AMNOG procedure for pharmaceuticals:

- + Analysis of the first listed DiGA according to the indication, the evidence which was provided by the app manufacturer, platforms, and the prescription prices.
- + Assessment of the possible impact of the DVG on the German healthcare system by conducting qualitative structured interviews (N=20) with relevant stakeholders (physicians, patients, app manufacturers, health insurance funds).

RESULTS II

Possible impact of the DVG on the German healthcare system

Central insights derived from interviews with stakeholders were:

- + **Physicians** are rather skeptical of DiGA designed to aid diagnosis but are more open towards DiGA for patient self-management especially in chronic diseases.
- + **Patients** attach great importance to the demanding requirements for data protection and other quality criteria in the DiGA assessment such as userfriendliness.
- + **DiGA manufacturers** welcomed the introduction of the DVG, but are skeptical whether the reimbursement prices for DiGA will be sustainable for them.
- + **Health insurance funds** are concerned that the reimbursement of DiGA will be a new burden for the German healthcare systems and that DiGA will not substantially enhance patient care.

RESULTS I

First DiGA listed in the DiGA directory

On November 4th 2020, 5 DiGA were listed in the DiGA directory at BfArM (Table 1).

Indications: All DiGA aim to support the treatment of chronic diseases by means of behavioral therapy or enhancing patient self-management.

Evidence: When the DVG was introduced, the evidence requirements of the BfArM were far from being clear. Judging from the preliminary experience, it seems now that an RCT is necessary to achieve a permanent listing.

Platforms: All DiGA are available for Android and iOS. somnio and velibra additionally offer web applications.

Listing: The listing in the DiGA directory can be temporary or permanent. To achieve a permanent listing, the manufacturer has to prove a “positive care effect” based on clinical studies. So far, only somnio and velibra have received a permanent listing as they are the only DiGA with RCT data to prove their “positive care effect”.

Prices: The prices of the already listed DiGA ranged from 117€ to 467€. This is much more expensive than typical prices for other apps, but it should be noted that these are not definitive prices. These will be negotiated upon completion of the DiGA process. In the AMNOG process for medicines the negotiated discount is typically in the range of 15-30% so this is what can also be expected for DiGA.

| DiGA | Manufacturer | Indication | Evidence | Platform | Listing | Costs |
|---------|---------------------------------|---|---------------------------------|-------------------------------|-----------|--------------|
| Kalmeda | mynoise GmbH, Germany | Behaviorial treatment of tinnitus | Prospective study planned | Android, iOS | Temporary | 117€/90 days |
| somnio | mementor GmbH, Germany | Behaviorial treatment of insomnia | RCT | Android, iOS, Web application | Permanent | 446€ |
| velibra | GAIA AG, Germany | Behaviorial treatment of panic disorder, agoraphobia, sociophobia | RCT | Android, iOS, Web application | Permanent | 476€/90 days |
| VIVIRA | Vivira Health Lab GmbH, Germany | Exercise therapy of back pain, knee pain, hip pain | Retrospective study RCT planned | Android, iOS | Temporary | 234€ |
| zanadio | aidhere GmbH, Germany | Holistic treatment of obesity | RCT planned | Android, iOS | Temporary | 499€ |

Table 1: DiGA listed in the DiGA directory at the BfArM as of November 4th 2020

CONCLUSIONS

- + With the introduction of the DVG, DiGA can get access to the German healthcare system more easily.
- + A crucial point in the process is that a DiGA can be listed temporarily for 12 months and prescribed to the patients to a price which is freely set by the manufacturer without any evidence for a positive outcome.
- + On the other hand, it should be taken into account that the fast innovation cycles in digital healthcare call for a faster reimbursement than for medicines.
- + As expected, different stakeholders have quite different opinions on the effect of the DVG.
- + As soon as more data are available, further analyses should be performed to better understand the impact of the DVG on the German healthcare system.