Major Changes in the 2021 amended Regulation of Supervision and Administration of Medical Devices

By
David Pan | Xun Yang | Nigel Zhu | Susan Deng | Vera Zhao

In October 2017, the General Office of the CPC Central Committee and the General Office of the State Council issued the *Opinions on Deepening the Reform of Review and Approval System to Encourage Innovation of Drugs and Medical Devices*, providing specific opinions on deepening the reform of the review and approval system for medical devices and other work. From 2019 to 2020, the epidemic ushered in the medicine and health sector, *Law on Administration of Vaccination, Law on Administration of Drugs, and Provisions for Drugs Registration* had all been amended in the field of immunization and regulation and supervision of drugs. Following the reformation of regulation and supervision of drugs, the amended *Regulation of Supervision and Administration of Medical Devices* ("**2021 Regulation**") had been published on March 20th 2021, and would be enacted on June 1st 2021.

As the key regulation in administration and supervision of Medical Devices, the Regulation of Supervision and Administration of Medical Devices, had been amended for 4 times from the first enactment in 2000. 2021 Regulation had been amended combining opinions from many departments, governments and industry associations, enterprises discussion meetings and professional discussion meetings, field researches from Sichuan, Hubei, Shanghai, and Jiangsu, reflecting PRC's attitude towards the revolution of administration of medical and health realm, which is, reinforce the administration through all steps, strengthen punishment, clarify scope of liabilities of different parties.

This article will analyze the amendment concerning the MAH system of medical devices, LDT, imported innovative medical devices, accelerated approval process, legal liabilities.

如果您需要本出版物的中文本，
请联系:

Publication@llinkslaw. com

For more Llinks publications,
please contact:

Publication@llinkslaw.com

I. Medical Device Registrant System

The official draft of the 2021 Regulation implements the medical device registrant system, and the registration certificate holder/record-filing parties are called the "registrant" and "filer" (hereinafter collectively referred to as "registrant"). Although the concept of "marketing authorization holder" in the previous exposure draft is not directly used eventually, the definition of registrant includes both conventional medical device companies and medical device research and development institutions. This is similar to the definition of drug marketing authorization holders in the "Drug Administration Law".

The medical device registrant system aims to untie the registration certificate and the production license, so that the registrant can make more flexible commercial arrangements through entrusted production, and promote the further refined division of labor in the medical device industry. The medical device registrant system began to be piloted from the Shanghai Free Trade Zone at the end of 2017. As of July 7, 2020, the State Council issued the "Notice on Doing a Good Job in the Duplication and Promotion of the Sixth Batch of Pilot Free Trade Zone Reforms", 22 provinces, cities and regions have implemented pilot work on the medical device registrant system.

The 2021 Regulation further clarify that implantable medical devices with high risks shall not be commissioned for production. At the same time, referring to the provisions of the "Drug Administration Law" on overseas marketing authorization holders, the process of registration/filing is clarified for overseas institutions.

II. Chinese Version of LDT

Article 53 of the 2021 Regulation has made a final breakthrough in the supervision of in vitro diagnostic products and puts an end to the controversy over self-built clinical testing projects in the past few years. Article 53 stipulates that “for in-vitro diagnostic reagents that do not have the same product on the market in China, qualified medical institutions may develop them on their own according to the clinical needs, and use them internally under the guidance of medical practitioners. Specific management measures shall be formulated by the drug regulatory department of the State Council in conjunction with the competent health department of the State Council".

Before the 2021 Regulation come into effect, medical institutions must meet four conditions to carry out clinical testing activities, including "in vitro diagnostic products (including reagents) must be registered in accordance with the law." Although the follow-up operation rules have yet to be promulgated, Article 53 provides a legal basis for self-developed in vitro diagnostic reagents by medical institutions, which creates a breakthrough for self-built in vitro diagnostic projects by medical institutions, and marks the emergence of the "Chinese version of LDT".

The term LDT (Lab Developed Test) originated from the United States, and refers to the laboratory's internal research and development, verification and use, using biochemistry, cytogenetics, and molecular biology

test methods to analyze DNA, RNA, mitochondrial, proteome and metabolome diseases and other biomarkers for diagnosis, in vitro diagnostic projects. LDT can only be used in laboratories. Purchased or self-made reagents can be used for clinical use in the specific laboratory only and cannot be sold to other users. LDT meets the needs of personalized clinical diagnosis, especially when certain test items or reagents are not commercially available, LDT can meet clinical needs in a low-cost and high-efficiency way.

The attitude of Chinese regulators towards LDT has been “reassessed” several times. The 2000 version of the "Regulation on the Supervision and Administration of Medical Devices" allowed medical institutions to develop medical devices based on clinical needs and use them in their units, but they still need to follow certain approval procedures. Class II medical devices developed by medical institutions should be reported to the drug regulatory authority of the people's government at or above the provincial level for review and approval; this clause has been deleted and never reappeared in subsequent revised versions; in 2016, the National Health and Family Planning Commission (withdrawn) issued a document encouraging Medical institutions to conduct timely demonstrations of clinical test items that are not listed in the "Clinical Test Items Catalog of Medical Institutions" but have clinical significance to meet clinical needs, but do not specify specific implementation methods; in 2018, the National Health Commission publicly stated on its official website that laboratory self-built methods and self-prepared reagents are indeed in demand in clinical work, and it is necessary to promote the introduction of LDT clauses in the 2021 Regulation.

In this way, the emergence of Article 53 of the 2021 Regulation is well-received, and this article provides a formal legal basis for laboratory self-built in vitro diagnostic projects. However, there are still ambiguities in this clause, as to what constitutes a "qualified medical institution"; who will determine if "there is no domestic product of the same kind on the market", etc., which still needs to be clarified by subsequent regulation.

III. Imported Innovative Medical Device

The 2021 Regulation break through the 2017 version of the "Regulations on the Supervision and Administration of Medical Devices" and the current "Measures for the Administration of Medical Device Registration", adding a special review mechanism for imported innovative medical devices. According to Article 15 and Article 16 of the 2021 Regulation, for innovative medical devices (including Class I, Class II, and Class III) that have not been listed overseas, it is not necessary to submit the certification documents. This is a major benefit for medical device products which are going through international multi-center clinical trials. In the future, there is no need to wait for overseas approval for listing, applications can simultaneously be made in China.

According to the “2020 Medical Device Registration Work Report” issued by the State Food and Drug Administration on February 5 this year, since the launch of the fast-track approval channel for innovative medical devices in 2014, as of the end of 2020, a total of 99 innovative medical devices have been approved. Among them, domestic Innovative medical devices involve 78 companies in 14 provinces, and the imported

innovative medical devices involve 4 companies in 2 countries. The provisions of the 2021 Regulation will undoubtedly further increase the number of approved imported innovative medical devices.

IV. Approval process acceleration

The long process of approval of drugs and medical devices in PRC leads to overstock of application, difficulty for urgently needed drugs and devices to enter into the market. Upon the worldwide epidemic, people pay much more attention to urgent approval of drugs, and medical devices in special circumstances. Law on Administration of Drugs amended in 2020 accelerated the approval process of clinically urgently needed drugs and orphan drugs in a newly promulgated drug accelerated approval process. The 2021 Regulation also provides the conditional approval process and emergency approval process of medical devices.

The 2021 Regulation provides two major accelerated approval methods, including (1) conditional approval for rare diseases, diseases which are life-threatening without effective treatment and for urgent public health events, (2) emergency use by the general office in severe urgent public health events or when other emergency which jeopardizes public health happens.

1. Conditional Approval

Opinions on Deepening the Reform of Review and Approval System to Encourage Innovation of Drugs and Medical Devices hold that, it is necessary to satisfy the needs of clinical treatment of life threatening diseases, accelerate the approval process of relevant medical devices. Provisions for Drugs Registration had stipulated acceleration approval process of clinically urgently needed drugs, including process of breakthrough of treatment drugs, drugs of compassionate use, conditional approval and priority approval process.

National Medical Products Administration ("**NMPA**") promulgated *Special Examination Procedure for Innovated Medical Devices (Trial) in 2014* (which had been amended as *Special Approval Procedure for Innovated Medical Device*s in 2018). Innovated medical devices whose technology solutions are novel, creative, advanced and remarkably clinically valuable, are entitled to accelerate the approval procedure in accordance with the said procedure. In 2019, NMPA further promulgated *Guide Principle of Conditional Market Approval of Medical Devices*, requiring that Medical devices are approved with condition if it is for life-threatening disease without effective treatment, and pre-market statistics had demonstrated the curative effect thereof and reasonably expected the clinical value thereof.
Said regulations allowed accelerated of approval procedure for innovated medical devices which fulfills the clinical demand to some extent.

However, the conditional approval process of medical device has not been included in the *Regulation of Supervision and Administration of Medical Devices* until this 2021 Regulation. Under article 19 of 2021 Regulation, medical devices for rare disease, disease which are life-threatening without effective treatment and urgent public health event are allowed to be approved conditionally, and should record

relevant event in the registration certificate of medical devices. Under article 22 of 2021 Regulation, unless completing recording relevant event within' a specific period, the registration certificate of medical devices under conditional approval will not be allowed to extend registration by Medical Products Administration.

In Law on Administration of Drugs, only medical devices for rare disease, disease which are life-threatening without effective treatment and urgent public health event are allowed to be approved conditionally. Further, 2021 Regulation allows medical devices for rare disease for conditional approval, encouraging the research and development of relevant rare diseases conducted by medical device enterprises.

2. Emergency Approval

In 2009, NMPA (the former CFDA) promulgated *Emergency Approval Procedure of Medical Devices*, allowing relevant administration for emergency approval for medical devices which are for urgent public health event, without similar devices in domestic, or the similar devices existed cannot fulfill the need for emergency. After the outbreak of Covid-19 in 2020, central and local medical products administration had activated emergency approval of medical mask, medical protective suits, nucleic acid testing kits, sequencing facility and other medical devices, alleviate the shortage of such anti-Covid medical devices effectively.

2021 Regulation clearly stipulates that when serious urgent public health event, or any other emergency which jeopardizes public health happens, medical devices can be approved to use in a limited realm and period, under the proposal of Ministry of Health of PRC and the reasoning and consent of NMPA. Compared with Emergency Approval Procedure of Medical Devices that applicant must file information and statement to activate the procedure, 2021 Regulation holds that Ministry of Health of PRC will be the party to propose, which is compliance with the reality, that it is the Ministry of Health of PRC who is in charge of important urgent health event, not the individual, and helps to activate the emergency approval.

2021 Regulation has principal stipulation of emergency approval, and its realm. In *Means of Supervision and Administration of Medical Devices (draft amendment)*, the emergency approval and conditional approval processes are stipulated in detail. Moreover, the draft also published the innovated products registration and priority registration. If the draft were confirmed in laws, such amendments will improve the acceleration approval procedure of medical devices, and satisfy the clinical treatment demand.

V. Impose high legal liability

2021 Regulation impose harsher punishment following the "4 harshest" rule.

Firstly, 2021 Regulation comprehensively enhance the punishment level. 2021 Regulation increase the penalty. Unauthorized manufacture and operation of medical devices in Class ii and iii would face penalty equal to 20 times the price of medical devices or no more than 100,000 RMB, now the penalty shall be 30 times the price of medical devices in 2021 Regulation. In addition, enterprise which constituted material violation of law will be exempted from market, certificate thereof will be revoked, relevant business and certificate thereof will be forbidden in a specific time.

Moreover, the liability will be attributed to individuals under 2021 Regulation. The legal representatives, principals, supervisors and other relevant employees are likely to be punished, in which they will be fined, restricted from relevant business for a certain period, and such unlawful income will be confiscated.

Finally, 2021 Regulation enhance the all-step supervision in research, manufacture, business and use of medical devices. On one hand, the article 20 emphasized the duty of supervision, monitoring and risk management, complying with central government's theory of registrant of medical devices taking responsibility of all step period of such devices. On the other hand, PRC will build a system of professional inspector, to supervise the activities of pre-market and post-market.

VI. Conclusion

The amendments in 2021 Regulation comply with the purpose of revolution of medical devices, improving the approval process, relieving the burden of medical devices enterprises, satisfying the clinical demands, and also enhancing the full life-cycle supervision of medical devices, establishing the MAH system of medical devices, clarify the duties and rights of different commercial parties in the market.

Compared with drugs, the medical devices are more diverse and its supervision is more complicated. From ordinary medical masks to AI diagnosis-assistant software, medical devices are getting more and more crucial in clinical treatment and diagnosis. The promulgation and implementation of 2021 Regulation is just the beginning, but not the end, remaining more issues on registration, manufacture, operation of medical devices to be clarified.

If you would like to know more information about the subjects covered in this publication, please contact:

David Pan
+86 21 3135 8701
david.pan@llinkslaw.com

Xun Yang
+86 21 3135 8799
xun.yang@llinkslaw.com

SHANGHAI	BEIJING	SHENZHEN
19F, ONE LUJIAZUI 68 Yin Cheng Road Middle Shanghai 200120 P.R.China T: +86 21 3135 8666 F: +86 21 3135 8600	4F, China Resources Building 8 Jianguomenbei Avenue Beijing 100005 P.R.China T: +86 10 8519 2266 F: +86 10 8519 2929	18F, China Resources Tower 2666 Keyuan South Road, Nanshan District Shenzhen 518063 P.R.China T: +86 755 3391 7666 F: +86 755 3391 7668

HONG KONG	LONDON
Room 3201, 32/F, Alexandra House 18 Chater Road Central, Hong Kong T: +852 2592 1978 F: +852 2868 0883	1/F, 3 More London Riverside London SE1 2RE United Kingdom T: +44 (0)20 3283 4337 D: +44 (0)20 3283 4323

www.llinkslaw.com

Wechat: LlinksLaw

WE LINK LOCAL LEGAL INTELLIGENCE WITH THE WORLD