The Pharma Legal Handbook

China

Regulatory, Pricing and Reimbursement Overview · Pre-clinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs · Orphan Drugs and Rare Diseases · Localization · Biosimilars and Biologics

PHARMA BOARDROOM

China

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in China.
It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with Fangda Partners, a leading chinese law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

*** THIS REPORT WAS ORIGINALLY PUBLISHED IN DECEMBER 2018 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**
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Mr. Shin leads the healthcare practice of the firm's corporate group. His experience in the sector includes major transactions in the sub-areas of pharmaceuticals, medical devices and medical services, as well as routinely offering advice to clients on regulatory developments in issues at the forefront of this area of law. Josh is regularly called on to offer comprehensive legal advices to MNCs and biotech start-ups on issues arising from daily operations to cover pipeline induction, clinical development, HGR administration, commercialization, patient programs, interaction with interest groups, etc., and was commissioned de facto general counsel roles in certain companies to oversee their legal establishment. He was mentioned as leading lawyer for healthcare by Chambers and Partners – Asia Pacific 2019 through 2021, and as leading individual for life sciences by Legal 500 2020 & 2021.

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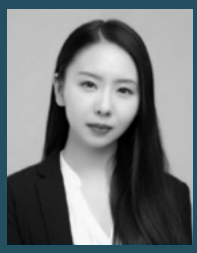

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

Several governmental agencies are responsible for the administration of drugs (including biologicals) and medical devices, including the following key players:

- The National Medical Product Administration ("NMPA"), formerly known as the China Food and Drug Administration, which is responsible for issuing marketing authorizations of drugs and medical devices and monitoring product quality.
- The National Health Commission ("NHC"), which is responsible for the overall guidance of healthcare reform, administering China's Essential Drug List ("EDL") and managing the drug tendering and procurement policies.
- The Ministry of Human Resources and Social Security ("MOHRSS"), the authority that takes the lead in formulating the National Drug Reimbursement List ("NRDL").

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

Drugs

Key Regulations

The fundamental pieces of legislation for the pharmaceutical industry are the Drug Administration Law and the Implementing Rules of Drug Administration Law. In addition, the NMPA has issued a wide range of other regulations and implementing measures to regulate the pharmaceutical industry.

Authorization

Steps to obtain the marketing authorization for drugs are mainly set out in the Drug Registration Administrative Measures. In general, all new drug candidates must go through four steps before being marketed: pre-clinical research, application for clinical trial of an investigational new drug, clinical trials and new drug application.

- Pre-clinical research of a drug candidate must be conducted in accordance with the Good Laboratory Practices ("GLP").
- After completing the pre-clinical research, a clinical study sponsor must obtain approval for clinical trials from the NMPA's Center for Drug Evaluation ("CDE") to conduct clinical trials on the investigational new drug. In July 2018, the NMPA promulgated a new rule that if an applicant for clinical trials does not receive any negative opinions from the CDE within 60 days after the date on which the application was accepted, the clinical trials may be initiated and conducted in accordance with the protocols previously submitted to the CDE in the application.

• After obtaining the approval of a clinical trial, the sponsor shall conduct the clinical trial at Good Clinical Practice ("GCP") certified institutions. Clinical trials are divided into Phase I, Phase II, Phase III and Phase IV, of which Phase IV refers to post-marketing clinical trials.
• Upon completion of the Phase III clinical trial, the sponsor may submit a new drug application for approval to manufacture and launch such investigational new drug.

Pricing

• **Terminal Units of Non-Public Hospitals**

The price of drugs was previously regulated under a scheme of maximum retail price ("MRP") of drugs set by the government, which was abolished (except for narcotic and certain psychotropic drugs) in June 2015.

• **Public Hospitals**

- Centralized Drug Procurement Program. Competitive bids shall be used to purchase medications and be carried out by local governmental authorities on a province-by-province basis under the central coordination of NHC. Public hospitals used to be allowed to mark up drugs by around 15% above procurement prices. This policy has been replaced with the "zero-mark-up" (i.e., no-profit, the drug price that a hospital charges the patient should be the same as it pays to the drug suppliers) policy in July 2017.
- Volume-Based Procurement. The National Healthcare Security Administration ("NHSA") will directly negotiate with pharmaceutical companies about drug supply for public hospitals and strive to get favorable terms by insisting on bulk purchasing. The participant with the lowest tender price will be the bid winner. By securing the purchase price at the terminal end, the cost at each distribution phase upwards will be reduced, which ultimately leads to an end lower price.

Reimbursement

In terms of reimbursement for the cost of drugs, China's medical insurance system was first adopted in 1998 and has now been gradually expanded to provide coverage for most of the population in China. Individual participants of the national medical insurance program and their employers (if any) are required to contribute to the medical insurance funds by paying an insurance premium monthly. Medical insurance program participants are eligible for full or partial reimbursement of the cost of medicines included in the NRDL, which contains over 2,000 Western and Chinese medicines that are divided into Class A and Class B drugs. Class A drugs typically include low-priced and clinically necessary drugs that can be fully reimbursed, and the Class B drug catalogue typically includes higher-priced or new drugs that generally require the patients to assume 10-40% of the drug's total cost.

The latest NRDL issued in 2020 includes a total of 2,800 drug products, of which 1,264 are Western medicines and 1,315 are proprietary Chinese

medicines. Two hundred and twenty-one (221) drug products are NHSA negotiation-based drugs which will be supplied at an agreed low price during the term of the applicable purchase agreement. Each province may formulate its own Provincial Drug Reimbursement List based on the NRDL and subject to certain restrictions and procedures, but it is likely that the provincial version of the Reimbursement Drug List may be abandoned in the future.

Medical Devices

Key Regulations

The fundamental legislation for the medical devices industry is the Medical Device Supervision and Administration Regulations. A wide range of other regulations and implementing measures have been issued by the NMPA to guide the medical devices industry.

Authorization

Under the Medical Device Registration Administrative Measures, devices can be categorized into Class I, Class II and Class III devices. Class I devices are simple devices that are exempted from clinical trials and are administered through a record-filing system. Class II and Class III devices are more complex devices with medium or high risks, and their safety should be evidenced by clinical trials (unless being on the list of devices exempted from clinical trials) and the devices shall be registered with the NMPA before entering the market.

Pricing

There is no MRP scheme in the medical devices industry. Similar to the mark-up policy previously applicable to drugs, public hospitals are still allowed to charge a certain mark-up on the medical devices purchased by them (for example, a maximum of 5% mark-up is allowed in Shanghai, provided that the purchase price for a medical device exceeds RMB4,000 and the mark-up should not exceed RMB200).

Reimbursement

At the national level, there is a negative list that precludes certain devices (such as glasses and massage devices) from governmental reimbursement. Detailed reimbursement coverage and rates for medical devices are subject to local policies in each province.

3. What are the steps to obtaining authorization to develop, test, and market a product?

Please refer to Question 2 of Chapter 1 regarding the authorizations of drugs and medical products.

4. What are the approximate fees for each authorization?

The table below lists the government fees charged by the NMPA for each category of registration: