How Digital Therapeutics (DTx) Products are Regulated in China?

Aaron Gu and Kevin Duan of Han Kun Law Offices discuss the regulation of DTx products in China, the question of registration, and best practices for collecting and processing data through DTx products.

Published on 15 December 2022

Aaron Gu

Han Kun Law Offices

Kevin Duan

Han Kun Law Offices

This article is also published by Chambers as an expert focus: https://chambers.com/legal-trends/how-digital-therapeutics-dtx-products-are-regulated-in-china

This article discusses the regulation of DTx products in China, the question of registration, and best practices for collecting and processing data through DTx products.

As a result of networks and big data becoming mature technologies, digital products have changed every aspect of modern life. Embracing virtualisation has been a major theme in the human experience, and healthcare is no exception. As internet hospitals and telemedicine have become commonplace, digital therapeutics (DTx), the digitisation of healthcare services, is now a trending topic in the industry.

"DTx product" currently does not have an official regulatory definition in China. Referring to the definition accepted by the European Data Protection Supervisor, DTx are evidence-based therapeutic interventions driven by software to prevent, manage or treat a medical disorder or disease. This article will discuss the development and current regulation of DTx products in China.

Registration pathway – Software as Medical Device

Although DTx products do not have pharmaceutical ingredients that enter the body, they influence or interact with human subjects (ie, patients) through information (eg, text, pictures, videos) and physical factors (eg, sound, light, electricity, magnetic fields, and combinations thereof), etc. In general, if the DTx product has any diagnostic, preventive, monitoring, therapeutic, or palliative functions, it falls into the definition of a medical device, which will require filing or registration

with the National Medical Products Administration (NMPA) or its local counterparts, depending on its classification. Currently, the major indications for DTx products are ophthalmic diseases, psychiatric diseases, endocrine system diseases and neurological diseases. Among the approved DTx products in China, products treating ophthalmic diseases account for the largest proportion, followed by products for cognitive function therapy. Most of these DTx products are registered as Class II medical devices.

> Developing and registering DTx products as medical devices allows more freedom in developing functions and making claims, but is subject to more stringent regulations and supervision, especially when it comes to promotion and advertisement.

At present, if deemed as medical devices, DTx products are most likely classified as medical device software (ie, Software as Medical Device – SaMD) under Classified Catalogues of Medical Devices. However, although there are five subcategories of medical device software, none of them may completely and perfectly suit DTx products. As there is no regulation or guidelines specifically promulgated for the registration of DTx products in China, the general requirements for medical device software apply, including the Guidelines for Technical Review of Medical Device Software Registration, the Guidelines for Technical Review of Mobile Medical Device Registration, and Guiding Principles for the Classification and Definition of AI-based Medical Software Products. DTx products can be registered as independent software or software components. The post-market updates of such software also require subsequent regulatory filing or approval depending on the outcome and impact of the update.

If a DTx product is developed, registered and operated as a medical device, it is subject to various medical device-related regulations in clinical trials, registration and filing, manufacturing, distribution and promotion, including but not limited to the Regulations on Supervision and Administration of Medical Devices, Administrative Measures for Registration and Filing of Medical Devices, Supervision and Administration Measures for Manufacturing of Medical Devices, Supervision and Administration Measures for Distribution of Medical Devices, Good Clinical Practices for Medical Devices (GCP), Good Manufacturing Practices for Medical Devices (GMP), Good Supply Practices for Medical Devices (GSP), and the special restriction for medical device promotions in the Advertising Law.

Whether to register DTx products as medical devices

Despite the fact that DTx products likely fall into the scope of medical devices, whether a specific DTx product should be developed and registered as a medical device depends largely on the business model/needs.

In general, developing and registering DTx products as medical devices allows more freedom in developing functions and making claims, but is subject to more stringent regulations and supervision, especially when it comes to promotion and advertisement. On the contrary, developing a DTx product as an ordinary product and not registering it as a medical device trades the freedom in functions and claims for the flexibility in distribution and less supervision or regulation.

Collection and processing data through DTx products

Collection and processing of patients' personal information are crucial parts of the development of DTx products, where results of the analysis will contribute to product iteration and upgrading. In particular, health records and other medical treatment data are often collected through DTx products and used in subsequent data processing activities related to algorithms training and automatic decision-making. However, the processing of such data is subject to relatively high scrutiny in accordance with the Personal Information Protection Law of the People's Republic of China (PIPL). Health records and medical treatment data are recognised as sensitive personal information, and the PIPL provides them with stricter protection requirements in comparison to other data with lower sensitivity. Before the processing of health records and the use of AI-based automatic decision-making technology, personal information handlers, ie, DTx product operators shall conduct a personal information protection impact assessment and keep relevant records of at least three years, notify the products users of relevant impact on their rights and interests, and obtain users' separate consent for such processing. Therefore, DTx product operators are advised to protect privacy by design and pay attention to PIPL compliance throughout the whole lifecycle of personal information processing.

> To address the compliance challenges arising from such CBDT supervision, it is a wise move for DTx product operators to sort out relevant data processing activities and get prepared early.

In addition, cross-border data transfer (CBDT) is also of great concern to DTx product operators, especially for multinational corporations. Among all CBDT scenarios regarding medical data, the export of personal information that reaches a certain quantity threshold and the export of data generated from medical devices that may be deemed important data are subject to a security assessment conducted by Chinese regulators in accordance with the Measures for Security Assessment of Cross-border Data Transfers. To address the compliance challenges arising from such CBDT supervision, it is a wise move for DTx product operators to sort out relevant data processing activities and get prepared early.

Favourable policies

Local governments across China have introduced policies to support the DTx industry, most of which target only the DTx products developed and registered as medical devices.

In October 2022, Hainan promulgated a special acceleration policy for the development of DTx products and planned to make Hainan a global DTx innovation hub; specific measures include building DTx clinical trial centers, developing guidance for DTx product classification and registration, establishing a special channel for Class II medical device DTx product registration, integrating DTx products and internet hospitals, and exploring price formation and healthcare insurance payment mechanisms. Hainan and Hangzhou are supporting local medical institutions to participate in piloting DTx products procurement, exploring the application of DTx products. Since the majority of DTx products potentially belong to the category of Class II medical devices, and shall be approved by the provincial Medical Product Administrations, registration acceleration policies may also apply. Hunan province provides especially simple and agile registration procedural requirements for Class II medical devices, so as a result, more DTx product medical devices have been approved in Hunan than in other provinces.

According to the National Institutes for Food and Drug Control (NIFDC), the NMPA is setting up the guiding principle for digital therapy classification; this would provide further support for the standardisation and success of DTx products in China.