Latest Chinese Guidance for Development, Evaluation, License Approval of Biosimilars

a comprehensive and thorough knowledge of the latest Chinese guidance for development, evaluation, license approval of biosimilars

BEJING, CHINA , June 4, 2015 /EINPresswire.com/ -- China has an indispensable biosimilar market for overseas and multinational pharmaceutical companies. Historical data shows 40 per cent of China's $1.5bn recombinant biologic product sales come from biosimilars, which have enjoyed approximately 25-30 per cent CAGR over the past decade. If the market continues to grow at 25 per cent per year, the biosimilar market could grow to $2bn, around 20 per cent of the global biosimilar market by 2015. It is attracting more and more overseas and multinational pharmaceutical manufacturers and producers to penetrate such market.

Responding to strong desire of overseas and multinational pharmaceutical manufacturers and domestic pharmaceutical manufacturers to carry out research and development of biosimilar products, this is first time in history, Chinese pharmaceutical authorities, China Food and Drug Administration officially issued a technical guidance for development and evaluation of biosimilars (Trial Implementation) on February 28, 2015, at the same time, announcement concerning implementing the Guidance issued by the CFDA defined the pathway of license approval for biosimilars. Chinese pharmaceutical authorities require that when conducting the research and development of biosimilar products, the applicant of biosimilar registration application and its sponsor should be in compliance with the Guidance and follow the pathway of license approval of biosimilars. There is a gigantically potential market of biosimilar products to meet the demand for Chinese patients. However, In China, the process of application and approval for clinical trials and marketing license approval of imported drug registration is very complex, because the Chinese pharmaceutical authorities administer and control this process by exorbitant administrative measures and regulations, moreover, these exorbitant administrative measures and regulations are variable and lack of transparency. In addition, the cultural difference between China and Western countries as well as the language barriers will increase the challenge faced by overseas and multinational pharmaceutical manufacturers and producers.

How to grasp the opportunity to smoothly conduct the research and development of biosimilar products in China and speed up your biosimilar product approval time? The overseas and multinational pharmaceutical manufacturers and their senior executive officers engaging in regulatory affairs must have a comprehensive and thorough knowledge of the latest Chinese guidance for development, evaluation, license approval of biosimilars.

Latest Chinese Guidance for Development, Evaluation, License Approval of Biosimilars provided a comprehensive and thorough knowledge of the latest Chinese guidance for development, evaluation, license approval of biosimilars and guide you use the Chinese trial venues to keep biosimilars development lean and to smoothly operate in China.

The organizations of this guidebook are arranged as follows. Chapter 2 introduces the applicable scope of the Guidance and some definitions involving to the Guidance. Chapter 3 gives an overview of general principles of development and evaluation of biosimilar products in China. Chapter 4

elaborates the research and evaluation of pharmacy. Chapter 5 elaborates the requirements for non-clinical research and evaluation. Chapter 6 elaborates the requirements for clinical research and evaluation in detail, from clinical pharmacology study covering pharmacokinetics study, pharmacodynamics study and (PK/PD) study, efficacy study, safety study, immunogenicity study to extrapolation of indications to smoothly navigate complex regulatory requirements step by step. Chapter 7 introduces the regulatory provisions for instructions of product and pharmacovigilance. Chapter 8 addresses the license approval of biosimilars in China, from China's registration category of biological products, specific pathway of license approval for imported biosimilar registration to application dossiers and data for license approval of biological products to guide you achieve a successful entry into the Chinese drug market, and smoothly operate your biosimilar products in China. Chapter 9 Appendix provides the China's Application Form of Drug Registration in English.

The audiences of this guidebook are overseas pharmaceutical manufacturers wishing to 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 how to apply for clinical trials and marketing license approval of their biosimilar products in China, how to comply with the latest Chinese guidance for development, evaluation, license approval of biosimilars.

After having skimmed through this guidebook, audiences can clearly acquire not only a comprehensive and thorough knowledge of the latest Chinese guidance for development, evaluation, license approval of biosimilars but also the practical operation how to comply with the latest Chinese guidance for development, evaluation, license approval of biosimilars. 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 products in China.

Report Highlights

_ The applicable scope of Guidance.
_ An overview of general principles of development and evaluation of biosimilar products in China.
_ The detailed requirements for research and evaluation of pharmacy.
_ The detailed requirements for non-clinical research and evaluation.
_ The detailed requirements for clinical research and evaluation, from clinical pharmacology study covering pharmacokinetics study, pharmacodynamics study and (PK/PD) study, efficacy study, safety study, immunogenicity study to extrapolation of indications to smoothly navigate complex regulatory requirements step by step.
_ An overview of marketing license approval of biosimilars in China, from China's registration category of biological products, specific pathway of license approval for imported biosimilar registration to application dossiers and data for license approval of biological products to guide you achieve a successful entry into the Chinese drug market, and smoothly operate your biosimilar products in China.
_ China's Application Form of Drug Registration in English.
For more information, please see http://www.accesschinainfo.com/articleview.php?id=326

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