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Regulatory Highlights in China: Analysis of Key Changes in 2021

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1. Introduction

China has introduced a number of important regulatory updates impacting manufacturers and importers in 2021. This white paper will examine the key legislative changes to help companies understand and manage their legal obligations to comply with product requirements.

We look at developments in the areas of:

Medical devices

- Introduction of the Management System of Medical Devices in China
- The newly revised Supervision and Administration of Medical Devices 2021

Climate change

- China's action plans to reduce carbon dioxide emissions and achieve carbon peak and carbon neutrality
- HFCs management and control under the Kigali Amendment

Chemicals management

- Legislative developments in the management of chemicals, including updates to some catalogues of chemicals

2. Medical Devices

2.1. Introduction of the Management System of Medical Devices in China

The authority for the administrative supervision and management of medical devices in China is the China Food and Drug Administration (CFDA). Medical devices refer to instruments, equipment, appliances, in-vitro diagnostic reagents and calibrators, materials, and other similar or related items that directly or indirectly act on the human body, including any computer software. These mainly work through physical and other methods, not through pharmacology, immunology or metabolism, or if these methods are involved they only play an auxiliary role.

Intended purposes include:

1. Diagnosis, prevention, monitoring, treatment or alleviation of diseases
2. Diagnosis, monitoring, treatment, mitigation or functional compensation of injury
3. Inspection, substitution, adjustment or support of physiological structure or physiological process
4. Life support or maintenance
5. Pregnancy control
6. Disinfection or sterilization of medical devices
7. Providing information for medical or diagnostic purposes by examining samples from the human body

China's classified management of medical devices is divided into the first category, the second category and the third category. For specific classification methods, refer to "Rules on Classification of Medical Devices" and the "Medical Device Classification Catalogue". CCC compulsory certification is not required for the sale of medical devices in the Chinese market.

The medical device registration review process requires 4 steps:

1. Submit the registration materials to the medical device administrative
2. Technical review
3. Administrative examination and approval
4. Delivery of the decision

2.2. Supervision and Administration of Medical Devices, 2021

The basic law governing the medical devices industry, the Supervision and Administration of Medical Devices, was first promulgated in 2000. It has been revised twice, first in 2014 and then in 2017. The newly revised Supervision and Administration of Medical Devices entered into force on 1 June, 2021.

Compared with the Supervision and Administration of Medical Devices (2017 Revision), the 2021 version pays more attention to the promotion of an innovative development of the medical device industry, while focusing on ensuring the quality and safety of medical device products. The five most important changes brought in by the 2021 version are:

1. The establishment of a medical device registrant and filing applicant system
2. The optimization of the approval and filing procedures
3. The encouragement of medical device innovation
4. The clarification of the regulatory requirements for contentions issues such as online sales of medical devices
5. The increase of penalties and punishment for illegal actions under the regulation

The 2021 version formally created a basic system that applies to both the medical device registrant and filing system across the country. In accordance with Article 13 and Article 103 of the 2021 regulations, medical device registrants and filing applicants refer to enterprises or research institutions that have obtained medical device registration certificates or handled medical device records. Medical device registrants and filing applicants are responsible for the safety and effectiveness of medical devices in the entire process of development, production, operation and use.

The 2021 regulations specify in the definition of medical device registrant and filing applicant that a "research institution" can become a medical device registrant or filing applicant after obtaining a registration certificate or record. According to this, the 2021 regulations laid the foundation for the feasibility of scientific research institutions and enterprises that do not have manufacturing capacity to become medical device registrants and filing applicants.

In the **research and development stage**, the registrant and the filing applicant are responsible for the safety and effectiveness of the medical devices developed in accordance with the law. The registrant and filing applicant should also formulate a post-marketing research and risk control plan and ensure effective implementation.

In the **manufacturing stage**, the 2021 regulation clarifies that registrants, filing applicants and entrusted manufacturing enterprises shall establish and improve a quality management system suitable for the medical devices manufacture in accordance with the medical device production quality management regulations. They should ensure the medical devices meet the mandatory standards and the registered or filed product technical requirements when leaving the factory, and regularly conduct self-checks on the operation of the quality

management system and submit self-examination reports in accordance with the regulations of the drug regulatory department of the State Council.

In the **operation and use stage**, the 2021 regulations set out that all medical device businesses should have a quality management system and a quality management organization or personnel. The registrant and filing applicant should also carry out adverse event monitoring and re-evaluation in accordance with the law, and establish a product traceability and recall system. If the adverse event monitoring and evaluation indicates that the medical device may have defects, the registrant and filing applicant must take the initiative to carry out the re-evaluation of the medical device that has been marketed.

According to Article 34.2 of the 2021 regulations, the medical device registrant and filing applicant shall be responsible for the quality of the medical device entrusted to produce, ensure that it is produced in accordance with the legal requirements, and shall sign an entrustment agreement with the entrusted production manufacturer. The entrusted production manufacturer shall manufacture in accordance with laws and regulations, medical device production quality management rules, mandatory standards, product technical requirements and entrusted agreements, and be responsible for the production activities, and accept the supervision of the entrusting party.

In accordance with Article 34.3, high-risk implantable medical devices shall not be produced by an entrusted manufacturer.

According to Article 20 of the 2021 regulation, domestic corporate legal persons designated by overseas medical device registrants and filing applicants shall assist them in fulfilling their obligations as registrants and filing applicants. Although the regulation does not explicitly require domestic enterprise legal persons designated by overseas medical device registrants and filing applicants to bear the statutory obligations and joint liabilities of overseas registrants and filing applicants, in accordance with Article 98, they also need to bear legal responsibilities such as ordering corrections, warnings, fines, and business bans.

The 2021 regulations allow applicants for category 2 and category 3 medical device product registration to submit product self-inspection reports.

Although both the 2017 version and the 2021 version of Supervision and Administration of Medical Devices contain exemption systems in the clinical evaluation stage, there are significant differences between the two exemption systems.

The 2017 version adopted a system of exemption from clinical trials, but medical device products which were exempted from clinical trials still needed to undergo clinical evaluation. According to the 2017 version of the regulations, the first category of medical device product registration does not require clinical trials, while the second and third category of medical device product registrations can be exempted from clinical trials if certain conditions are met.

The 2021 version directly stipulates the circumstances which would allow an exemption from the clinical evaluation system. According to Article 24, the registration and filing of medical device products shall be subject to clinical evaluation. However, if one of the following conditions is met, clinical evaluation can be exempted:

1. The working mechanism is clear, the design is completed, and the production process is mature. Medical devices of the same type that have been marketed for many years have been clinically used without serious adverse event records, and do not change their routine use.
2. Other medical devices that can be proved to be safe and effective through non-clinical evaluation.

Compared with the 2017 version of the regulations, the 2021 version adopts a more thorough exemption system, and qualified medical device products can not only be exempted from clinical trials, but even clinical evaluation. Accordingly, the 2021 version reduces the burden of medical device product registration and filing applicants in some circumstances.

Article 57 of the 2021 regulations stipulates that medical devices urgently needed to be imported in a small volume for clinical purposes may be imported upon approval of the CFDA or the governments of provinces, autonomous regions, and municipalities authorized by the State Council. Imported medical devices should be used for specific medical purposes in designated medical institutions.

With the promulgation of the 2021 regulations, the regional pilot program has been incorporated in administrative regulations, applicable nationwide.

Online retail of medicines and medical devices is currently a contentious issue in the circulation of the pharmaceutical field. Earlier than it had with medicines, China had regulated the online sales of medical devices. In 2017, the former State Food and Drug Administration promulgated the Administrative Measures on Online Sale of Medical Devices, which stipulates the qualification requirements, filing requirements and permitted online sales activities for companies engaged in online medical device sales, and third-party platform providers of medical device online transactions. The 2021 regulations clarify the regulatory requirements for online sales of medical devices.

In accordance with Article 46.1 of the 2021 regulations, those engaged in online retail of medical devices shall be medical device registrants, filing applicants or medical device operating companies. Operators engaged in online retail of medical devices shall submit the relevant information to the department responsible for drug supervision and management of the government at the municipal level, except for those dealing in Class I medical devices and Class II medical devices exempted from registration.

Regarding the obligations of online trading platform operators, in accordance with Article 46.2 of the 2021 regulations, the platform operators that provide services for online medical device transactions shall register their medical device operators with real names, review their business licenses and filing record of medical device products, and manage their business activities. If an e-commerce platform operator discovers that the medical device business operator has violated the provisions of this regulation, the platform operator shall stop and immediately report to the government where the medical device operator is located. If a serious violation is found, the platform operator must immediately stop providing these online trading platform services.

It is worth noting that there are some inconsistencies between the 2021 regulations and the Administrative Measures on Online Sale of Medical Devices. Since the Administrative Measures on Online Sale of Medical Devices was promulgated earlier, and the 2021 regulation is a higher-level law, the possibility of subsequent revisions of the Administrative Measures on Online Sale of Medical Devices in accordance with the provisions of the 2021

regulations cannot be ruled out. Compliance & Risks will continue to monitor any possible changes in the regulatory regime around the online sale of medical devices.

3. Climate Change and Carbon Emissions

3.1. Carbon Peak and Carbon Neutrality

China's State Council has published an action plan to reduce carbon dioxide emissions by 2030. The plan was released ahead of the 2021 United Nations Climate Change Conference (COP26). The State Council also published an opinion on the complete, accurate and comprehensive implementation of the new development concept in carbon peak and carbon neutrality.

China has developed a plan to achieve the following:

By 2025, an economic system of green and low-carbon circular development will be established, and the energy efficiency of key industries will be greatly improved. Energy consumption per unit of GDP will be reduced by 13.5% compared to 2020; carbon dioxide emissions per unit of GDP will be reduced by 18% compared to 2020; the proportion of non-fossil energy based usage will reach about 20%; the forest coverage rate will reach 24.1%; and the forest stock will reach 180 billion cubic meters, laying a solid foundation for achieving carbon peak and carbon neutrality.

By 2030, significant results will be achieved in the overall green transformation of economic and social development, and the energy efficiency of key energy-consuming industries will reach the level of advanced economies. Energy consumption per unit of GDP will have dropped significantly; carbon dioxide emissions per unit of GDP will have dropped by more than 65% compared to 2005; non-fossil energy consumption will have reached about 25%; the total installed capacity of wind and solar power will reach more than 1.2 billion kilowatts; the proportion of forest coverage will be about 25%; and the forest stock volume will have reached 190 billion cubic meters. Carbon dioxide emissions will have already reached the peak and will be undergoing a steady decline.

By 2060, a green and low-carbon circular economic system and a clean, low-carbon, safe and efficient energy system will be fully established. The energy utilization efficiency will have reached the level of advanced economies internationally advanced level, the proportion of non-fossil energy consumption will be in excess of 80%.

3.2. List of Controlled Ozone-Depleting Substances

In 2010, China's State Council promulgated the regulations on Ozone Depleting Substances which provided a legal basis for the management of ozone depleting substances (ODS). In the same year, the list of controlled ozone-depleting substances was formulated and published in accordance with the requirements of the regulations on Ozone Depleting Substances.

In October 2016, 18 hydrofluorocarbons (HFCs) were included in the scope of the Kigali Amendment and they became the ninth class of controlled substances. Approved by the State Council on 15 September 2021, the Kigali Amendment officially entered into force in China. In fulfilling the new requirements of HFCs management and control under the framework of the protocol, China had to include HFCs in the list.

In order to implement the Kigali Amendment, a revision of the list of controlled ozone-depleting substances was published in China, and a new category of 18 HFCs has been included, for which the main uses and obligations were to reduce usage as indicated.

According to the compliance requirements of the Kigali Amendment, China must freeze the production and use of HFCs at the baseline level from 2024, HFCs production and use will not exceed 90% of the baseline from 2029, 70% of the baseline from 2035, 50% of the baseline from 2040, and 20% of the baseline from 2045. In the next step, China will study, formulate and issue relevant policies and measures for HFCs in accordance with the performance requirements.

The first step is to study the overall strategy of HFCs reduction, and to propose areas, roadmaps, and policy management measures for priority reduction in the future. Secondly, in accordance with the requirements of the protocol, in conjunction with the Ministry of Commerce and the General Administration of Customs, the import and export license

management of HFCs is to be implemented before 15 December 2021. The third step is to formulate and promulgate the policies for HFCs chemical production and construction project management and control, with clear ecological environment requirements and industrial policy guidelines. The fourth step is to conduct in-depth research and implement quotas and record management on the production, sales, and use of HFCs, so as to ensure that China successfully achieves the HFCs production and use performance targets in 2024 and subsequent years. Also, "Controlling the Emission of the By-product Trifluoromethane" was issued on 10 September 2021, which clarified the protocol's compliance requirements for by-product HFC-23 and related regulatory measures.

To improve the management of the list, this revision to the list of controlled ozone-depleting substances mainly revised the following aspects:

1. According to the Kigali Amendment's requirements, 18 types of HFCs are included, and their main uses and reduction obligations are indicated.
2. The definition of "controlled substances" in the protocol is included in the list in the form of footnotes, which further clarifies that controlled substances refer to substances contained in the annex to the protocol that exist alone or in a mixture. Unless otherwise specified, isomers of such substances shall be included, but such controlled substances or mixtures contained in finished products shall not be included, but such substances or mixtures in containers for transporting or storing the substances shall be included.
3. In response to the original list of CFC-113 and CFC-114, given that the Chinese chemical name did not include their isomers, the names were revised accordingly, so it is consistent with the controlled substances contained in the annex to the protocol.
4. The addition of the global warming potential (GWP) of some controlled substances in accordance with the content of the annex to the current protocol to ensure that the list is consistent with the content of the protocol.

3.3. Catalogue of Ozone Depleting Substances subject to Import and Export Control

China accepted the Kigali Amendment in 2021. According to the requirements of the Amendment, an import and export license system for hydrofluorocarbons (HFCs) should be established before 15 December 2021. In order to implement HFCs import and export

license approval in accordance with the law, the Ministry of Ecology and Environment has adjusted the list of controlled substances based on the Montreal Protocol and its amendments on the basis of the existing catalogue and combined with the requirements of the world customs for commodity coding of controlled substances. For the substance list, some ODS commodity codes have been adjusted, and HFCs commodity codes were added at the same time.

According to the coding requirements of the world customs for HFCs and their mixtures, the first 6 digits of HFCs single substances in the catalogue are coded as "290339", and the first 6 digits of HFCs mixtures are coded as "382478". For the 13 types of HFCs substances that currently have import and export trade, including HFC-41, HFC-32, HFC-923, HFC-152a, HFC-143a, HFC-134a, HFC-125, HFC-245fa, HFC-365mfc, HFC-236ea, HFC-236fa, HFC-227ea, HFC-236cb and 4 types of mixture including R410A, R407C, R404A, R507A are separately coded. Therefore in the catalogue, there are a total of 19 commodity codes for HFCs and their mixtures.

According to the requirements of the Kigali Amendment, the General Administration of Customs (GAC) and Ministry of Commerce, starting from 1 November, will officially begin to implement an import and export license system for the import and export of HFCs. Enterprises engaged in the import and export of HFCs should apply for import and export licenses in accordance with the "Management Measures on Import and Export of Ozone Depleting Substance" and comply with relevant laws and regulations.

3.4. Controlling the Emission of By-product Trifluoromethane

After the Kigali Amendment entered into force, China must fulfill the management requirements for controlling the emission of by-product trifluoromethane (HFC-23).
From 15 September 2021, HFC-23 created as a by-product in the production of difluorochloromethane (HCFC-22) or hydrofluorocarbons (HFCs) should not be directly discharged.

Enterprises should establish operating ledgers for HFC-23 by-product facilities and destruction and disposal facilities, monitor and measure the amount of HFC-23 produced, destroyed, stored, used, and sold, and report data in accordance with relevant regulations.

Enterprises should strengthen HFC-23 emission management, supporting HFC-23 storage facilities (equipment), or adopt other measures to avoid direct emission of HFC-23 into the atmosphere during emergency situations such as the shutdown of destruction and disposal facilities.

Enterprises should strengthen the maintenance and management of installations and equipment to prevent leakage and discharge of HFC-23, and accept inspections by the competent department of ecological environment.

4. Catalogues of Chemicals Governed by Chinese Law

4.1. Catalogue of Existing Chemical Substances

The catalogue of existing chemical substances was published for the first time in 2013. This catalogue is used as the basis for distinguishing new chemical substances from existing chemical substances. Any chemical substance not listed in the catalogue is deemed to be a new chemical substance which must be registered and controlled under the **Measures Governing the Environmental Management and Registration of New Chemical Substances.**

In 2021, Announcements No. 11, 12, 25, 32 and 48 were published and added substances to the catalogue of existing chemical substances.

4.2. Catalogue of Goods Prohibited from Import and Goods Prohibited from Export

The catalogue of goods prohibited from import and goods prohibited from export was published for the first time in 2001. This catalogue is to implement the "Stockholm Convention on Persistent Organic Pollutants" and the "Minamata Convention on Mercury", in

accordance with the "Foreign Trade Law" and the "Administration of the Import and Export of Goods". These new versions of the catalogue entered into force on 1 January 2021.

Goods covered by the catalogues include a number of substances and various mercury-containing products, such as:

- Packaging containing substances such as aldrin, toxaphene, chlordane, DDT, endosulfan, heptachlor, hexachlorobenzene, α-hexachlorocyclohexane, lindane or pentabromodiphenyl ether, etc.
- Various types of batteries, including:
    - Button-type alkaline zinc-manganese primary battery and primary battery pack containing mercury (mercury content ≥ 0.0005% of battery weight)
    - Cylindrical alkaline zinc manganese primary battery and primary battery pack containing mercury (mercury content ≥ 0.0001% of battery weight)
    - Other alkaline zinc manganese primary battery and primary battery pack containing mercury (mercury content ≥ 0.0001% of battery weight)
    - Other manganese dioxide primary battery and primary battery pack containing mercury (mercury content ≥ 0.0001% of battery weight, button battery mercury content ≥ battery weight of 0.0005%)
    - Primary batteries and primary battery pack of mercury oxide
    - Silver oxide primary cells and primary batteries (containing mercury) (mercury content ≥ 0.0001% of battery weight, button battery mercury content ≥ battery weight of 0.0005%)
    - Zinc-air primary batteries and primary battery pack (containing mercury)(mercury content ≥ 0.0001% of battery weight, button battery mercury content ≥ battery weight of 0.0005%)
    - Fuel cell containing mercury (mercury content ≥ 0.0001% of the battery weight, and button cell mercury content ≥ 0.0005% of the battery weight)
    - Other primary batteries and primary battery pack containing mercury (mercury content ≥ 0.0001% of battery weight, button battery mercury content ≥ battery weight of 0.0005%)
- Various types of mercury-containing switches
- Various types of fluorescent lamps, including:
    - Compact hot cathode fluorescent lamps (no more than 30 watts, single tube containing more than 5 mg of mercury)

- Other compact cold cathode fluorescent lamps (no more than 30 watts, single tube containing more than 5 mg of mercury)
- Straight tube hot cathode fluorescent lamp (straight tube fluorescent lamp with less than 60 watts and a single mercury content of more than 5 mg (using tri-primary phosphors)
- Straight tube hot cathode fluorescent lamp (less than 40 watts (including 40 watts), a single straight tube fluorescent lamp with a mercury content of more than 10 mg (using halophosphate phosphors)
- Other straight tube fluorescent lamps (straight tube fluorescent lamp with less than 60 watts and a single tube containing more than 5 mg of mercury - use three primary color phosphors)
- Other straight tube fluorescent lamps (less than 40 watts (including 40 watts), a single straight tube fluorescent lamp with a mercury content of more than 10 mg (using halophosphate phosphors)
- High-pressure mercury lamps for general lighting purposes
- Cold cathode tube fluorescent lamp for electronic display (if the length is less than or equal to 500 mm, the mercury content of a single tube exceeds 3.5 mg; if the length is less than 500 mm, the mercury content of a single tube exceeds 5 mg; if the length is more than 1500 mm, the mercury content of a single tube exceeds 13 mg)
- External electrode fluorescent lamp for electronic display (if the length is less than or equal to 500 mm, the mercury content of a single tube exceeds 3.5 mg; if the length is less than 500 mm, the mercury content of a single tube exceeds 5 mg; if the length is more than 1500 mm, the mercury content of a single tube exceeds 13 mg)

- Mercury-containing cosmetics, pesticides and non-electronic medical devices

5. Conclusion

2021 saw a lot of change to the Chinese regulatory landscape, bringing new obligations and challenges for product manufacturers. In particular, climate change and carbon emissions

were at the forefront as China revised their management of hydrofluorocarbons (HFCs) to fulfil the compliance requirements of the Kigali Amendment.

Of note for the medical device industry, China introduced updates to the law relating to medical devices and the medical devices management system.

Developments in the area of chemicals management was also a big topic, with the Catalogue of Existing Chemical Substances and the Catalogue of Goods Prohibited from Import and Goods Prohibited from Export both updated.

As the volume and complexity of laws and regulations continues to rise globally, we can expect that China will continue to see regulatory growth on a large scale.

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