DTx REGULATORY & REIMBURSEMENT PATHWAYS

DIGITAL THERAPEUTICS ALLIANCE

GERMANY Regulatory

Category Name	Medical Device
Conformity Assessment	CE Mark granted by a designated Authorized Notified Body
Responsible National Regulatory Agency	Federal Institute for Drugs and Medical Devices (BfArM) Authorized Notified Bodies (25 as of January 2022)
Products that Qualify For Regulatory Review	DTx manufacturers complete a self-assessment risk classification (MDCG) to determine which level of CE Mark is necessary. Class I products do not qualify for regulatory review. Some DTx products that were initially certified as Class I MDD, remain Class I under MDR. *Products that qualify for regulatory review include:* • Class IIa: Most DTx software falls under this classification, with some exceptions. • Class IIb: Includes DTx products with higher risks or consequences. • Class III: No Class III DTx products currently exist, but this is possible in the future.
Pre-Submission Opportunities	No process exists.
Guidelines To Be Met	Key systems: • Company-wide quality management system (QMS) according to MDR article 10, compliant with ISO 13485 and product-specific technical documentation (MDR annex II and III, covering IEC 62304, IEC 62366, and ISO 14971). • Clinical evaluation report according to MDR Article 61 (annex XIV and XV), MDCG, and MEDDEV 2.7 • Post-market surveillance report according to MDR Article 85 for Class I and Article 86 for Class IIa, IIb, and III. Personnel requirements: • Minimum of one Person Responsible for Regulatory Compliance (PRRC) and one Medical Device Consultant. • Manufacturers not registered in the EU must appoint an Authorized European Representative. Full regulation: MDR 2017/745
Other Guidelines	CE Mark applies to all European countries at this time. Significant changes to the software may require a re-certification by the responsible authority. GDPR (General Data Protection Regulation) compliance is required; data hostage within the EU is necessary due to a currently invalid EU-US data privacy shield. *Note: Class I products need to fulfill the same guidelines as higher risk products, but do not need to involve a notified body in the process.*
Product Recognition	Notified bodies: CE Mark granted BfArM: DiGA (also known as Digital Health Applications or Digitale Gesundheitsanwendungen in German) *Note: Not all DiGA are DTx products and not all DTx products are DiGA.*
Approximate Timing For Process Completion	For CE mark: 12–18 months, although the timeline is currently extended due to the limited number of notified bodies.
Cost	Cost dependent on internal regulatory expertise and capacity. Total cost: ~ 60.000-100.000 EUR (including notified body and external consultants)

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GERMANY Reimbursement

Prescription Required?

No, but an official diagnosis is required and depends upon approval from the health insurance.

Despite an alternative non-prescription path to receive DiGA, clinicians are seen as the main gatekeeper in driving adoption.

Public Insurance Coverage

Main market for reimbursement in Germany, as statutory health insurances (SHIs) cover ~90% of the population

Two main options: DiGA and selective contracts

DiGA: listed on DiGA directory according to the Digital Care Act (SGB V § 33a) and 100% reimbursed by all SHIs

BfArM is the competent authority for DiGA listing.

Actual price is set by DiGA manufacturer and replaced after 12 months by the remuneration negotiated with the National Association of statutory health insurances (GKV-SV).

Requirements:

- General requirements: Class I or IIa medical device (CE mark), compliant with Annex I and II of DiGAV on data protection and information security, interoperability, robustness, consumer protection, ease of use, support of healthcare providers, quality of medical content, and patient safety (appx. 120 questions).
- Clinical evidence: DiGA has to prove at least one positive healthcare effect (pVE) which can be a medical benefit (mN) or a patient-relevant improvement of structure and processes (pSVV).
- Clinical evidence has to be demonstrated at least in a retrospective comparative study with a preference in practice for RCTs.

Two paths to enter DiGA directory.
Details provided in BfArM Guide.

- Permanent listing: DiGA application fulfills all requirements and has sufficient clinical evidence.
- Preliminary listing: DiGA fulfills all general requirements and has 12 months to submit clinical evidence according to the approved evaluation concept to be listed permanently. If claims are not met, DiGA will be removed from DiGA directory and no longer reimbursed.

Selective Contracts: full or partial reimbursement from individual SHIs

Statutory health insurances can decide to reimburse individual DTx in selective contracts (e.g. SGB V §140a).

Selective contracts have to be negotiated with each statutory health insurance (currently 103 in Germany), requiring a lot of effort due to high fragmentation.

Private Health Insurance

10% of the German population is privately insured (option to switch to a private health insurance above certain salary threshold).

Private health insurances are currently not obliged to cover DiGA and no dedicated alternative path for DTx reimbursement exists.

Possibility to negotiate reimbursement agreement with each private health insurance (currently 47).

Employer-Sponsored Healthcare

Not common as of today, but can become part of corporate health management schemes.

Few examples for DTx exist already.

Consumer-Funded

Very low willingness to pay out of pocket in healthcare.

Possibility to use D2C marketing mechanisms for DiGA or selective contracts as prescription is not always necessary.

Note: This document represents pathways that continue to evolve. It does not provide legal advice.