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Summary of contents

The patent and regulatory exclusivities under United States law are complex. Developing a life cycle management plan in the early stages of product development is essential to maximise the benefits of the available patent and regulatory exclusivities to recoup investment and maximise profits.

§ 25 Regulatory framework of drug entry to China[13]

1. Introduction

The pharmaceutical industry in China faces many challenges, including drug quality, access and affordability, and drug approval delays. In recent years, policy makers and central government have recognised the quality gaps in drugs and medical devices (MDs) between Chinese and international markets. They have issued reform policies and measures to simplify the evaluation and approval system of pharmaceutical products (ie, introduced a marketing authorisation [MA] holder system as a pilot program) and to encourage innovation in the pharmaceutical industry in China. Such reforms certainly give better opportunities for international pharmaceutical companies to deliver their innovative pharmaceutical products to Chinese patients.

a) Key regulatory bodies

Governance of the Chinese pharmaceutical industry's health care issues falls under the responsibility of many different ministries, commissions and organisations at the national, provincial and local level.

[13] The following paragraph was written by Fiona Gao 高悦, Attorney at Law (New York), China desk, VISCHER AG, Basel.

The China Food and Drug Administration (CFDA) is the primary regulatory body for pharmaceutical products. Its responsibility also includes registering and reviewing new drugs, reviewing and approving clinical trials, importing drugs and issuing good manufacturing practice (GMP), good supply practice (GSP), good clinical practice (GCP), etc. The National Health and Family Planning Commission provides national guidance for health care reform, manages the Essential Drug List (including the basic drugs that medical institutions at all levels shall make available to patients) and public tender. The Ministry of Human Resources and Social Security regulates reimbursement of the basic medical insurance.

b) Regulatory framework

The regulatory framework of drugs in China comprises a large amount of legislation. The key legislation is the Drug Administration Law (revised in 2015) and its Implementing Regulations (revised in 2016), issued by the Standing Committee of the National People's Congress and the State Council respectively. This legislation covers issues in the area of drug manufacturing and distribution, packaging, pricing, advertising, supervision of drugs and legal liabilities. The CFDA issued a number of administrative measures to provide more detailed guidance in those areas. Much of the aforementioned legislation has been revised or issued in the last three years and a number of new administrative measures are in the pipeline. The legislative trend is to simplify the drug approval and importation process and requirements and to provide more protection to patent owners of innovative drugs.

2. Clinical trials

Clinical trials for new drugs (including imported drugs) are governed by the Drug Administration Law and its Implementing Regulations, the Administrative Measures for Drug Registration, the

Drug Good Clinical Practices and the Ethics Committee Review Guidelines.

In order to obtain drug approvals, a clinical trial authorisation is required before conducting Phase I to Phase III clinical trials. The key steps in applying a clinical trial authorisation include formality review of the application, sample testing to verify the drug quality standards, technical review by the Centre for Drug Evaluation (CDE) and administrative review and issuance of the clinical trial authorisation by the CFDA.

On 10 October 2017, the CFDA issued the Decision on Adjusting Relevant Issues Concerning the Administration of Imported Drug Registration (the Decision). This is a milestone legislation expected to greatly expedite drug approval and encourage international pharmaceutical companies to consider China in their global R&D strategy at a much earlier stage.

For a new drug (excluding biological products for preventive use) aiming to conduct an international multicentre clinical trial, the Decision allows Phase I clinical trials to be carried out concurrently in China and in other countries. After completing international multicentre clinical trials, sponsors can apply for new drug applications in China directly.

3. Manufacturing

China's current drug registration mechanism ties the Drug Manufacturing Authorisation with the Drug Approval Number. For international pharmaceutical companies with R&D capacity that have developed innovative drugs, traditionally, there are three possibilities to introduce these new drugs to the Chinese market.

	Options	Potential shortfalls
1.	Set up GMP-certified manufacturing facilities in China	Upfront investment and a sizable experienced local team
2.	License the manufacturing and marketing rights to a Chinese partner	Limited control
3.	Manufacture outside of China and import to China	VAT and import tariffs drive up the drug price

Table 35: Introducing new drugs to the Chinese market.

China introduced the Pilot Plan for the Drug Marketing Authorisation Holder (MAH) System, which is similar to the marketing authorisation system in Europe and in the United States. The Pilot Plan became effective on 26 May 2016 and will expire on 4 November 2018. Currently, the Pilot Plan only applies to drug manufacturers, drug R&D institutes and researchers in 10 provinces and municipalities in China. If the Pilot Plan is ultimately considered successful and the CFDA adopts the MAH system, however, international pharmaceutical companies would have more options to develop their business in China.

4. Drug importation

Drug importation is governed by the Drug Administration Law and its Implementing Regulations, the Administrative Measures for Drug Registration, the Administrative measures for the Import of Drugs, the Customs Law, and the Decision.

An Import Drug Authorisation is required in order to import a drug. The key steps involved include formality review by CFDA, sample inspection and technical review by the China's National Institute for the Control of Pharmaceutical and Biological Products, comprehensive application review by the CDE and issuance of the Import Drug Certificate by the CFDA.

Before each import, the importer must file for a record with the local FDA at the port of entry, where the port drug inspection institute conducts sample quality inspection. The port-based FDA issues a Drug Import Customs Clearance Permit and port inspection notice for imported drugs. The relevant drug inspection institution samples the imported drugs at the port and issues the inspection report within 20 days of sampling.

After the issuance of the Decision (cf. p. 306) on 10 October 2017, imported drugs are no longer required to be marketed in an overseas market before importing to China.