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Latest Chinese Guidebook for Regulations on the Administration of Overseas Inspection for Imported Drugs and Medical Devices (2019 Edition)

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Abstracts

China is one of the fastest growing global economies with one fifth population in the world. Nowadays, China has become the world's second largest healthcare market after the United States. Along with sustained economic and population growth, and rapid population aging, the Chinese healthcare market has maintained annual compound growth rate above 16 % since 2010s. The statistical data showed that scale of the Chinese healthcare market has reached RMB 6464.1 billion by 2017(about equivalent to US$973.5 billion). Among them, the total value of drug sales was RMB 2001.6 billion (US$301.1 billion) based on the statistical data of three sales terminals for public hospitals, retail pharmacies and grassroots medical institutions with annual compound growth rate of 14.37%; the total value of medical device sales was RMB 663.2 billion (US$95.2 billion) with annual compound growth rate of 20.27%. Facing a gigantic population and rapid population aging, the Chinese government, on one side, accelerated the priority approval of innovative drugs and medical devices and relaxed the market access for overseas drugs and medical devices, on other side, intensified the supervision and administration for drugs and medical devices at the post—marketed and expecting into the market. In recent years, China’s fast-track approval time is much shorter than any other country, which attracts more and more overseas pharmaceutical and medical device manufacturers to enter the Chinese healthcare market. Undoubtedly the Chinese healthcare market of nearly 1.4 billion populations is a huge business opportunities for the overseas pharmaceutical and medical device manufacturers. At the same time, the Chinese regulatory authorities are changing regulatory framework to intensify the supervision and administration.

The Chinese National Medical Products Administration ('NMPA') has enacted the latest “Regulations on the Administration of Overseas Inspection for Imported Drugs and

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Medical Devices” on December 26, 2018, which has been come into immediately effective from the date of issuance. The supervision and administration for China’s healthcare market is not only the domestic full-coverage, but also start to get involved overseas manufacturers exporting drugs and medical devices to China. The latest “Regulations” clearly state that, overseas inspections targeting drugs and medical devices that have been or will be launched on the Chinese market, are not limited to on-site inspections carried out in the production location, but are expanded to cover inspections conducted at places of the overseas research and development, even on production sites of suppliers or other contracting agencies of the raw materials, auxiliary materials, and packaging materials. In deciding whether to carry out an overseas inspection, the Chinese regulatory authority will give consideration to multiple risk factors related to a drug or a medical device that arise in different processes, including the evaluation and approval of its registration, supervisory checks, tests, complaints and reports, and the monitoring of adverse reactions or events. Moreover, the “Regulations” require that the comprehensive assessment for inspection results should be made under the principle of risk assessment, adding that inspection conclusions should be drawn by comprehensively taking account of the nature and gravity of product defects and the category of the product under evaluation, and are classified into three types which are 'up-to-standard', 'up-to-standard after the completion of rectification work' and 'substandard'. Furthermore, the “Regulations” state that, inspection results will be responded differently through risk control measures and through case establishment and investigations. In the event that grave quality risks are found in such inspections, immediate measures must be taken to bring the risks under control. This is challenge to overseas pharmaceutical and medical device manufacturers. To capture the huge business opportunities of the Chinese healthcare market and seize a larger part of Chinese healthcare market, how do the foreign pharmaceutical and medical device manufacturers in compliance with the latest Chinese regulations on pharmaceutical and medical devices? How do the overseas pharmaceutical and medical device manufacturers operate business smoothly in China? Most importantly, the overseas and multinational pharmaceuticals and medical device manufacturers should always stand ready to respond to further regulation and policy changes occurred in China.

The overseas and multinational pharmaceutical and medical device manufacturers and their senior executive officers engaging in regulatory affairs need a thorough knowledge of the Chinese “Regulations on the Administration of Overseas Inspection for Imported Drugs and Medical Devices”. China’s regulatory approach and culture are unique.

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for Imported Drugs and Medical Devices (2019 Edition) is an essential resource for overseas and multinational pharmaceutical and medical device manufacturers to respond the Chinese regulatory authorities' overseas inspection for imported drugs and medical devices, which provided a detailed guidance of comprehensive and thorough knowledge of the Chinese regulations on the administration of overseas inspection for imported drugs and medical devices, and to smoothly navigate complex regulatory requirements step by step.

This guidebook is organized as follows. Chapter 2 provides a brief description for the China's healthcare market landscape and rapidly changing regulatory framework as background for audience. Chapter 3 introduces the general regulations for overseas inspection for imported drugs and medical devices, which cover the applicable objects and scopes, who will be responsible for the overseas inspection of drugs and medical devices, who will be responsible for the specific organization and implementation of overseas inspection of drugs and medical devices, and how will announce the basic situation of the overseas inspection and the processing results. Chapter 4 elaborates how to determine the overseas inspection task for drugs and medical devices. Chapter 5 expounds the initiating procedures for overseas inspection. Chapter 6 elaborates the overseas on-site inspections for drugs and medical devices. Chapter 7 expounds the audit and disposal for results of overseas on-site inspections. Chapter 8 introduces the Chinese regulatory authority's requirements for the overseas marketing authorization holder to authorize an agency within the territory of China to undertake the overseas inspection affairs. Chapter 9 introduces the lists and contents of site master files. Chapter 10 describes and sketches a panoramic view of the overseas inspection for drugs and medical devices. Chapter 11 provides a full set of the English and Chinese bilingual annexes, which cover the notification of overseas inspection, the basic situation form of overseas inspection product, the pre-notification for overseas inspection, and the notification for overseas inspection results.

The audiences of this guidebook are the overseas pharmaceutical and medical device companies wishing to enter into the Chinese healthcare market, and the multinational pharmaceutical and medical device companies have penetrated into the Chinese healthcare market, and their senior executive officers engaging in regulatory affairs expecting to understand the latest Chinese regulations on the administration of overseas inspection for imported drugs and medical devices. After having skimmed through this guidebook, audiences can clearly acquire a comprehensive and thorough knowledge of the latest Chinese regulations on administration of overseas inspection for imported drugs and medical devices. Access China Management Consulting Ltd hopes this guidebook, based on the full and accurate regulations, can guide overseas and

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multinational pharmaceutical and medical device manufacturers to achieve a successful entry into the Chinese healthcare market, and smoothly operate their companies in China.

REASONS TO BUY

The Chinese National Medical Products Administration ('NMPA') has enacted the latest “Regulations on the Administration of Overseas Inspection for Imported Drugs and Medical Devices” on December 26, 2018, which has been come into immediately effective from the date of issuance. The supervision and administration for China’s healthcare market is not only the domestic full-coverage, but also start to get involved overseas manufacturers exporting drugs and medical devices to China. The latest “Regulations” straightway involved with the overseas pharmaceutical and medical device manufacturers exporting drugs and medical devices to China. The latest “Regulations” clearly state that, overseas inspections targeting drugs and medical devices that have been or will be launched on the Chinese market, are not limited to on-site inspections carried out in the production location, but are expanded to cover inspections conducted at places of the overseas research and development, even on production sites of suppliers or other contracting agencies of the raw materials, auxiliary materials, and packaging materials. In deciding whether to carry out an overseas inspection, the Chinese regulatory authority will give consideration to multiple risk factors related to a drug or a medical device that arise in different processes, including the evaluation and approval of its registration, supervisory checks, tests, complaints and reports, and the monitoring of adverse reactions or events. Moreover, the “Regulations” require that the comprehensive assessment for inspection results should be made under the principle of risk assessment, adding that inspection conclusions should be drawn by comprehensively taking account of the nature and gravity of product defects and the category of the product under evaluation, and are classified into three types which are 'up-to-standard', 'up-to-standard after the completion of rectification work' and 'substandard'. Furthermore, the “Regulations” state that, inspection results will be responded differently through risk control measures and through case establishment and investigations. In the event that grave quality risks are found in such inspections, immediate measures must be taken to bring the risks under control. This is challenge to overseas pharmaceutical and medical device manufacturers. To capture the huge business opportunities of the Chinese healthcare market and seize a larger part of Chinese healthcare market, how do the foreign pharmaceutical and medical device manufacturers in compliance with the latest Chinese regulations on pharmaceutical and medical devices? How do the overseas pharmaceutical and medical device manufacturers operate business smoothly in China? The overseas and multinational

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pharmaceutical and medical device manufacturers and their senior executive officers engaging in regulatory affairs need a thorough knowledge of the Chinese “Regulations on the Administration of Overseas Inspection for Imported Drugs and Medical Devices”. China’s regulatory approach and culture are unique.

KEY HIGHLIGHTS

A brief description for the China’s healthcare market landscape and rapidly changing regulatory framework that let the overseas and multinational drug and medical device manufacturers clearly understand the present-day realities of the Chinese healthcare market landscape and rapidly changing regulatory framework, and tell the overseas and multinational drug and medical device manufacturers the opportunities and challenges.

The general regulations for overseas inspection for imported drugs and medical devices, which clarify the applicable objects and scopes of overseas inspection, who will be responsible for the overseas inspection of drugs and medical devices, who will be responsible for the specific organization and implementation of overseas inspection of drugs and medical devices, and how will announce the basic situation of the overseas inspection and the processing results.

How the Chinese regulatory authority determines the overseas on-site inspection task for drugs and medical devices.

How the Chinese regulatory authority initiates procedures for overseas on-site inspection for imported drugs and medical devices, which is important for the overseas and multinational manufacturers of imported drugs and medical devices and the agents within the territory of China designated by the overseas marketing authorization holders, because they must be in compliance with these procedures.

How the Chinese regulatory authority implements the overseas on-site inspections for imported drugs and medical devices to smoothly navigate complex regulatory requirements step by step, which is important for the overseas and multinational manufacturers exporting drugs and medical devices to China, because they must be in compliance with these complex regulatory requirements.

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How the Chinese regulatory authority conducts the audit and disposal for results of overseas on-site inspections, which is a key step that decide whether the drugs and medical devices imported into China can be firmly stood on the Chinese healthcare market.

The Chinese regulatory authority’s requirements for the overseas marketing authorization holder to authorize an agency within the territory of China to undertake the overseas inspection affairs are the Chinese distinct regulatory approach. The overseas marketing authorization holders must abide by this distinct Chinese regulatory approach.

The detailed Chinese regulatory authority‘s the specific requirements of lists and contents of Site Master Files for overseas on-site inspection of imported drugs and medical devices guide the overseas marketing authorization holders how smoothly navigate complex regulatory requirements step by step.

A panoramic view of the Chinese overseas inspection for imported drugs and medical devices that let the overseas MA holders and overseas drug and medical device manufacturers wishing to enter into the Chinese healthcare market clearly understand the Chinese regulatory authorities’ distinctive regulatory current status.

A full set of the English and Chinese bilingual notifications and form relating to the overseas on-site inspection for imported drugs and medical devices facilitate the overseas MA holders and overseas drug and medical device manufacturers wishing to enter into the Chinese healthcare market to respond to Chinese regulatory authority‘s overseas on-site inspection.

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