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Chinese guidebook for Adverse Drug Reaction Reporting and Monitoring Regulations (2014)

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Abstracts

China is one of the fastest growing global economies with a fifth population in the world, and is one of the largest healthcare markets around the world. Along with sustained economic and population growth, Chinese healthcare market has maintained annually average growth rate above 16 % since 1990s. By 2013, total value of drugs on Chinese healthcare market has reached RMB 1114 billion. On the Chinese healthcare market, imported drugs made by overseas and multinational pharmaceutical manufacturers account for about one fourth. It is estimated that total value of drugs on Chinese healthcare market will be likely to be more than 1450 billion RMB by 2015, and will surpass Japan to become the second largest drug market following the United States. The Chinese healthcare market will attract more and more overseas pharmaceutical manufacturers and producers to penetrate such market.

However, when searching on website of the Chinese regulatory authority of drugs, China Food and Drug Administration, you may find there are many announcements of adverse drug reaction reports for those that drugs made by overseas and multinational pharmaceutical manufacturers. How to report an adverse drug reaction and event to the Chinese regulatory authorities? Who should report adverse drug reaction and event to the Chinese regulatory authorities? How the Chinese regulatory authorities to monitor the adverse drug reaction and event reporting? How to comply with Chinese regulations for adverse drug reaction reporting and monitoring? A series of questions are facing overseas and multinational pharmaceutical manufacturers. The overseas and multinational pharmaceutical manufacturers and their senior executive officers engaging in regulatory affairs need a comprehensive and thorough knowledge of the Chinese regulations for adverse drug reaction reporting and monitoring. The regulations on adverse drug reaction reporting and monitoring between China and US-EU are different. Moreover, the cultural difference between China and Western countries as well as the

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language barriers will increase the challenge faced by overseas and multinational pharmaceutical manufacturers and producers.

Chinese guidebook for Adverse Drug Reaction Reporting and Monitoring Regulations (2014) is an essential resource for overseas and multinational pharmaceutical manufacturers and producers to handle an adverse drug reaction reporting smoothly in China, which provides a detailed guidance of comprehensive and thorough knowledge of the Chinese adverse drug reaction reporting and monitoring regulations.

The organizations of this guidebook are arranged as follows. Chapter 2 provides the general regulations for adverse drug reaction reporting and monitoring, and the special regulations for overseas manufacturers of imported drugs. Chapter 3 provides an overview of Chinese monitoring network for adverse drug reaction reporting, which covers the detailed regulatory authorities at various administrative levels and their functions, and the complete picture of Chinese monitoring network for adverse drug reaction reporting and monitoring. Chapter 4 introduces the detailed manufacturer's duty for adverse drug reaction and event reporting, from the responsibilities and obligations, the operation procedures of adverse drug reaction and event reporting, the control and evaluation for adverse drug reaction, the focal point monitoring for drugs, the special regulations for reporting serious adverse event occurred outside of the territory of China to an entire process of adverse drug reaction and event reporting for manufacturer, which is important for agents within the territory of China designated by overseas and multinational pharmaceutical manufacturers, because they must be in compliance with these regulations. Chapter 5 addresses the distributor's duty for adverse drug reaction reporting, also from the responsibilities and obligations, the operation procedures of adverse drug reaction and event reporting to the control and evaluation for adverse drug reaction, which is important for the distributors within the territory of China of overseas and multinational manufacturers of imported drugs, because they must be in compliance with these regulations. Chapter 6 elaborates the medical institution's duty for adverse drug reaction reporting. Chapter 7 provides a brief introduction of citizens, legal persons and other social organizations' right for adverse drug reaction reporting. Chapter 8 introduces the disclosure and feedback of information about adverse drug reactions and events. Chapter 9 addresses the legal liabilities for manufacturer, distributor and medical institution. Chapter 10 provides a full set of the English and Chinese bilingual forms relating to adverse drug reaction and event reporting to facilitate audiences to clearly understand submitted forms for adverse drug reaction and event reporting.

The audiences of this guidebook are overseas pharmaceutical companies wishing to

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enter into the Chinese drug market, and multinational pharmaceutical companies have penetrated into the Chinese drug market, and their senior executive officers engaging in regulatory affairs expecting to understand the latest Chinese Adverse Drug Reaction Reporting and Monitoring Regulations. After having skimmed through this guidebook, audiences can clearly acquire a comprehensive and thorough knowledge of the latest Chinese Adverse Drug Reaction Reporting and Monitoring Regulations. Access China Management Consulting Ltd hopes this guidebook, based on full and accurate regulations, can guide overseas and multinational pharmaceutical manufacturers and producers to achieve a successful entry into the Chinese drug market, and smoothly operate their companies in China.

Report Highlights

Chinese general regulations for adverse drug reaction and event reporting and monitoring, and the special regulations for adverse drug reaction and event reporting and monitoring of overseas manufacturers of imported drugs into the Chinese drug market.

The detailed Chinese regulations for the manufacturer’s duty for adverse drug reaction and event reporting, from the responsibilities and obligations, the operation procedures of adverse drug reaction and event reporting, the control and evaluation for adverse drug reaction, the focal point monitoring for drugs, the special regulations for reporting serious adverse event occurred outside of the territory of China to an entire process of adverse drug reaction and event reporting for manufacturer to guide agents within the territory of China designated by overseas and multinational pharmaceutical manufacturers to smoothly handle complex regulatory requirements step by step, because they must be in compliance with these regulations.

The detailed Chinese regulations for the distributor’s duty for adverse drug reaction and event reporting, from the responsibilities and obligations, the operation procedures of adverse drug reaction and event reporting to the control and evaluation for adverse drug reaction to guide distributors within the territory of China of overseas and multinational manufacturers of imported drugs to smoothly navigate complex regulatory requirements step by step, because they must be in compliance with these regulations.

The detailed Chinese regulations for medical institution’s duty for adverse drug reaction reporting.

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

A brief introduction of citizens, legal persons and other social organizations' right for adverse drug reaction reporting.

The Chinese regulations for disclosure and feedback of information about adverse drug reactions and events.

The Chinese regulations for legal liabilities of manufacturer, distributor and medical Institution to report and monitor the adverse drug reactions and events.

A full set of the English and Chinese bilingual forms relating to adverse drug reaction and event reporting to facilitate audiences to clearly understand submitted forms for adverse drug reaction and event reporting.

The detailed Chinese regulations for the user facility's duty for medical device adverse event reporting.

An overview of Chinese monitoring network for medical device adverse event reporting, 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.

The Chinese regulations for adverse event reporting of medical device in clinical trials.

A full set of the English and Chinese bilingual forms relating to medical device adverse event reporting to facilitate audiences to clearly understand submitted forms for medical device adverse event reporting.

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