

# Electronic diary smart medication™ for patients with haemophilia in the context of the Digital Care Act (Digitale-Versorgung-Gesetz, DVG)

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## Background:

The German government recently launched the Digital Supply Act. The law foresees the use of medical apps on prescription in patient care. Doctors and manufacturers are to receive appropriate remuneration for the use of medical apps. The aim is to promote digitalization in the health care system in Germany and to introduce reasonable digital products in standard care. With the DVG, Germany is breaking new ground in digitization in the health care sector and is thus a pioneer within the European Union.

## Methods:

A large number of criteria must be observed when approving medical apps. For example, the law provides that only medical devices in the low risk classes I and IIa are permitted in the list of prescribable apps. In addition, the intended purpose of the app must support the patient in outpatient care through the service providers (HCPs). The federal agency BfArM is to be responsible for approval and inclusion in the directory for digital health applications (Digitale Gesundheits-Anwendungen, DiGA). The requirements for security, quality, functionality, data protection and data security must be guaranteed. After 12 months, the medical benefit and thus the positive effects of care must be demonstrated.

## Results:

It could be shown that the requirements of the DVG are met with smart medication™. In particular, the medical benefits have been demonstrated in numerous retrospective and prospective cohort studies conducted since the introduction of smart medication™ in 2012.

## Conclusion:

DVG requirements for prescription medical apps are discussed in the context of electronic diary smart medication™ for patients with haemophilia and the suitability for inclusion in the DiGA directory is presented.

