DS NEWSLETTER savoir, faire
NEWSLETTER – LEGAL INFORMATIONS
PROPOSED BY DS AVOCATS

New Medical Device Regulations in China

ASIE

On March 18th, 2021, the State Council promulgated the Regulations on Supervision and Administration of Medical Devices, which will take effect on June 1st, 2021 (the "**2021 Regulations**"). Compared with the existing Regulations on Supervision and Administration of Medical Devices (lastly revised in 2017), the 2021 Regulations focuses more on innovation and development of the medical device industry, as well as quality and safety of medical device products.

We have briefly summarized the amendments brought by the 2021 Regulations as follows:

EASING OF OVERSEAS MARKETING REQUIREMENTS FOR INNOVATIVE MEDICAL DEVICES

Under the current medical device regulatory framework, before an applicant can apply for registration of an imported medical device in China, the imported product needs to be marketed and sold in the country where the applicant is registered or has its manufacturing address. Now, according to the 2021 Regulations, applicants will no longer need to submit proof of marketing in their home countries for innovative medical devices[1].

R&D PHASE

Simplified clinical evaluation requirements for medical devices and lowered threshold for marketing mature products. The 2021 Regulations introduces the concept of "exemption from clinical evaluation". If non-clinical evaluation suffices to prove that certain mature product[2] is safe and effective, clinical evaluation materials will not be required. For some of the mature products with lower risks, the exemption of clinical evaluation requirements can greatly reduce the burden of registration.

60-day implied permission for clinical trials. "A decision shall be made and the applicant for clinical trial shall be notified within 60 working days from the date of receipt of the application. Late notification is considered as consent." The 2021 Regulations introduces "implied consent for clinical trial approval" to reduce the time cost and unpredictability of clinical trial approval.

REGISTRATION PHASE

Implementation of medical device registration (record) holder system. Before the 2021 Regulations, the registrant of the medical device had to be the manufacturer (except for innovative medical device and in certain pilot areas). With the 2021 Regulations, the registrant can manufacture the medical devices by itself or entrust such manufacturing to qualified contract manufacturing organization (CMO).

Chinese domestic company designated by foreign medical device registration (record) holder. Besides the obligations already set under the current regulations (such as submission of registration or record-filing application materials), the 2021 Regulations further clarifies on the national law level that the domestic company (previously called the agent) designated by the foreign medical device registration (record) holder shall assist the holder to fulfill its obligations in below matters:

1 Article 2 of the Announcement of the National Medical Products Administration on Promulgating the Procedures for the Special Evaluation of Innovative Medical Devices (创新医疗器械特别审查程序) (promulgated by NMPA on November 2, 2018) provides a descriptive definition of "innovative medical device" as:
(1) the applicant concerned, by virtue of the activities of technological innovation led by itself, holds the invention patents of the core technologies of the product in China in accordance with the law, or acquires the invention patents or the right to use thereof in China by way of transfer in accordance with the law, and there has been no more than five years between the date of application for special evaluation of innovative medical devices and the date of announcement of patent authorization; or the application for the invention patent of the core technologies has been announced by the patent administrative department of the State Council, and a search report has been issued by the Patent Search Advisory Center of the National Intellectual Property Administration, which states that the product's core technology plan is novel and creative.
(2) the applicant has accomplished the early-stage research of the product, and has determined the basic shape of the product. In addition, the research process is real and controlled, and the research data are complete and traceable; and
(3) the main working principles or mechanisms of the product represent domestic initiatives, product performance or safety has been fundamentally improved as compared with similar products, and the product is technically-advanced internationally and has significant clinical practical value.

2 Mature product generally refers to products that (1) the working mechanism is clear, design is finalized and production process is mature, the medical device of the same variety on the market has been applied in clinical practice for years with no record of serious adverse event or the general purpose is not changed; or (2) such medical device can be proved to be safe and effective through non-clinical evaluation. See Article 24 of the 2021 Regulations.

(1) establish a quality management system suitable for the products and maintain its effective operation;
(2) formulate a post-marketing research and risk control plan and ensure its effective implementation;
(3) carry out monitoring and re-evaluation of adverse events in accordance with the law;
(4) establish and implement a product traceability and recall system; and
(5) other obligations provided for by the drug regulatory department under the State Council.

OPERATION PHASE

Incorporation of online sales of medical devices. The 2021 Regulations specifies that an entity engaging in online sales of medical devices shall be a company with Medical Device Registration License or with Medical Device Operation License. An operator of an e-commerce platform that provides services for online trading of medical devices shall conduct real-name registration for network operators of medical devices, examine their operation licensing, record-filing information and the registration and record-filing of the medical devices they operate and manage their business activities.

Revisions to advertisement examination for medical devices. Medical device advertising adopts a "pre-censorship plus daily supervision" scheme. To be specific, the content of advertisement shall be examined by the relevant authorities before the advertisement is made. The authorities will also supervise and inspect the advertisement of medical devices after such advertisement has been made. The 2021 Regulations basically follows the 2017 Regulations on advertising, with the only new incorporation or clarification that "advertisements shall be based on the instructions for medical devices as registered or filed with relevant drug supervision and management authorities".

USE PHASE

Recognition of LDTs. The 2021 Regulations recognizes the clinical use of laboratory developed test (the "LDT") in the test business, that is, for domestic vitro diagnostic reagents that are not yet available in the same species, medical institutions (including independent medical testing laboratories) can develop and use such on their own.

EUA. The 2021 Regulations provides that in case of any extremely serious public health emergency or any other emergency that severely threatens the health of the general public, the competent authorities shall put forward suggestions on urgent use of medical devices (the "EUA") according to the needs for prevention and control of the event. Upon demonstration and approval by the competent authorities, medical devices may be used in emergency within a certain scope and time limit.

Expanded Compassionate Use. The 2021 Regulations establishes for the first time the expanded compassionate use system for medical devices, emphasizing on free use for patients. Expanded compassionate use is to apply un-marketed drugs or medical devices to terminally ill patients outside of clinical trial subjects within a certain controlled range.

Recognition of urgent clinical need to import a small amount of medical devices. The 2021 Regulations for the first time allows medical institutions to import a small amount of Class II or Class III medical devices (not marketed in the territory) due to clinical urgency. Such imports should be approved by authorized authorities, and the use should be limited to designated medical institutions for specific medical purposes.

Enhanced supervision for used medical devices. Chinese laws and regulations have not yet provided a clear definition of "used medical devices". Yet we can see clear enhanced supervision for used medical devices, such as expansion of scope of used medical devices, prohibition of import of expired, invalid, obsolete and other used medical devices, as well as strengthened legal liability for non-compliance with the import, operation, use and transfer of expired, invalid and obsolete medical devices.

POST-MARKET PHASE

Per the 2021 Regulations, registration (record) holders shall take the overall responsibility for post-market phase, that is to carry out adverse event monitoring and re-evaluation and establish and implement a product traceability and recall system. The Manufacturers, business operators and users shall assist the registration (record) holders in such post-market phase.

LEGAL LIABILITIES

The 2021 Regulations has created new circumstances for penalties in Article 89 (the registration (record) holder failing to fulfill its obligations), Article 92 (operator of an e-commerce platform failing to perform the management obligations) and Article 98 (a domestic company designated by an overseas registration (record) holder of medical devices failing to perform the relevant obligations). It has also increased penalties for various types of violations and significant increase of the amount of fines (up to 30 times the amount of the value of the products). Meanwhile, the 2021 Regulations introduces a dual penalty system (company + personal penalties) for certain violations, such as transfer of expired, invalid, obsolete or unqualified medical devices in use. The 2021 Regulations also provides strengthened supervision for overseas medical devise registrant that when the overseas registrant or record-filing party of medical devices refuses to perform the decision on administrative penalty made in accordance with this 2021 Regulation, it shall be banned from importing medical devices within ten years.

Medical device regulations are quite comprehensive in China. This newsletter is our first commentary article on medical device regulations. DS will keep posting a series articles related to clinical evaluation and clinical trials, registration of medical device, business operation, medical data in the next few weeks. Please do not hesitate to follow us if you are interested in any further updates.

For any additional information please contact:

XU Sissi
Associate- Shanghai Office
XUsissi@dsavocats.com

Isabelle DOYON
Lawyer- Shanghai Office
doyon@dsavocats.com