# DTx REGULATORY & REIMBURSEMENT PATHWAYS

DIGITAL THERAPEUTICS ALLIANCE

## FRANCE Regulatory

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| **Category Name** | Medical Device |
| **Conformity Assessment** | CE Mark granted by a designated Authorized Notified Body |
| **Responsible Regulatory Agency** | National Agency for the Safety of Medicines and Health Product (ANSM) |
| **Products that Qualify For Regulatory Review** | DTx manufacturers complete a self-assessment risk classification (MDCG) to determine which level of CE Mark is necessary.<br>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.<br>*Products that qualify for regulatory review include:*<br>• Class IIa: Most DTx software falls under this classification, with some exceptions.<br>• Class IIb: Includes DTx products with higher risks or consequences.<br>• 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:<br>• 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).<br>• Clinical evaluation report according to MDR Article 61 (annex XIV and XV), MDCG, and MEDDEV 2.7<br>• Post-market surveillance report according to MDR Article 85 for Class I and Article 86 for Class IIa, IIb, and III.<br>Personnel requirements:<br>• Minimum of one Person Responsible for Regulatory Compliance (PRRC) and one Medical Device Consultant.<br>• Manufacturers not registered in the EU must appoint an Authorized European Representative.<br>Full regulation: MDR 2017/745 |
| **Other Guidelines** | CE Mark applies to all European countries at this time, but DTx product documentation and labelling must be translated into French.<br>Significant changes to the software may require a re-certification by the responsible authority.<br>General Data Protection Regulation (GDPR) compliance is required; data hostage within the EU is necessary due to a currently invalid EU-US data privacy shield.<br>Notes:<br>• Class I products need to fulfill the same guidelines as higher risk classes, but do not need to involve a notified body.<br>• DTx product may be recognized as a connected medical device; this is established after CE Marking, but before reimbursement. |
| **Product Recognition** | CE Mark |
| **Approximate Timing For Process Completion** | For CE Mark: 12–18 months, although timeline is currently extended due to the limited number of notified bodies.<br>Registering CE mark with ANSM: 2–3 weeks. |
| **Cost** | For CE Mark: Cost is dependent on internal regulatory expertise and capacity.<br>Total cost: ~ 60.000-100.000 EUR (including notified body and external consultants).<br>No fee for registering CE mark with the ANSM. |

# FRANCE Reimbursement

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| **Prescription Required?** | Formal requirements are not yet established; however, currently reimbursed digital health products are prescribed. |
| **Public Insurance Coverage** | The main pathway for product reimbursement, covering the entire population is:<br>No general process for DTx product reimbursement currently exists, but individual funding decisions are possible. The National Commission for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) of the Haute Autorité de Santé (HAS) is the health technology assessment (HTA) body responsible for evaluating and recommending DTx products.<br>The Commitee for the Evaluation of Healthcare Products (CEPS) evaluates the additional benefits and expected service improvements, and classifies products into four levels compared to the current standard of care. Based on recommendation, CEPS can add medical devices, including DTx, to the list of reimbursable products (Liste des Produits et Prestations Remboursables, LPPR). Reimbursement may be granted for a limited time only, requiring a re-evaluation.<br>The social security fund Caisse Primaire d'Assurance Maladie (CPAM) is responsible for funding, but is not involved in initial decision for reimbursement.<br>Experimental coverage options currently include:<br>• Article 51: Limited duration experimental program for innovative products. Conditions of eligibility include product innovation, feasibility, ease of distribution, and price to quality ratio.<br>• Innovation Package for Medical Devices (forfait innovation): Temporary funding system to facilitate early patient access to innovative technologies. Conditions of eligibility include product innovation and relevant clinical and health economic studies. |
| **Private Health Insurance** | Private health insurance accounts for 7% of total healthcare expenditures. 95% of the population has some form of private, voluntary insurance to cover costs such as copayments for drugs, glasses, and dental health. |
| **Employer-Sponsored Healthcare** | Not common. |
| **Consumer-Funded** | Low willingness for consumers to pay out-of-pocket. |

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