133292

Digital therapeutics (DTX): Market access challenges and stakeholder perspectives in Germany

Dorothea Heldt[1] and Emanuele Arcà[2]

[1]OPEN Health, Berlin, Germany
[2]OPEN Health, Rotterdam, The Netherlands

OPEN HEALTH

INTRODUCTION

- In December 2019, the German Ministry of Health implemented the Digital Healthcare Act, which stipulates that digital health applications (Digitale Gesundheitsanwendung, DiGAs) are medical products and can be prescribed by doctors as well as be reimbursed by the statutory health insurance funds.[1]
- Three years after the first DiGA was approval by the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), 49 DiGAs are currently on the market. With the longest-standing health technology assessment and reimbursement framework in the EU, Germany offers the most extensive information on challenges associated with digital therapeutics (DTx) access, reimbursement, and uptake.

OBJECTIVES

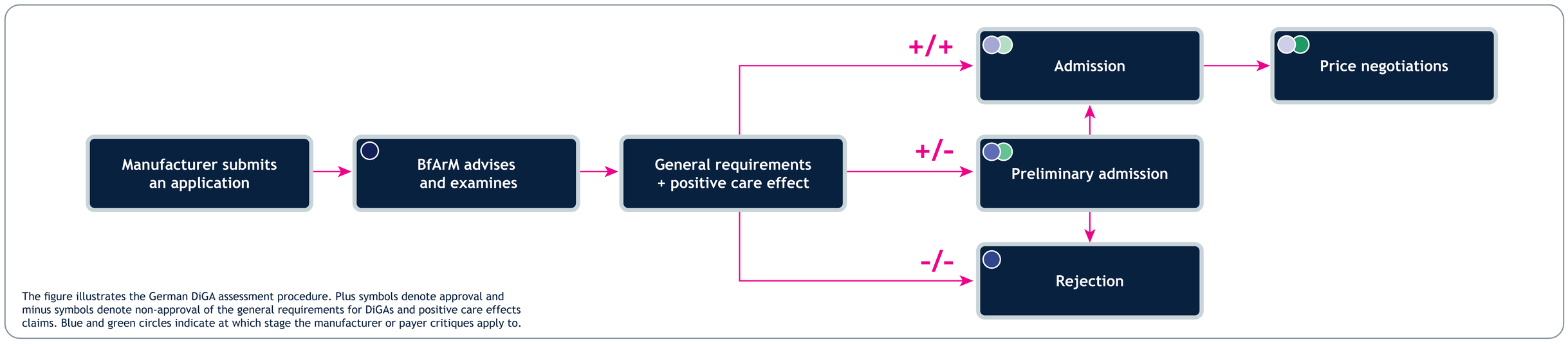
- To assess the market access challenges, both pre- and post-launch, faced by DTx in Germany and to map stakeholders' positions toward DTx implementation and use.

METHODS

- Targeted searches of peer-reviewed literature using PubMed were conducted. In addition, grey literature and relevant stakeholders' websites were used as information sources. Subsequently, stakeholder positions were mapped along the German DiGA assessment procedure.

RESULTS

Figure 1. German DiGA assessment procedure



The figure illustrates the German DiGA assessment procedure. Plus symbols denote approval and minus symbols denote non-approval of the general requirements for DiGAs and positive care effects claims. Blue and green circles indicate at which stage the manufacturer or payer critiques apply to.

Manufacturer critiques[2]

- BfArM sometimes requests changes or further information on very short notice, often towards the end of the three-month fast-track process. It is challenging for manufacturers to address certain requests, such as additional subgroup analyses, within a few days.
- Contrary to the legislation, manufacturers of DiGAs that aim to improve patient-relevant structures and processes are often required to submit evidence for clinical endpoints.
- It is difficult for manufacturers and researchers to investigate and analyse HTAs for DiGAs, and there is very little context around the decisions of admission or rejection.
- The evidence requirements for preliminary listings have become increasingly more onerous. Whilst single-arm trials or retrospective studies used to be sufficient to provide a plausible justification for a positive care effect, often a small RCT that shows clinically meaningful and statistically significant outcomes is requested.
- If an extension of the trial phase is required, BfArM often only grants shorter extensions than requested, which doesn't allow for the generation of the required evidence.
- Subgroup analyses were required for approval despite not being agreed upon prior between BfArM and the manufacturer.
- For unconditional admission, manufacturers are often asked to provide double-blind studies. However, due to the nature of many indications for which DiGAs are assessed, an appropriate comparator for trials is often no intervention, as this best reflects the care reality. Thus, a double-blind study would require a placebo-DiGA, which would be easily identified.
- Manufacturers face substantial price reductions. In the past, an arbitration board had to settle the price, leading to a reduction of 30% to 67%.[3]

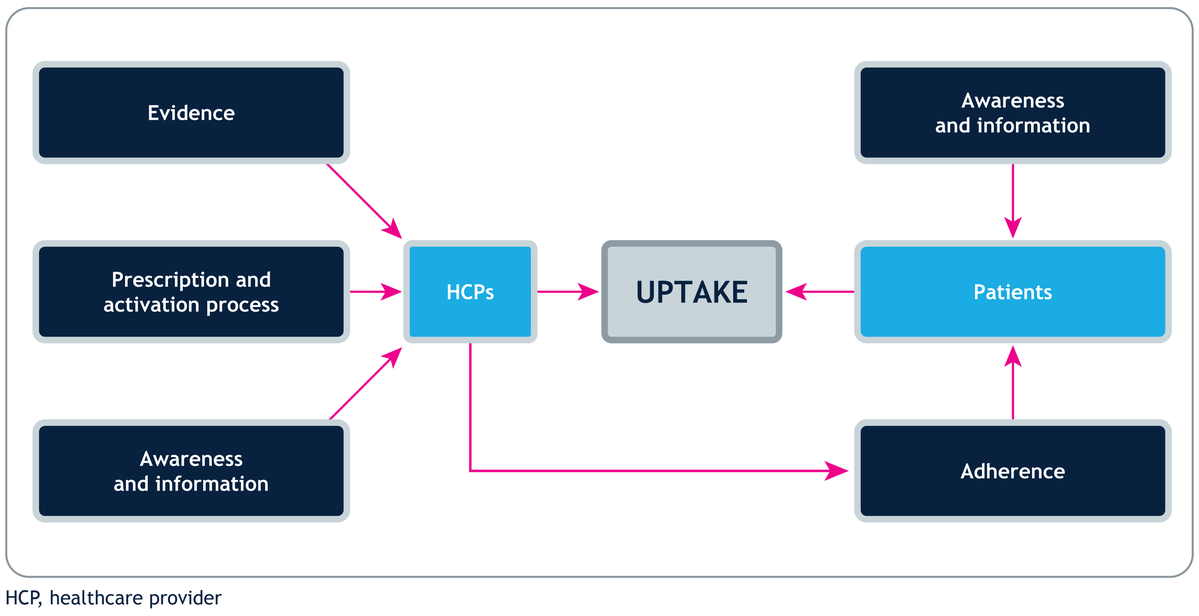
Payer critiques

- Statutory health insurances argue that manufacturer prices are too high and that the current maximum price regulation is not working, as apps are too expensive (the most expensive app is currently €2.077,40/90 days).[5,7]
- At the preliminary admission stage, most manufacturers are not able to prove efficacy within 1 year, and insurers do not want to pay manufacturer prices until efficacy is proven.[5]
- Fewer than half of the apps can prove efficacy and are directly accepted for unconditional admission.[5,8]
- Payers have been flagging a high risk of bias in submitted studies.

Critical uptake factors

Some healthcare providers (HCPs) share the criticism voiced by payers, stating that studies for DiGAs show a high risk of bias, and fewer than half of the apps are unconditionally listed with proven efficacy.[8] Furthermore, HCPs have stated that the prescription and activation procedure is cumbersome and that the reimbursement for consulting on DiGAs and monitoring them is too low.[4] Physician and patient awareness and knowledge is another critical factor, which is essential for the DiGA uptake. Finally, patient adherence is crucial for the success of DTx as a treatment benefit can only be achieved if patients use the product over the intended time.

Figure 2. Critical factors for DiGA uptake



HCP, healthcare provider

CONCLUSIONS

Our findings show that manufacturers face many hurdles in the process of bringing their products to the market. On one hand, BfArM appears to respond to payer and HCP critiques by increasing evidence requirements. On the other hand, generating this evidence has become increasingly more challenging for manufacturers and comes with additional financial implications. This may be a significant factor contributing to the withdrawal of applications by many manufacturers in the past. However, providing solid and high-quality evidence is a key success factor in driving the adoption of DTx, which is highly dependent on HCPs' trust. In fact, the association of statutory health insurance physicians in Bavaria advised HCPs not to prescribe DiGAs based on the high risk of bias and other quality concerns found in submitted studies.[4] The lack of trust might be one of the reasons why DiGAs have only been accessed approximately 164,000 times between the launch of the first DiGA In September 2020 and September 2022.[5] Another contributing factor could be that HCPs often lack knowledge and ability to integrate DTx into their practice.[6] Therefore, initiatives should be developed to inform and educate HCPs, as this may help to attenuate scepticism and promote an openness to trying DTx. In addition, patient awareness can play a role in promoting the adoption of DTx as patients can discuss the option of using a DiGA directly with their physician or therapist.

To conclude, the success of DTx depends on HCP trust and education. However, an environment that allows and promotes innovation must be maintained for manufacturers to further invest in DTx.

REFERENCES

1. BfArM. DiGA: Digital health applications. Accessed 29 September 2023. www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/Digital-Health-Applications/_node.html.
2. Spitzenverband Digitale Gesundheitsversorgung. Mehr Konsistenz und Planbarkeit im DiGA-Zulassungsverfahren. 2022. https://digitalversorgt.de/wp-content/uploads/2022/11/Konsistenz-DiGA-Zulassung-BfArM.pdf.
3. Müller T, Padmanabhan P, Richter L, Silberzahn T. McKinsey & Company E-Health Monitor 2022/Deutschlands Weg in die digitale Gesundheitsversorgung – Status quo und Perspektiven. 2022. www.mwv-berlin.de/produkte/!/title/e-health-monitor-2022/id/887.
4. Kassenärztliche Vereinigung Bayerns. Gutachten kritisiert fehlende Evidenz bei Gesundheits-Apps. 19 Dezember 2022. www.kvb.de/fileadmin/kvb/Ueber-uns/Pressearbeit/Presseinformationen/2022/KVB-PI-221219-DiGA-ScienceDirect.pdf.
5. Bericht des GKV-Spitzenverbandes. Über die Inanspruchnahme und Entwicklung der Versorgung mit digitalen Gesundheitsanwendungen (DiGA-Bericht). 2022. www.gkv-spitzenverband.de/media/dokumente/krankenversicherung_1/telematik/digitales/2022_DiGA_Bericht_BMG.pdf.
6. Dahlhausen F, Zinner M, Bieske L, Ehlers JP, Boehme P, Fehring L. There's an app for that, but nobody's using it: Insights on improving patient access and adherence to digital therapeutics in Germany. *Digit Health*. 2022;8:20552076221104672. doi:10.1177/20552076221104672.
7. AOK-Bundesverband Die Gesundheitskasse. Prescription apps need to be better integrated into care: AMS interview with Dr. Katrin Krämer, head of the supply management department in the AOK Federal Association. 24 January 2023.
8. Kolominsky-Rabas PL, Tauscher M, Gerlach R, Perleth M, Dietzel N. Wie belastbar sind Studien der aktuell dauerhaft aufgenommenen digitalen Gesundheitsanwendungen (DiGA)? Methodische Qualität der Studien zum Nachweis positiver Versorgungseffekte von DiGA. Z Evid Fortbild Gesund Wesen. 2022;175:1-16. doi:10.1016/j.zefq.2022.09.008.

ACKNOWLEDGEMENTS

We would like to thank Christina DuVernay for her editorial support.

DISCLOSURES

This study was funded by OPEN Health. DH and EA are employees of OPEN Health.