Temporary Import of Clinically Urgent Use Medical Devices

On 19 July 2024, the National Medical Products Administration ("**NMPA**") and the National Health Commission ("**NHC**") jointly issued the *Announcement on the Temporary Import and Use of Clinically Urgent Medical Devices for Medical Institutions* ("**Announcement**"), with immediate effect.

The Announcement has been issued to implement Article 57 of the *Regulation on the Administration of Medical Device* (effective as of 1 June 2021) which enables the NMPA or authorized provincial governments to grant approval for the import of Class II and Class III medical devices, that are urgently needed for clinical purposes, even if such medical devices have not been registered yet in China.

In fact, as early as in 2018, designated medical institutions in Hainan Hope City were allowed to temporarily import clinically urgent use medical devices where there was no medical device of the same kind approved for registration in the PRC, after obtaining approval by Hainan provincial level government[1]. Further, in 2020, designated medical institutions in nine cities within Guangdong-Hong Kong-Macao Greater Bay Area were allowed to import those clinically urgent use medical devices meeting certain criteria after obtaining approval by Guangdong provincial-level government[2].

Therefore, the latest version of Regulations on Supervision and Administration of Medical Devices as well as the above Announcement show the intention to transform previous local pilot practice into a nation-wide regulation.

After some months of observation on this development of this Announcement, we noticed that on 14 September 2024, Beijing Drug Administrative Authority, together with three other local departments, issued the Beijing Municipal Implementation Plan for Facilitating the Temporary Import of Clinically Urgent Use Medical Devices (Trial). As far as we know, currently, there are no other local policies in this regard except for the ones in Hainan, Guangdong and Beijing as abovementioned.

1. Application Scope

All imported Class II and Class III medical devices shall be registered in China before they are placed on the Chinese market.

[1] According to the Decision on the Suspension of Relevant Provisions of the Regulations on the Supervision and Administration of Medical Devices in the Hainan Hope City International Medical Tourism Pilot Zone by the State Council (《国务院关于在海南博鳌乐城国际医疗旅游先行区暂停实施《医疗器械监督管理条例》有关规定的决定》).
[2] According to the Work Plan for Innovative Development of Drug and Medical Device Regulation in the Guangdong-Hong Kong-Macao Greater Bay Area (《粤港澳大湾区药品医疗器械监管创新发展工作方案》).

However, Article 57 of the *Regulation on the Administration of Medical Device* provides for a temporary import exception for clinically urgent use medical devices. According to the Announcement, this exception only applies to the medical devices that meet the following requirements:

- the medical device is under an "urgent clinical need" of patients;
- the medical device has been placed on foreign market;
- there is no "substitute of the same kind" in China;
- the medical device falls under Class II or Class III according to the Medical Device Catalogue; and
- the medical device is not a Large Medical Equipment (such as a PET/MR) subject to configuration license management.

Among the above-mentioned requirements, the term "urgent clinical need" shall refer to the clinical need to combat a seriously life-threatening disease when there is no effective treatment or prevention available in the country. The term "substitute of the same kind" is defined as to the products registered in China that are basically equivalent in terms of basic principle, structural composition, main raw materials, production process, performance indicators, safety evaluation, compliance with national/industry standards, intended use/scope of application, etc.

The Announcement sets forth conditions with respect to therapeutic capacity, personnel, quality management system and adverse event monitoring system of the medical institutions who apply for the temporary import of medical device. For example, only medical institutions which shall be leading Grade 3A hospitals in the concerned clinical subject with proper experience and capacity can provide healthcare service to difficult and critical diseases. The qualified medical institutions shall be equipped with experienced professionals, such as members of the Chinese Academy of Sciences or the Chinese Academy of Engineering, who are able to use the medical devices correctly and properly.

2. Responsible Parties

According to the Announcement, qualified hospitals that apply for the temporary import of medical device shall be responsible for the use of such medical devices.

To make clear each party's obligations and responsibilities, including without limitation those related to compensation and liability, the Announcement requires that hospital, operating enterprise, and manufacturer/agent shall sign a quality agreement or an agency agreement.

3. Procedure

To apply for the temporary import of medical device, qualified hospitals shall provide evaluation statements assessing the necessity and feasibility according to the standards outlined in the Announcement. Besides, they are required to prepare a comprehensive set of documents, including the application form, detailed profiles of the medical devices, relevant certificates and agreements from all parties involved, as well as undertaking letters from both the hospital and the operating enterprise.

The NMPA will initiate the examination process to ascertain that all requisite conditions have been satisfied. The NMPA will verify whether the medical device is approved for sale in foreign markets and determine whether a comparable substitute is available within China. Regarding hospital's qualifications, urgency of clinical need, and projected quantity of medical device required, the NMPA may convene an expert panel consisting of no fewer than seven specialists. Following the panel's written assessment, the NMPA shall render a decision on the application within three working days.

When the quantity of the medical device is insufficient or there is a demand for the device from other patients, an additional approval process must be undertaken with the NMPA.

4. Requirements after Approval

The Announcement aims to ensure the safety and efficacy of such temporarily imported medical devices throughout their entire life cycle. After the approval of clinically urgent use medical devices, and prior to the use of any medical device for such clinically urgent use, the hospital is mandated to secure approval from its ethical review committee, as well as to obtain informed consent from the patient or the patient's legal guardian. In the event of a serious adverse event or a quality or safety hazard directly associated with the medical device, the hospital is required to immediately discontinue its use.

Furthermore, the said hospital shall make annual report of clinical data pertaining to the safety and effectiveness of the medical device to the provincial drug administrative authorities.

In addition, the medical records of the affected patient must be retained by the hospital for a minimum period of 30 years.

5. Comments

The Announcement will be conductive for the implementation of temporary importation of clinically urgent use medical devices in the PRC. It should also be noted that the real-world data generated out of such temporary importation and use of medical devices in accordance with relevant management systems and clinical technical specifications, and supported by rigorous data collection and systematic processing, scientific statistical analysis, and multidimensional result evaluation, can be used to support product registration[3].

The Announcement, along with the latest version of the Regulations on Supervision and Administration of Medical Devices, in some way offers more motivation for foreign medical device enterprises to enter into the Chinese market and also encourage more Chinese companies to attract foreign medical devices into China. With the enlarged geographic scope of this policy to a nationwide level, this may to some extent increase the interest of foreign medical devices enterprises to introduce their products into China. On the other hand, the introduction of this Announcement may also have a negative impact on the existing policies in Hainan and Guangdong area, as foreign medical devices are no longer bound to go through these two channels for the clinically urgent use medical device as a preliminary step into Chinese market, when other provinces are authorized to grant approval for the import of such clinically urgent use medical devices.

Local regulation, such as the Beijing Municipal Implementation Plan for Facilitating the Temporary Import of Clinically Urgent Use Medical Devices as mentioned above, serves as a supporting policy for such momentum. Anticipately more local supporting regulations and policies will be put into place in the future.

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[3] According to the Announcement of the National Medical Products Administration on Issuing the Guiding Technical Principles for the Application of Real-world Data in Clinical Evaluation of Medical Devices (for Trial Implementation) (《用于产生真实世界证据的真实世界数据指导原则（试行）》).

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