DTx REGULATORY & REIMBURSEMENT PATHWAYS

DIGITAL THERAPEUTICS ALLIANCE

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CHINA Regulatory

Category Name	Medical Device	
Responsible Regulatory Agency	National Medical Products Administration (NMPA)	
Product Risk Classifications	**Class II** (Typically have a **limited impact** on clinical behavior changes)	**Class III** (Typically have a **higher risk profile and greater impact** on clinical behavior changes)
Regulatory Review	Class II products qualify for review at the provincial level of NMPA, where different requirements may apply (e.g. the registration fee)	Class III products qualify for review by NMPA
Pre-Submission Opportunities	Not mandatory, but recommended, refer to Medical Device Priority Review Process (2016) or Innovative Medical Device Special Review Procedure (2018), etc. There are some existing practices in Hainan province, Class II products have been included in the relevant mechanism.	
Guidelines To Be Met	The specific DTx regulations and standards are currently under intensive discussion and in the process of being formulated, and guidelines are determined on a case-by-case basis. They mainly refer to the following relevant regulations and might need to consult the relevant regulatory authorities regarding the details. 1. Classification: • The Medical Device Classification Catalogue (No. 104 of 2017) and related classification guidance documents • The classification opinions related to DTx products from the classification results published by the CMDS of NMPA in 2023 • Guiding Principles for Classifying Rehabilitation Digital Therapeutic Software (Draft for Soliciting Opinions) Aug. 2023, etc. 2. Registration: • Guidelines for the Technical Review of Mobile Medical Device Registration (2017) • Guiding Principles for Registration and Regulatory Approval of Artificial Intelligence Medical Devices (2022), etc. 3. Clinical evaluation, Randomized Control Trial may be required: • Guidelines for the Clinical Evaluation Review of Artificial Intelligence-Assisted Diagnostic Medical Devices (Software), Nov. 2023, etc. 4. Relevant technical standards: • The first technical standard specifically for digital health: Technical Specifications for Respiratory Function Data Monitoring and Analysis Software, Apr. 2024, etc. 5. Cybersecurity requirements 6. Other requirements for medical devices: • ISO13485:2016 Medical devices—Quality management systems • GB/T 25000.51-2016 Systems and software Quality Requirements and Evaluation (SQuaRE)—Part 51: • Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing • YY/T 0316-2016 Medical devices—Application of risk management to medical devices • YY/T 0664-2020 Medical device software—Software life cycle processes, etc.	
Product Recognition	Registration license for class II products (approved cases: Magnetic sleep status assessment device for humans, Pediatric spine development risk alert software, Dynamic cardiopulmonary function data monitoring and analysis software, Speech disability rehabilitation assessment and training system, etc.)	Registration license for III products (approved cases: Cognitive dysfunction assessment and treatment software, Insulin calculation software, depression auxiliary assessment software, Insomnia recovery training system, Cognitive function rehabilitation software, etc.)
Approximate Timing For Process Completion	Normal registration review period after application submission: depends on specific local requirements (e.g. Jiangsu - 50 days; Zhejiang - 45–55 days), usually 6~12 months to obtain license in practice (Clinical trial duration is not considered)	Normal registration review period after application submission: 90 days for review, usually 1.5–2.5 years to obtain license in practice (Clinical trial duration is not considered)
	Fast-track registration approval: provincial NMPA preliminary review within 20 days, NMPA review within 40 days, publicity period at least 10 days	

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CHINA Reimbursement

Public Insurance Coverage	Basic Medical Insurance (BMI) does not cover DTx products at this time, while some leading practices are observed, for example, Hainan province will provide over 1,000 children with autism spectrum disorder free access to DTx intervention projects.
Private Insurance Coverage	Private insurance coverage for DTx is encouraged in China, but existing plans have not cover DTx products yet, which requires long-term and continuous monitoring.
Employer-Sponsored Healthcare	Critical illness insurance may cover DTx products in the future for condition-specific products (i.e., cancer).
Consumer-Funded	Patient awareness of DTx is relatively low and requires further education; clinical validation of DTx effectiveness is also necessary.

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