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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?

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 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 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
Domestic devices[1]	Class III	Marketing authorization	15.36
		Post-marketing amendment registration	5.04
		Renewal registration	4.08

[1] Government fees for domestic or imported Class I and Class II medical devices are set by the provincial authority.

CATEGORY	SUB-CATEGORY		FEE (RMB 10,000)
Imported devices	Class II	Marketing authorization	21.09
		Post-marketing amendment registration	4.2
		Renewal registration	4.08
	Class III	Marketing authorization	30.88
		Post-marketing amendment registration	5.04
		Renewal registration	4.08

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

Marketing authorizations for drugs and medical devices are valid for a term of five years. The applicant must prepare and submit the renewal application documents to the provincial NMPA six months before the expiry of the marketing authorization. In addition to reviewing of the application documents, the authority may determine to conduct technical review and on-site inspection when it deems necessary.

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

In March 2016, NMPA issued the Reform Plan for Registration Category of Chemical Drugs which reclassified drug applications as follows:

CATEGORY 1 DRUGS	New drugs that have not been marketed anywhere in the world.
CATEGORY 2 DRUGS	Improved new drugs that are not marketed anywhere in the world.
CATEGORY 3 DRUGS	Drugs that have equivalent quality and efficacy to the brand-name drugs have been marketed abroad but not yet in China.
CATEGORY 4 DRUGS	Drugs that have equivalent quality and efficacy to the brand-name drugs and have been marketed in China.
CATEGORY 5 DRUGS	Drugs that have already been marketed abroad, but are not yet approved in China.

In general, generic drugs follow similar registration pathways to brand-name drugs. The applicant needs to conduct bioequivalence (BE) tests for generic drugs to demonstrate conformity with the brand-name drugs. BE tests are administrated through the record-filing system, instead of the review and approval process applicable to new drugs. The BE applicant only needs to file record on the Clinical Trial Management Public Platform designated by NMPA and can start the clinical trial after obtaining the filing number. In addition, Category 1 new drugs may be entitled to certain preferential policies that are