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Latest Chinese Guidebook for Medical Device Adverse Events Reporting, Monitoring and Re-Evaluation (2019 Edition)

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Abstracts

Executive Summary

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 (about equivalent to US$973.5 billion) by 2017. Among them, the total value of medical device sales was RMB 663.2 billion (US$95.2 billion) with annual compound growth rate of 20.27% by 2017. Medical devices have been widely used in the process of disease prevention, diagnosis, therapy, care and rehabilitation. However, large and medium-sized medical devices, high-end medical equipments and high-value medical materials are mainly relying on imported, such as the high-tech and high-valued imaging systems and navigation and positioning systems. Facing a gigantic population and rapid population aging, the Chinese government, on one side, accelerated the priority approval of innovative medical devices and relaxed the market access for overseas medical devices, on other side, intensified the supervision and administration for medical devices at the post—marketed. In recent years, China’s fast-track approval time is much shorter than any other country, which attracts more and more overseas medical device manufacturers to enter the Chinese healthcare market. Undoubtedly the Chinese healthcare market of nearly 1.4 billion populations is the huge business opportunities for the overseas medical device manufacturers. At the same time, the Chinese regulatory authorities are changing regulatory framework to intensify the supervision and administration. The Chinese “State Administration for Market Regulation” and the

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"National Health Commission" jointly issued the latest version of "Measures for Medical Device Adverse Event Monitoring and Re-evaluation" in August 2018, which has been implemented on January 1, 2019. This is challenge to overseas 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 medical device manufacturers in compliance with the latest Chinese regulations on medical devices? How do the overseas medical device manufacturers operate business smoothly in China? Most importantly, overseas and multinational medical device manufacturers should always stand ready to respond to further regulation and policy changes occurred in China.

The overseas and multinational medical device manufacturers and their senior executive officers engaging in regulatory affairs need a thorough knowledge of the Chinese regulations for medical device adverse event reporting, monitoring and re-evaluation. China's regulatory approach and culture are unique.

Latest Chinese Guidebook for Medical Device Adverse Events Reporting, Monitoring and Re-Evaluation (2019 Edition) is an essential resource for overseas and multinational medical device manufacturers to handle the medical device adverse event reporting, monitoring and re-evaluation smoothly in China, which provided a detailed guidance of comprehensive and thorough knowledge of the Chinese medical device adverse event reporting, monitoring and re-evaluation regulations.

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 medical device adverse event reporting, monitoring and re-evaluation. Chapter 4 introduces the Chinese regulatory authorities and their respective functions and the Chinese huge medical device adverse event monitoring information network. Chapter 5 expounds the marketing authorization holders' duties and obligations, which is important for the overseas and multinational medical device manufacturers and the agents within the territory of China designated by the overseas medical device manufacturers, because they must fulfill these duties and obligations that are stipulated by the Chinese regulatory authorities. Chapter 6 expounds the medical device distributors' and medical device user facilities' duties and obligations, which is important for the distributors within the territory of China of the overseas and multinational manufacturers of imported medical devices, because they must also fulfill their duties and obligations that are stipulated by the Chinese regulatory authorities. Chapter 7 elaborates the medical device adverse event reporting and evaluation, from the basic requirements, the

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different types of medical device adverse event reporting, and the time limitations for different types of medical device adverse event reporting to an entire process of medical device adverse event reporting, which is important for the overseas and multinational manufacturers of imported medical devices and the agents within the territory of China designated by the overseas medical device manufacturers, because they must be in compliance with these regulations. Chapter 8 introduces how Chinese regulatory authorities implement the key monitoring on certain medical devices. Chapter 9 elaborates that the marketing authorization holders should adopt what risk control measures under what circumstances and report to the drug regulatory authorities. Chapter 10 elaborates that the marketing authorization holders should proactively conduct the re-evaluation under what circumstances and report to the drug regulatory authorities. Chapter 11 introduces that the Chinese regulatory authorities will carry out the focusing inspections on the marketing authorization holders under what circumstances. Chapter 12 describes and sketches a panoramic view for the Chinese network for medical device adverse event reporting and monitoring.

The audiences of this guidebook are the overseas medical device companies wishing to enter into the Chinese medical device market, and the multinational medical device companies have penetrated into the Chinese medical device market, and their senior executive officers engaging in regulatory affairs expecting to understand the latest Chinese regulations on medical device adverse events reporting, monitoring and re-evaluation. After having skimmed through this guidebook, audiences can clearly acquire a comprehensive and thorough knowledge of the latest Chinese regulations on medical device adverse events reporting, monitoring and re-evaluation. Access China Management Consulting Ltd hopes this guidebook, based on the full and accurate regulations, can guide overseas and multinational medical device manufacturers to achieve a successful entry into the Chinese medical device market, and smoothly operate their companies in China.

Report Highlights

A brief description for the China’s healthcare market landscape and rapidly changing regulatory framework that let the overseas and multinational 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 medical device manufacturers the opportunities and challenges.

The Chinese regulatory authorities at various administrative levels and their

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respective functions and the Chinese huge medical device adverse event monitoring information network.

The detailed Chinese regulations for the marketing authorization holders' duties and obligations that are important for the overseas and multinational medical device manufacturers and the agents within the territory of China designated by the overseas medical device manufacturers, because they must fulfill these duties and obligations that are stipulated by the Chinese regulatory authorities.

The detailed Chinese regulations for the medical device distributors' and medical device user facilities' duties and obligations that are important for the distributors within the territory of China designated by the overseas and multinational manufacturers exporting medical device products to China, because they must also fulfill their duties and obligations that are stipulated by the Chinese regulatory authorities.

The detailed Chinese regulations for the medical device adverse event reporting and evaluation, from the basic requirements, the different types of medical device adverse event reporting, and the time limitations for different types of medical device adverse event reporting to an entire process of medical device adverse event reporting to smoothly navigate complex regulatory requirements step by step, which is important for the overseas and multinational manufacturers of imported medical devices and the agents within the territory of China designated by the overseas medical device manufacturers, because they must be in compliance with these regulations.

The detailed description of how Chinese regulatory authorities implement the key monitoring on certain medical devices.

The detailed guidance for the marketing authorization holders of the overseas and multinational medical device manufacturers exporting medical device products to China, they should adopt what risk control measures under what circumstances and report to the drug regulatory authorities to smoothly navigate complex regulatory requirements step by step.

The detailed guidance for the marketing authorization holders of the overseas and multinational medical device manufacturers exporting medical device products to China, they should proactively conduct the re-evaluation under what circumstances and report to the drug regulatory authorities to smoothly navigate

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complex regulatory requirements step by step.

The detailed introduction for the Chinese regulatory authorities will carry out the focusing inspections on the marketing authorization holders under what circumstances.

An overview of Chinese monitoring network for medical device adverse event reporting and monitoring , which covers the detailed regulatory authorities at various administrative levels and their functions, and the complete picture of Chinese monitoring network for medical device adverse event reporting and monitoring to provide a direction of gateway for medical device adverse event reporting and monitoring.

Who should buy this report?

Overseas medical device companies wishing to enter into the Chinese medical device market.

Multinational medical device companies have penetrated into the Chinese medical device market.

Companies interested in understanding the latest Chinese Medical Device Adverse Event Reporting, Monitoring and Re-evaluation Regulations.

Senior executive officers engaging in regulatory affairs for imported medical device into Chinese lucrative medical device market.

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