China Insight

Highlights on New Regulations on Supervision and Administration of Medical Devices

Dear Sir or Madam,

On 18 March 2021, the State Council promulgated the *Regulations on Supervision and Administration of Medical Devices (Revised in 2021)*, which will take effect on 1 June 2021 (the "New Medical Device Regulations"), to replace the existing *Regulations on Supervision and Administration of Medical Devices*, effective on 4 May 2017. Please find below an overview of the New Medical Device Regulations.

Kind regards,
CMS, China

On 18 March 2021, the State Council promulgated the *Regulations on Supervision and Administration of Medical Devices (Revised in 2021)*, which will take effect on 1 June 2021 (the **"New Medical Device Regulations"**), to replace the existing *Regulations on Supervision and Administration of Medical Devices*, effective on 4 May 2017 (the **"Old Medical Device Regulations"**). The New Medical Device Regulations provide comprehensive provisions on encouraging medical device innovation and development, full life cycle quality supervision, clinical evaluation of medical devices, conditional approvals, emergency use authorization, registration and filing formalities, liabilities and punishments for violation, etc. In this regard, we intend to sort out some of the prominent highlights on the New Medical Device Regulations as follows:

1. Background

According to the press conference held by the Ministry of Justice, the State Market Supervision Administration and the National Medical Products Administration (the **"NMPA"**) on 22 March 2021, the medical device industry has developed rapidly in recent years, and the Old Medical Device Regulations can hardly match the needs of the current situation and development of the medical device industry. Therefore, it is necessary to make amendments to further promote industry innovation from the institutional level to meet the expectations for high-quality medical devices.

2. Whole Process Quality Management

Compared to the Old Medical Device Regulations, the New Medical Device Regulations set higher and more specific requirements on the establishment of quality management and control system of medical devices, including the followings:

a) Specify that the medical device registrant (**"Registrant"**) and record-filing applicant (**"Filing Applicant"**)[1] are required to strengthen the quality management of medical devices throughout the whole process of development, production, operation, distribution and use, including to establish a quality management

system suitable for medical devices and maintain effective operation, formulate and implement post-approval research and risk control plan, carry out adverse event monitoring and revaluation, establish and implement medical device traceability and recall mechanisms, etc.. As for overseas Registrant or Filing Applicant, it shall designate an enterprise registered in the PRC to assist it in fulfilling its life-cycle quality management obligations.

b) The competent medical product administrations (**"MPAs"**) shall check whether the Registrant or the Filing Applicant has sufficient quality management capabilities. The New Medical Device Regulations provide that regardless of domestic or imported medical devices, as long as the Centre for Medical Device Evaluation of the NMPA considers necessary, it has the power to check the quality management system of the Registrant which was only imposed on imported medical devices under the Old Medical Device Regulations.

c) The Registrant and the Filing Applicant are allowed to entrust third-party manufacturers that have established production quality specifications and quality management systems to produce medical devices. However, the Registrant or the Filing Applicant shall still be responsible for the quality of the medical devices produced by such third-party manufacturer, and shall conclude an engagement agreement with the said manufacturer to clarify respective responsibilities. Implanted medical devices with high risk are prohibited from commissioned production according to the New Medical Device Regulations.

d) Not only the medical device manufacturer (including commissioned manufacturer) but also the Registrant and the Filing Applicant are required to check the operation of their quality management system regularly, and submit self-inspection reports to the competent MPA if required.

3. Medical Device Registrant Regime

Although the New Medical Device Regulations do not adopt the term "Medical Device Market Authorization Holder", which was used in the draft for comment version of the New Medical Device Regulations back in 2018, the nature of the medical device registrant regime (the **"Medical Device Registrant Regime"**) is basically the same as the market authorization holder regime under the *Drug Administration Law of the PRC*, effective as from 1 December 2019.

The Medical Device Registrant Regime was firstly implemented in Shanghai Free Trade Zone as a pilot in 2017 and further expanded to more than 20 provinces, cities and regions by the end of 2019. In fact, the Medical Device Registrant Regime has been implemented in the said pilot areas for more than 3 years, local regulatory authorities (i.e. MPAs in Shanghai, Jiangsu, Zhejiang and Anhui, collectively known as *"Yangtze River Delta Region"*[2]) have accumulated cross-provincial practical experiences on the supervision and implementation of the Medical Device Registrant regime. The New Medical Device Regulations, as the highest level of legislation in the medical device industry, establish the legal basis for the implementation of the Medical Device Registrant Regime nationwide.

Before the implementation of the Medical Device Registrant Regime, the medical device registration certificate and the medical device production license must be held by the same entity (except for innovative medical devices), which indicates that the holder of the medical device registration certificate shall obtain the medical device production license before outsourcing production[3]. The Medical Device Registrant Regime separates the holder of the medical device registration certificate from the medical device production license which allows the Registrant not to put in a lot of investment in the construction of medical device production lines and factories at the early stages of its business but also offers more flexible commercial arrangements through outsourcing production, thereby driving investment in the medical device industry.

In practice, in order to reduce the management and production costs, some multinational medical device companies let their group holding companies hold all medical device certificates and filing records and entrust their affiliate companies or third-party manufacturers to produce relevant medical device products.

4. Encouragement of Medical Device Innovation

a) Import of Innovative Medical Device

According to Articles 10 and 11 of the Old Medical Device Regulations, the Registrant or the Filing Applicant is required to provide the local MPA with market authorization relevant documents evidencing that such medical device has been approved by the competent authority where such applicant is located and launched in the market of such applicant for sale. The New Medical Device Regulations provide a new solution for innovative medical devices that have not been launched on overseas markets but are intended to be sold in the PRC. Articles 15 and 16 of the New Medical Device Regulations allow the Registrant or Filing Applicant of imported innovative medical devices that have not been launched overseas may not to submit the foregoing

market authorization documents to the local MPA.

In terms of medical devices that carry out simultaneous international clinical trials, the Registrant or the Filing Applicant does not need to wait for the overseas registration or approval but can concurrently apply for registration or filing in the PRC and abroad. This new mechanism provides a more convenient way to import innovative medical devices to China. Going forward, where the overseas manufacturer of certain innovative medical device that is not launched on the market in its own country (region), can consider applying for the registration or filing of such innovative medical device in China first[4], and then legally enter the Chinese market in the name of imported medical devices by obtaining special treatment exemption from submitting marketing authorization documents.

b) Import of Medical Device for Urgent Clinical Need

Article 57 of the New Medical Device Regulations provides that medical institutions can import a small amount of Class II and Class III medical devices that are urgently needed for clinical use and have been launched abroad but without obtaining registration approvals from the NMPA or the competent MPA. The use of such imported medical devices should be limited to designated medical institutions for specific medical purposes. Before this, such import of medical device for urgent clinical need has been implemented in Hainan Boao Lecheng Pioneer Zone and Guangdong-Hong Kong-Macao Greater Bay Area. In theory, it should be viable for all medical institutions in the PRC to apply for such import after the implementation of the New Medical Device Regulations. For the time being, the provision is rather a principle and innovative clause. Whether it can be widely used in practice to benefit clinical patients remains to be seen.

c) Conditional Approval of Medical Device

According to paragraph 1 of Article 19 of the New Medical Device Regulations, the medical devices regulatory authorities can grant conditional approvals to medical devices that are used to treat rare diseases, severely life-threatening diseases without effective treatment, and in response to public health incidents and other urgently needed medical devices. Such conditions shall be indicated in the medical device registration certificate. However, Article 22 of the New Medical Device Regulations states that if the Registrant fails to achieve relevant conditions before the expiry (i.e. each medical device registration certificate is valid for 5 years) of the medical device registration certificate, such certificate shall not be renewed.

d) Emergency Use Authorization System

Paragraph 2 of Article 19 of the New Medical Device Regulations, for the first time, grants powers to the competent health department of the State Council to make recommendations for the emergency use of medical devices in the event of a particularly major public health emergency or other emergencies that seriously threaten public health. After certification and approval by the drug regulatory authority of the State Council, medical devices that have not been registered or filed within a certain scope and period of time can be used for emergency purposes.

e) Extended Clinical Trials

Article 29 of the New Medical Device Regulations establishes the system of compassionate use of medical devices in clinical trials which targets patients who suffer from diseases that threaten their lives but could not be effectively treated with existing approaches. After ethical review and obtaining the patient's informed consent, it can be used free of charge, and the safety data of such medical devices can be used for registration applications of such medical devices.

In fact, the *Administrative Measures for Drugs Sympathetically Used in Extended Clinical Trials (Draft for Comment)* were issued on 15 December 2017; however, we have not found many cases where such system is truly widely used in practice. Positively, the New Medical Device Regulations should further promote the compassionate use of medical devices in clinical trials in the future.

f) Laboratory Developed Tests of In Vitro Diagnostic Reagents

Article 53 of New Medical Device Regulations provides a legal basis for medical institutions (including third-party independent laboratories) to clinically use in-vitro diagnostic reagent (**"IVD"**) developed by such institution or laboratory that is not available on the Chinese market. The specific operating rules, including specific requirements or thresholds of the use of laboratory-developed IVD, will be further issued by the NMPA and the National Health Commission.

g) Online Sales of Medical Devices

According to Article 46 of the New Medical Device Regulations, except for the general management requirements on medical devices (i.e. the operator shall obtain the medical device registration or filing certificate, and it shall be a qualified Registrant or Filing Applicant, etc.), the Registrant or the Filing Applicant shall also need to inform the competent MPA of relevant information about the online sales of medical devices it is engaged in (except for Class I and Class II medical devices that are exempt from registration[5]). In addition, the e-commerce platform operator shall complete the authenticity registration and qualification examination of such Registrant or Filing Applicant who engages in online sales and manage such parties' online sale actions accordingly.

5. Reform of Review and Approval Procedures

a) Exemption of Clinical Evaluation for Certain Medical Devices

Article 24 of the New Medical Device Regulations provides that medical device registration or filing shall be subject to clinical evaluation; however, if one of the following conditions is met, clinical evaluation may be exempted:

(1) The working mechanism is clear, the design is finalized, the production process is mature, the medical devices of the same variety that have been launched on the market and have been used in clinical practice for many years, and there is no record of serious adverse events, and the conventional use is not changed;

(2) Other non-clinical evaluations can prove that the medical device is safe and effective.

The New Medical Device Regulations simplify the registration procedure of medical devices. The NMPA shall formulate guidelines for the clinical evaluation of medical devices. We believe the current *Technical Guidelines for Clinical Evaluation of Medical Devices*, effective on 16 February 2015 will be further amended to be consistent with the New Medical Device Regulations.

b) Clinical Trial Implied Permission Mechanism

Article 27 of the New Medical Device Regulations establishes the implied permission for clinical trials[6], according to which a decision on whether to approve registration application of certain medical device shall be given within 60 working days upon the acceptance of the application. Failure to make any decision within the foregoing period shall be deemed as approval of registration is granted to the Registrant. The purpose of this mechanism to reduce time costs and unpredictability of obtaining the approval of clinical trials. In fact, such implied permission mechanism for clinical trials of medical devices has been implemented back in March 2019 when the NMPA issued the *Announcement on Adjusting the Approval Procedures for Clinical Trials of Medical Devices*. According to the information available on the official website of the Centre for Medical Device Evaluation of the NMPA, there are medical device products that have been approved to carry out clinical trials through this clinical trial implied permission mechanism.

c) Shortened Approval Time

Registrants apply for the production license of Class II and Class III medical devices, the approval time limit of the competent MPA is shortened from 30 working days to 20 working days according to Article 32 of the New Medical Device Regulations.

6. More Severe Punishments for Violation

Generally speaking, the New Medical Device Regulations increase the penalties for various violations, for instance:

- If the Registrant or the Filing Applicant provides false information or use other deceptive ways to obtain relevant approvals, the competent authority has the power to revoke the approval granted to such Registrant or Filing Applicant, any illegal gains shall be confiscated and fines shall be imposed upon such Registrant or Filing Applicant;

- Where the value of illegal products is less than RMB 10,000, the maximum fine is increased from RMB100,000 to RMB150,000;

- Where the value of illegal products is more than RMB10,000, a fine of 15-30 times the value of illegal products shall be imposed;

- The New Medical Device Regulations also add the responsibilities of the person-in-charge of the Registrant

and the Filing Applicant, who may be imposed a fine up to 3 times of his/her income during the period of violation and may be permanently banned from engaging in medical device businesses;

- For those overseas medical device manufacturers who refuse to fulfill relevant administrative penalties, they shall be prohibited from importing any medical device to China for 10 years.

7. Summary

Overall, the New Medical Device Regulations bring innovation and development on supervision and management devices, integrate various regulations and policies with respect of medical devices, and enhance the collaboration between drugs and medical devices, In addition to the above, the New Medical Device Regulations also have other provisions including encouraging the research, development and innovation of medical devices and ensuring the safety of medical devices, etc. Also, a unique identification system for medical devices will be implemented to achieve traceability of medical devices. More detailed implementation rules need to be further elaborated in the near future.

[1] According to Article 13 of the New Medical Device Regulations, for Class I medical devices, the record-filing management shall be implemented, while for Class II and Class III medical devices, the registration management shall be implemented. Therefore, the party who applies for the registration of Class II or Class III medical device is considered as a medical device registrant, whilst the party who applies for the filing of Class I medical device is considered as a record-filing applicant.

[2] The collaboration of the Yangtze River Delta Region on the pilot regime of medical device holder, please refer to our newsletter here: https://cms.law/en/chn/publication/outlook-for-the-pilot-regime-of-medical-device-market-authorization-holder-in-yangtze-river-delta-region

[3] Article 28 of the Old Medical Device Regulations.

[4] In our view, it may be subject to other requirements or supporting documents, detailed rules need to be further clarified in the future.

[5] According to paragraph 2 of Article 41 of the New Medical Device Regulations, subject to the regulations of the NMPA, Class II medical devices which safety and effectiveness are not affected by the circulation can be exempted from registration.

[6] According to Article 27 of the New Medical Device Regulations, the clinical trials of Class III medical devices that have a higher risk to humans shall be approved by the competent MPA. This is the pre-approval applies to Class III medical devices. Normally, for other medical devices with lower risks, the filing of clinical trial with the local MPA before it starts is enough.

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