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Latest Guidebook for Review and Approval Procedures of Overseas Imported New Drugs for Chinese Clinical Urgent Demand (2019 Edition)

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Abstracts

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. Facing a gigantic population and rapid population aging, the Chinese government accelerated the priority approval of innovative drugs and relaxed the market access for overseas drugs to cope with the clinical urgent demand. In recent years, China’s fast-track approval time is much shorter than any other country, which attracts more and more overseas pharmaceutical manufacturers to enter into the Chinese healthcare market. Undoubtedly the Chinese healthcare market of nearly 1.4 billion populations is a huge business opportunities for the overseas pharmaceutical manufacturers.

The Chinese “National Medical Products Administration (NMPA)” and the “National Health Commission (NHC)” jointly issued the latest “Review and Approval Procedures of Overseas Imported New Drugs for Clinical Urgent Demand” on October 23, 2018, which provided a dedicated pathway for priority review and approval of overseas drugs importing to Chinese healthcare market and clarified the specific review and approval procedures.

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 manufacturers in compliance with the latest “Review and Approval Procedures of Overseas Imported New Drugs for Clinical Urgent Demand”? How do the overseas pharmaceutical manufacturers operate business smoothly in China? The overseas and

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multinational pharmaceutical manufacturers and their senior executive officers engaging in regulatory affairs need a thorough knowledge of the latest regulations for priority review and approval procedures of overseas imported new drugs for Chinese clinical urgent demand. The Chinese regulatory approach is unique.

The Latest Guidebook for Review and Approval Procedures of Overseas Imported New Drugs for Chinese Clinical Urgent Demand (2019 Edition) is an essential resource for overseas and multinational pharmaceutical manufacturers to successfully acquire the marketing authorization in China, which provided a detailed guidance for comprehensive knowledge of the latest regulations on review and approval procedures of overseas imported new drugs for Chinese clinical urgent demand to navigate regulatory requirements step by step.

This guidebook is organized as follows. Chapter 2 provides a latest description of the Chinese changing healthcare market landscape and rapidly changing regulatory framework as background for audience. Chapter 3 introduces that review and approval procedures of overseas imported new drugs of Chinese clinical urgent demand are applicable to what scope of drug varieties. Chapter 4 expounds the selection process of drug varieties. Chapter 5 elaborates the details of review and approval procedures of overseas imported new drugs of Chinese clinical urgent demand. Chapter 6 expounds the Chinese drug regulatory authority's requirements for application materials that overseas applicants apply for overseas imported new drugs of Chinese clinical urgent demand. Chapter 7 expounds the duties and obligations of overseas pharmaceutical manufacturers for drugs exported to Chinese healthcare market. Chapter 8 elaborates the Chinese drug regulatory authority's latest “Administrative Measures for Communication and Exchange on Drug Research and Development and Technical Review and Approval” to guide the overseas applicants to take the key first step entry into the dedicated pathway of priority review and approval procedures and to smoothly pass the review and approval procedures. Chapter 9 exhibits the first batch list of overseas imported new drugs of Chinese clinical urgent demand that has been selected by the Chinese drug regulatory authority, which is calling the overseas applicants to submit the application for marketing in China to the Chinese drug regulatory authority, also let the overseas pharmaceutical manufacturers understand the Chinese drug regulatory authority’s distinctive regulatory current status.The list covers 40 drug varieties that have been approved to market in the United States, EU or Japan but that have not been yet marketed in China, and involves with 33 overseas pharmaceutical manufacturers.

The audiences of this guidebook are the overseas pharmaceutical manufacturers

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wishing to enter into the Chinese healthcare market, and the multinational pharmaceutical manufacturers have penetrated into the Chinese healthcare market, as well as their senior executive officers engaging in regulatory affairs expecting to understand the latest regulations on review and approval procedures of overseas imported new drugs for Chinese clinical urgent demand. After having skimmed through this guidebook, audiences can clearly acquire a comprehensive and thorough knowledge of the latest regulations on priority review and approval procedures of overseas imported new drugs for Chinese clinical urgent demand. Access China Management Consulting Ltd hopes this guidebook, based on the full and accurate regulations, can guide the overseas and multinational pharmaceutical 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)” and the “National Health Commission (NHC)” jointly issued the latest “Review and Approval Procedures of Overseas Imported New Drugs for Clinical Urgent Demand” on October 23, 2018, which provided a dedicated pathway for priority review and approval of overseas drugs importing to Chinese healthcare market and clarified the specific review and approval procedures. This is a huge business opportunities for the overseas pharmaceutical 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 manufacturers in compliance with the latest “Review and Approval Procedures of Overseas Imported New Drugs for Clinical Urgent Demand”? How do the overseas pharmaceutical manufacturers operate business smoothly in China? The overseas and multinational pharmaceutical manufacturers and their senior executive officers engaging in regulatory affairs need a thorough knowledge of the latest regulations for review and approval procedures of overseas imported new drugs for Chinese clinical urgent demand. The Chinese regulatory approach is unique.

The Latest Guidebook for Review and Approval Procedures of Overseas Imported New Drugs for Chinese Clinical Urgent Demand (2019 Edition) is an essential resource for overseas and multinational pharmaceutical manufacturers to successfully acquire the marketing authorization in China, which provided a detailed guidance for comprehensive knowledge of the latest regulations on review and approval procedures of overseas imported new drugs for Chinese clinical urgent demand to navigate regulatory requirements step by step.

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KEY HIGHLIGHTS

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

The latest regulations on priority review and approval procedures of overseas imported new drugs of Chinese clinical urgent demand to smoothly navigate regulatory requirements step by step.

The scope and selection of drug variety for the priority review and approval procedures of overseas imported new drugs for Chinese clinical urgent demand.

The detailed Chinese drug regulatory authority's requirements for application materials that the overseas applicants apply for the overseas imported new drugs of Chinese clinical urgent demand. The overseas applicants should prepare the application materials in strict accordance with these requirements.

The duties and obligations of the overseas applicants on the drugs on the post-marketing in China that are stipulated by the Chinese drug regulatory authority. The overseas applicants must undertake their duties and obligations of their drugs on the post-marketing in China. Otherwise, when the drug on post-marketing has been confirmed to have serious adverse reactions, the Chinese drug regulatory authority will take the emergency control measures to stop sale and use of the drug.

The detailed Chinese drug regulatory authority's latest “Administrative Measures for Communication and Exchange on Drug Research and Development and Technical Review and Approval” to guide the overseas applicants to take the key first step entry into the dedicated pathway of priority review and approval procedures and to smoothly pass the review and approval procedures.

A full set of the English and Chinese bilingual application form, materials and minutes template for Communication and Exchange Meeting, which cover the “Application Form of Communication and Exchange Meeting” (annex 1), “The

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Materials for Communication and Exchange Meeting” (annex 2) and the 'Communication and Exchange Meeting Minutes Template' (annex 3) to guide the overseas applicants how to communicate with the Chinese drug regulatory authority.

The first batch list of overseas imported new drugs for Chinese clinical urgent demand that has been selected by the Chinese drug regulatory authority, which is calling the overseas applicants to submit the application for marketing in China to the Chinese drug regulatory authority, also let the overseas pharmaceutical manufacturers understand the Chinese drug regulatory authority’s distinctive regulatory current status. The list covers 40 drug varieties that have been approved to market in the United States, EU or Japan but that have not been yet marketed in China, and involves with 33 overseas pharmaceutical manufacturers.

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CHAPTER 9 A LIST OF OVERSEAS IMPORTED NEW DRUGS FOR CHINESE CLINICAL URGENT DEMAND

Table 9. List of Overseas Imported Drugs for Chinese Clinical Urgent Demand (The First Batch)

COMPANIES MENTIONED

Janssen Biotech, Inc.
BioMarin Pharmaceutical Inc.
Actelion Pharmaceuticals Ltd.
Kyowa Hakko Kirin Co., Ltd.
Novartis Pharmaceuticals Corporation
Amgen Europe B.V.
Ariad Pharmaceuticals Inc.
Takeda Pharmaceuticals U.S.A., Inc.
Genzyme Corp
Novartis Pharma K.K.
Eli Lilly and Company
CELGENE CORP
Shire Orphan Therapies GmbH
Acorda Therapeutics Inc.
Genentech Inc.
Celgene Corporation
Regeneron Pharmaceuticals, Inc.
Prestwick Pharmaceuticals, Inc.
Dyax Corp.
Shire Human Genetic Therapies Inc.
Pfizer Ltd.
Aegerion Pharmaceuticals Inc.
United Therapeutics Corporation
Biogen Idec Ltd.
Teva Pharmaceutical Industries Ltd.
EUSA Pharma (UK) Limited
Dompé Farmaceutici, s.p.a.
Ultragenyx Pharmaceutical Company

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GlaxoSmithKline Biologicals S.A.
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Cardiome UK Limited
Merck Sharp & Dohme Corp.
Gilead Sciences Inc.

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