Germany: Leading The Way For Digital Health Technology Assessment In Europe

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BACKGROUND & OBJECTIVES

In 2018 Germany were ranked 17th out of 18 countries for their level of digitisation of healthcare delivery, as reported by the SmartHealthSystems study. Just 2 years later, the German government introduced the Digital Healthcare Act, stimulating the implementation of the DiGA system (Digitale Gesundheitsanwendung), in combination with the use of electronic health records and e-prescribing. These changes have propelled the German method of leveraging Digital Health Technologies (DHTs) to the forefront of European healthcare digitization, such that several other European countries are modelling their approach on Germany's methodology. Here, we explore the key success factors of the German program, and how other EU markets are adapting their national frameworks based on the German exemplar.

METHODS

This study analyses the changes brought in by the Digital Healthcare Act, and the impact this has had on the use of DHTs. Through scrutiny of governmental policy we also assessed how other EU markets structured and implemented their DHT assessment systems to compare similarities and differences between theirs and Germany's frameworks, and the influence the German model has had on their construction.

RESULTS

DiGA legislation ultimately aims to allow physicians to prescribe DHTs and medical devices to patients in much the same way as medications are currently prescribed. For a product to be prescribable and reimbursed it must be on the DiGA directory, which requires assessment by the BfARM (Federal Institute for Drugs and Medical Devices). The procedure for DiGA fast track is shown below.

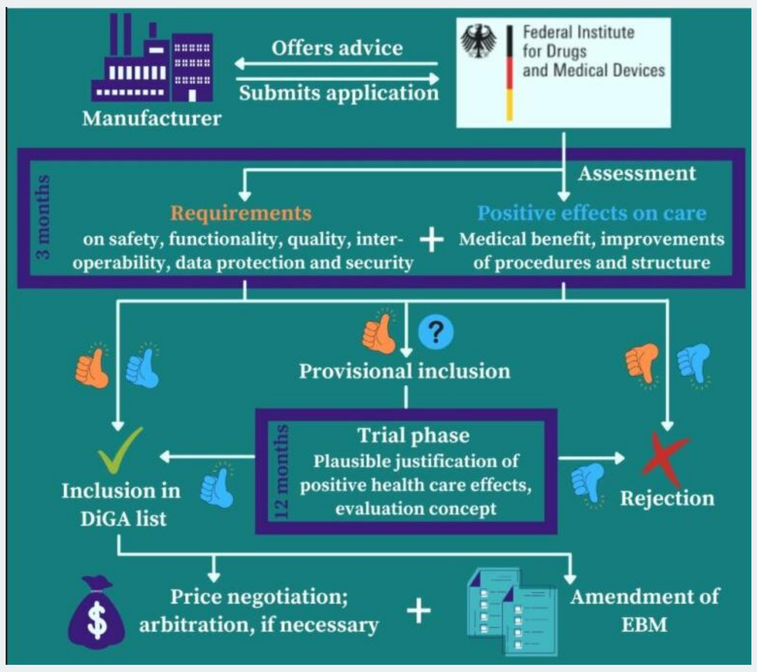

Figure 1. Sequence of the Fast Track procedure

DiGA legislation sets out the requirements a manufacturer must meet in order to demonstrate their digital application is safe, easy to use and effective. Crucially, the process allows for a 12-month 'preliminary admission', which serves as a product / service trial phase. This allows manufacturers to gather real-world evidence around the safety and efficacy of their offering. The results from this stage can then stimulate either inclusion in the DiGA directory, or rejection, all within just a years' time frame. Inclusion on the directory results in full reimbursement from all insurances. Prior to this legislation there was no ordinance to define the procedure for assessing the eligibility for access and reimbursement of DHTs; no centralized database of DHTs which meet the necessary requirements and so can be prescribed; and manufacturers had to negotiate access and pricing separately with each insurer, of which there are over 50.

DiGA legislation has had a drastic impact on the use of digital technologies in Germany, with DHT prescriptions tripling from ~50,000 in 2021 to over 153,000 in 2022.

DiGA legislation has attracted eyes from all over the world. Whilst some countries adopt a 'wait and watch' approach, likely due to the time and effort required in changing policy and legislation, other countries have been quick to model their own DHT approval systems, many of which are based on the German DiGA blueprint.

For instance, the DHT assessment procedure in France, PEC-AN (Prise en Charge Anticipée) is heavily inspired by DiGA. Similarities include:

- Provision of one year 'trial' period to gather real-world data which ultimately impacts reimbursement & pricing potential. This allows for 'fast-track' approval and access.
- Assessment of the overall healthcare benefit of the offering. DiGA reviews DHT medical benefit and positive healthcare effects on the health system; PEC-AN considers improvements in the organization of care in addition to the DHT's clinical benefits.
- Requirement for technologies to be CE- certified and compliant with data protection and cybersecurity standards.

One major *difference* between the two pathways is that PEC-AN allows for a wider range of medical devices / applications to be reimbursed; the thinking is that DiGA will also expand approvable product types within the next year.

Belgium introduced reimbursement for DHTs, via the mHealth Belgium system, in 2021. As with PEC-AN, mHealth Belgium shares stark similarities with the DiGA model, requiring that DHTs meet clear targets to be reimbursed. The assessment process does differ slightly, in that the mHealth validation pyramid in Belgium has 3 levels of assessment, which evaluates risk, interoperability and clinical evidence. Unlike the PEC-AN and DiGA systems, mHealth Belgium does not offer a one-year transitional reimbursement period to collect patient data and ultimately inform reimbursement.

Aside from the 3 examples listed, which represent the best EU market entry channels for reimbursement of DHTs, several other EU markets are formulating their own models, including Italy, Denmark, Switzerland, Austria and the Nordics. Health representatives from many of these markets are using the DiGA model as a template, with DHTs being assessed across a similar range of metrics, and allowing for a one-year trial period. The expected time until the first digital health app gains access to statutory health plans differs in these markets but an average of two years should be considered in any go-to-market road mapping.

CONCLUSIONS

Germany's DiGA fast track process for DHTs is considered best-in-class and well suited for European health systems. Germany is the first EU country to have implemented such a standardised process for DHTs to be prescribed by a physician and reimbursed by health insurances. This required a substantial change in legislation, but decisive and focused action has resulted in 1000's of patients now benefiting from using DHTs, as well as allowing for high levels of innovation.

Whilst highly rated, there are still many improvements to be made to the DiGA system, beginning with potential for wider classes of DHTs to be reimbursed, as in France. Regardless, the DiGA is a system that will continue to be replicated by other countries, and with the potential for a European policy (digital health action plan) for DHTs, DiGA is well positioned to be a reference point for any future polices.

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