The Pharma Legal Handbook

Asia

Regulatory, Pricing, and Reimbursement Overview

PHARMA BOARDROOM

Regulatory, Pricing and Reimbursement Overview

This Pharma Legal Handbook answers essential questions about the legal and regulatory environment in 8 countries.

Prepared in association with leading local and international law firms and consultancies, it is a must-have for any company operating in/or looking to enter these niches in any of these countries.

* THIS REPORT WAS ORIGINALLY PUBLISHED IN OCTOBER 2019 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.
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China

This chapter about Regulatory, Pricing and Reimbursement in China was published in association with:

FANGDA PARTNERS
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Fangda Partners is one of the first private PRC law firms established under China's contemporary legal system. We have over 550 lawyers serving international and domestic clients in various commercial matters through our teams in Beijing, Guangzhou, Shanghai, Shenzhen and Hong Kong. We are one of the leading full service PRC and Hong Kong commercial law firms with practices covering general corporate, merger and acquisition, private equity, capital markets, intellectual property, real estate, construction, infrastructure development, dispute resolution, banking and finance, labour and employment, dispute resolution and other important areas of legal practices.

We pride ourselves on the quality of our work. Our goal is to be the firm of choice for the most challenging transactions and most difficult legal issues in China. The two characters of the firm's Chinese name, "fang" and "da", meaning "integrity" and "open-mindedness", are a short-form mission statement of our practice.

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THE AUTHORS

China

JOSH SHIN

PARTNER

Mr. Josh Shin specializes in M&A, general corporate advices, private equity investment, and overseas capital markets, with a strong track record in various legal issues in the pharmaceutical, life science and healthcare sectors.

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 regularly offering advice to clients on regulatory developments in issues at the forefront of this area of law. Josh's recent experience in the healthcare area includes proposed acquisition by private equity fund of Cardinal Health's China business, Bayer's acquisition of Dihon Pharmaceuticals, Wuxi AppTec's joint venture with Mayo Clinics, exclusive commercialization/licensing arrangement of a number of drugs owned by big pharma, and the overseas IPO of a number of biotech companies. Mr. Shin is nominated as recognized practitioner for Healthcare by Chambers Asia Pacific 2019.

TIANSHAN WANG

ASSOCIATE

Mr. Tianshan Wang is a corporate lawyer based in the Shanghai office of Fangda Partners. He has extensive experience over healthcare related matters, including: representing BeiGene in its secondary offering on the main board of Hong Kong Stock Exchange; representing J.P. Morgan in the initial public offering and listing of Zai Lab on NASDAQ; representing Novartis and AstraZeneca in its granting of exclusive commercialization rights to other pharmaceutical companies; and advising multi-national pharmaceutical corporations including Bayer, AstraZeneca, Mylan, Carestream Dental on their general corporate matters such as FDI, liquidation, merger and division, compliance, sales and distribution. Tianshan Wang is qualified to practice in the PRC.

REGULATORY, PRICING AND REIMBURSEMENT OVERVIEW

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

Responsibilities for the administration of drugs (including biologicals) and medical devices are assumed by several governmental agencies, including the following key players:

- National Medical Product Administration (NMPA), formerly known as China Food and Drug Administration, which is responsible for issuing marketing authorizations of drugs and medical devices and monitoring product quality.
- 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.
- 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 legislations for the drug industry are the Drug Administration Law and its Implementing Rules. A wide range of other regulations and implementing measures have been issued by the NMPA to guide 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 drugs must go through four steps before being marketed: pre-clinical research, application for clinical trial, clinical trial and approval for production.

- Pre-clinical research of a drug shall be conducted in accordance with the Good Laboratory Practices (GLP).
- After completing the pre-clinical research, the applicant must obtain approval for clinical trials from the NMPA's Center for Drug Evaluation (CDE) to conduct new clinical drug trials. In July 2018, NMPA promulgated a new rule that if an applicant for clinical trial does not receive any negative opinions from the CDE within 60 days after the date of accepting the application, the drug clinical trials may be conducted in accordance with the plan submitted to the CDE.
- After the approval of a clinical trial, the applicant shall conduct the clinical rial at good-clinical-practice (GCP) certified institutions. Clinical trials

are divided into Phase I, Phase II, Phase III and Phase IV, among which, Phase IV is post-marketing clinical trials.

• Upon completion of Phase III clinical trial, the applicant can submit a new drug application for approval to manufacture and launch such new drugs.

Pricing

The price control of drugs was previously based upon a scheme of maximum retail price (MRP) of drugs set by the government, which was abolished (with the exception of narcotic and certain psychotropic drugs) in June 2015. On the other hand, public hospitals were allowed to mark-up drugs by around 15% above procurement prices, which has been replaced by the "zero-mark-up" (i.e., no-profit, the drug price that hospital charges the patient should be the same as it pays to the drug suppliers) policy since July 2017.

Reimbursement

In terms of the reimbursement of drugs, China's medical insurance system was first adopted in 1998 and has now been gradually expanded to provide coverage for the majority of the population. Participants of the national medical insurance program and their employers (if any), are required to contribute to the payment of an insurance premium on a monthly basis. Medical insurance program participants are eligible for full or partial reimbursement of the cost of medicines included in the NRDL, which includes 2,535 drugs that are divided into Class A and Class B drugs. Class A drugs typically include low-priced and clinically necessary drugs that are fully reimbursed, and the Class B drugs catalogue typically includes higher-priced or new drugs that generally require the patients to assume 10-30% of the drug's cost. Each province is allowed to issue its own drug reimbursement list (PRDL) based upon the NRDL, provided that Class A drugs in the NRDL should be kept and maintained and the adjustment to the Class B drugs should not be greater than 15%.

MEDICAL DEVICES

Key Regulations

The fundamental legislation for the medical device 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 device 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 administered through a filing system. Class II and Class III devices are more complex devices with medium or high risks and should be supported by clinical trials (unless being on the list of devices exempted from clinical trials) and registered with the NMPA before entering into the market.

Pricing

There is no MRP scheme in the medical device sector. 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 RMB 4,000, and the mark-up should not exceed RMB 200).

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 rate for medical devices are subject to local policies at each province.

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

Please refer to **Question 2** 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 NMPA for each category of registration:

CATEGORY	SUB-CATEGORY		FEE (RMB 10,000)
Domestic drug	New drug	Clinical trial approval	19.2
		Marketing authorization	43.2
	Generic drug	Marketing authorization (clinical trial is waived)	18.36
		Marketing authorization (clinical trial is required)	31.8
	Supplementary registration	Regular registration items	0.96
		Registration items requiring technical review	9.96
	Renewal application		Set by the provinical authority
Imported drugs	New drug	Clinical trial approval	37.6
		Marketing authorization	59.39
	Generic drug	Marketing authorization (clinical trial is waived)	36.76
		Marketing authorization (clinical trial is required)	50.2
	Supplementary registration	Regular registration items	0.96
		Registration items requiring technical review	28.36
	Renewal application		22.72