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A LEGISLATIVE PRESCRIPTION FOR THE ILLS OF
THE DRUG INDUSTRY

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PUBLISHED IN *CHINA LAW & PRACTICE*
APRIL 2001



A Legislative Prescription for the Ills of the Drug Industry

On February 28, 2001 the Standing Committee of the National People's Congress (NPC) significantly amended the *PRC, Administration of Pharmaceuticals Law* (the Law). The Law governs China's pharmaceutical industry, a multi-billion dollar industry that has attracted investment from most of the world's largest pharmaceutical companies and has been growing about 20% annually for several years. After more than a year and a half of drafting and deliberation, more than 100 articles were deleted, modified or added to the Law. Only four articles from the original Law were left untouched, and the total number of articles increased from 60 to 106. Because the changes were so extensive, the NPC Standing Committee restated the Law in its entirety rather than issuing a list of particular changes.

BACKGROUND

The Law was originally adopted in 1984 and became effective on July 1, 1985. The amended Law will go into effect on December 1, 2001. Generally, the amended Law follows the organizational structure of the original Law. The amended law strengthens the legislative foundation over pharmaceutical regulation, including approvals, manufacturing, storage, packaging, prescriptions, advertising and pricing. Several changes merely codify, at the legislative level, what had already been implemented through administrative regulations or in practice. The amended Law will apply to foreign-invested enterprises and market participants even though domestic issues within the PRC pharmaceutical industry and its evolving regulatory system largely drive the amendments.

EVOLVING REGULATORY STRUCTURE

The pharmaceutical industry remains subject in certain respects to state planning under Article 5 because of the industry's social and economic importance, and because the state directly or indirectly bears much of the cost of pharmaceuticals. Since the original Law was adopted in 1984 a number of changes have been made in the regulation of the pharmaceutical industry. The State Drug Administration (SDA) was created in 1998, combining functions formerly under the Ministry of Public Health, former State Pharmaceutical Administration and State Administration of Traditional Chinese Medicines (TCMs).¹ While the original Law created the pre-SDA regulatory structure, the amended Law reflects the centralization of authority over drugs in the SDA and other organizational reforms. The amended Law specifies that the SDA (referred to as the State Council department of drug supervision and administration) is in charge of national drug administration, and a number of articles in the amended Law relate specifically to the role that SDA plays in relation to other government departments and provincial drug administrations (the PDAs).

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KEY POINTS

- Amendments to the *PRC, Administration of Pharmaceuticals Law (Revised)*.
- Third-party manufacturing allowed.
- Tougher and more extensive anti-corruption measures.
- Imports permitted only at designated ports.
- New standards for wholesalers and retailers.
- Drugs classified as prescription or over-the-counter.
- No mass-media advertising of prescription drugs.

The amended Law lessens the administrative burden with respect to the:

- (a) establishment of enterprises to manufacture or sell drugs; and
- (b) approval of new drugs.

Chapters 2 and 3 maintain the distinction between manufacturing enterprises (*shengchan qiye*) and trading or non-manufacturing enterprises (*jingying qiye* either retail or wholesale). An approval certificate is needed to engage in manufacturing or non-manufacturing of activity. Previously, approval was required from two local government departments before a company could even apply for registration. Under the original Law, the provincial health administration and the provincial pharmaceutical administration *both* had to grant approvals and issue permits before an enterprise could register with the local Administration of Industry and Commerce (AIC), meaning a drug company required two industry permits as well as a business license before commencing operations. Article 14 now requires approval only by the PDA and local AIC for establishment of a drug manufacturing or non-manufacturing enterprise (one permit and one business license). Approval authority for a retail non-manufacturing enterprise rests with the drug administration at the county level or above.

The operations of such enterprises are made subject to more stringent regulations. Chapter 3 establishes substantially more comprehensive requirements for the operations of trading enterprises with respect to record keeping, qualifications of personnel and the storage of pharmaceuticals. Articles 26-28 establish similar requirements for medical institutions.²

Overlapping approval powers and local protectionism also are reduced with respect to approval procedures for new drugs. Some PDAs had exercised their own approval authority over drugs so that national approval of a new drug could mark just the beginning, rather than the end, of a manufacturer's administrative travails. Articles 29 through 31 eliminate local approval authority for drugs and vest sole responsibility with

the SDA drug approvals. Article 69 similarly proscribes local governments and PDAs from implementing any drug inspections or examination and approval procedures that limit or exclude non-local products.

The accompanying chart details the allocation of key regulatory duties under the amended Law. The SDA and/or PDAs hold responsibility for most tasks, while the Ministry of Health, State Development and planning Commission (SDPC) and the State Administration of TCMs also have certain specified regulatory duties with respect to pharmaceuticals as generally provided in Article 5 of the amended Law.

INTELLECTUAL PROPERTY

Article 4 provides for State research support and intellectual property protection with respect to the research and development of new medicines. This change essentially reflects the patent and administrative protections that already exist for new drugs. However, the statute's broad language (which remains a characteristic of Chinese legislative drafting) about encouraging and protecting new drugs is not without significance. When the Law was initially adopted in 1984, the PRC afforded no patent protection to drugs, and the industry's over-capacity for generic production and paltry investment in research continue to be of concern. Thus, the amended Law signals both the evolution that has already occurred with regard to IP protection for drugs in China and the potential for further improvement.

Article 36 also provides that the State Council will establish a protection system for pharmaceutical materials, which will be especially important for botanical resources. Article 3 also provides State protection for wild plants with medicinal value.

TOLL MANUFACTURING ALLOWED

It has been impermissible until recently for an approved drug manufacturer to manufacture drugs on behalf of another business, even though the drug had already been approved for manufacturing in China.³ Now third-party or "entrusted manufacturing" (*weituo shengchan*), that is, toll manufacturing, is allowed under Article 13 upon SDA approval (or approval by a PDA specially authorized by the SDA to grant such approval). The amended Law oddly provides, however, that drug manufacturers may *accept* entrusted manufacturing but does not explicitly authorize them to entrust manufacturing to others.

PRESCRIPTION DRUGS V NON-PRESCRIPTION DRUGS

Article 37 codifies the regulatory distinction between prescription and non-prescription or over-the-counter drugs in PRC law,⁴ and charges the State Council to formulate detailed measures.

ADVERTISING RESTRICTIONS

The advertising of pharmaceuticals is heavily restricted. Drug ads under Articles 60 and 62 must be approved in advance by PDAs (requiring multiple local approvals for a national marketing campaign) and cannot use the images or titles of any state organization, medical research institution, academic institution, expert, academic, doctor or patient. These restrictions are codified in the amended Law.⁵ Additional restrictions on advertising content are found in the 1994 *PRC, Advertising Law* that further proscribes advertising content related to curative rates and comparisons with other medicines in terms of safety or efficacy.

Importantly, Article 60 completely bans advertising directed to mass audiences for prescription drugs. Prescription drugs can only be advertised through certain publications jointly designated by the SDA and the Ministry of Health that are directed to a professional medical and pharmacological audience.

PRICE CONTROLS

Over recent years the cost of pharmaceutical products has been of particular concern in China. According to a 1998 report by the U.S. Foreign and Commercial Service, drug costs constitute 60% of health care spending in China, in contrast to 8% in the United States. However, because the domestic pharmaceutical industry is characterized by low R&D investment and sluggish innovation, price competition has been the main battleground among suppliers. Hospitals, which dispense most medicines in China, have relied on the sale of drugs to patients and their leverage over suppliers to maximize their own revenue. PRC authorities have attempted to reign in these costs by creating a list of drugs for which reimbursement is available and by instituting price controls in 1996.⁶

Who Regulates What in PRC Pharmaceuticals	
Actions	Approval Authority or Authorities
New Drug Approval	SDA
Import Drug Approval	SDA
License to Make a Drug (other than TCMs)	SDA
Set Drug Prices	SDPC
Establish List of Reimbursable Drugs	Ministry of Labour and Social Security (partially subject to local modification)
Permit to Establish a Drug Manufacturing Enterprise	PDA AIC
Permit to Establish a Wholesale Drug Trading Enterprise	PDA AIC
Permit to Establish a Retail Drug Trading Enterprise	Drug administration authority at or above the county level AIC
Certificate of Compliance with Manufacturing Quality Standards	SDA makes the standards and issues compliance certificate Initial application to PDA
Certificate of Compliance with Drug Trading (<i>jingying</i>) Standards	SDA makes the standards and issues compliance certificate Initial application to PDA
Permission to Conduct Clinical Trials	Under current SDA regulations, PDA has preliminary approval and SDA issues final approval — no explicit change in amended Law
Qualification to Conduct Clinical Trials	SDA MOH
Authorization for Hospital to Prepare Drug Compounds (<i>peizhi zhiji</i>)	Provincial Health Bureaus (<i>weisheng xingzheng bumen</i>) to examine and verify (<i>shenhe</i>) and consent (<i>tongyi</i>) PDA-approval (<i>pizhun</i>) and issuance of permit

Chapter 7 sets out broad principles that apply to drug pricing and seeks to control profiteering by medical institutions and their staff members by establishing reporting obligations and prohibiting suppliers from conferring benefits on those who make purchasing decisions on behalf of medical institutions. Articles 55 and 56 distinguish drugs with government fixed prices, government guidance prices and market prices. The State Development and Planning Commission (SDPC) is to set prices in accordance with costs, supply and demand and “society’s capacity to absorb prices.” It is charged with protecting the interests of consumers.

Even with regard to drug prices set through market mechanisms, drug companies and medical institutions under Article 56 are instructed “to provide drug users with reasonably priced drugs,” to be fair and reasonable, to act in good faith and to ensure that prices accord with quality. Exorbitant profits (*bao li*) are prohibited.

Medical institutions are required under Article 58 to provide patients with a price list of all drugs used in the patient’s care, and medical institutions that are designated (*ding dian*) to provide treatment covered by medical insurance must periodically make publicly available the price list of commonly used drugs. The Ministry of Health is to stipulate specific measures for these reporting obligations.

NEW STANDARDS FOR RESELLERS

For some time the PRC has required all newly approved drug manufacturers or those seeking approval to produce a new drug to meet standards for Good Manufacturing Practices (GMP).⁷ Article 16 requires that non-manufacturing pharmaceutical companies meet standards for Good Supply Practices (GSP). These standards are set by the SDA, and enterprises that meet the standards are given a certificate of compliance, although it is unclear whether the SDA or PDAs will manage this.

To date, less than 10% of the PRC’s more than 6,300 domestic drug makers have obtained GMP certification, and even fewer resellers have met GSP standards.⁸

IMPORT CONTROLS

Articles 38 to 42 and 45 to 46 codify administrative procedures with respect to imported drugs, apparently in accordance with the controls imposed on domestically manufactured drugs, especially for new drugs.⁹ Article 40 requires that drugs be imported through designated ports (although the procedures for designating ports are not specified). Importers register with the drug administration authority at the port of entry. Customs officials are prohibited from releasing drugs that are not on a drug import clearance list issued by the drug administration (presumably the SDA, though the level of government is not specified). The amended Law permits exceptions from drug importation approval formalities for drugs to be used in small quantities by medical institutions for urgent clinical needs or for individual use.

Import duties on pharmaceuticals will drop from an average of approximately 12% to 6% or less as part of China's WTO accession, so the drug importation rules will become even more important.

ANTI-CORRUPTION MEASURES

Article 70 prohibits PRC drug regulators from commercially participating in the industry they regulate. It bans the SDA, PDAs, their affiliated departments, officially authorized drug inspection entities, and personnel in any of these organizations from participating in the pharmaceutical business. Violations are punishable under Articles 94 and 95. The department or supervisory organ at the next higher level shall issue a stop order, illegal income will be confiscated and, in serious cases, directly responsible personnel will be subject to administrative punishment.

To curb corruption, Article 65 prohibits the collection of fees as part of the selective drug inspection process and provides that expenses for inspections will be handled in accordance with State Council regulations. Article 96 prescribes sanctions for drug quality inspectors who illegally collect fees for inspections.

Article 90 makes it illegal for drug companies to give any property, benefits or off-the-books kickbacks (*huikou*) to doctors, purchasing agents, responsible personnel, or other relevant personnel at medical institutions who can select drug suppliers. Article 91 correspondingly prohibits such personnel from receiving such benefits. The prohibitions on such practices codify recent regulations.¹⁰ The ban on conferring benefits to those who control the purchasing decisions is intended to work in conjunction with price controls to lower health care costs. Increasing penalties for violations enhances deterrence.

PENALTIES FOR VIOLATIONS

The most-expanded section of the Law is the section on legal responsibility. Chapter 9 spells out the range of penalties for violations of specific provisions. The general menu of punishments includes administrative penalties, criminal sanctions and a duty to pay compensation to those harmed. Administrative penalties include confiscation of illegally earned revenue or illegally made drugs, fines up to five times the amount of the illegal revenue or the value of the illegal drugs (or their legitimate equivalent, if fake), suspension or cancellation of permits and business licenses, and banishment from the pharmaceutical industry for long periods. Criminal penalties are not spelled out and therefore refer to such generally applicable provisions of the *PRC, Criminal Law* as Section 1 on Crimes of Manufacturing Fake and Shoddy Goods.

Many penalty provisions are directed at "directly responsible personnel." Penalties were previously assessed solely against business entities, which apparently was insufficient as a deterrent. Moreover, many penalty provisions are directed at officials. The amended Law subjects officials to criminal penalties for a range of unauthorized acts, including the approval of non-compliant advertisements under Article 92.

Article 77 also provides liability for those who provide shipping, storage, protection or otherwise facilitate drugs that the party “knows or should have known” were fake or inferior. Penalties for such knowing facilitation can include income confiscation, fines ranging from 50% to three times the amount of such income, and criminal penalties.

OVERALL ASSESSMENT

Enactment of the amended Law updates the statute and demonstrates that PRC authorities are concerned about the clarification and streamlining of regulatory duties, the high cost of drugs, local protectionism, corruption, and fake and inferior quality medicines. The amended Law seeks to address these problems by simplifying procedures and more clearly demarcating official administrative responsibilities, establishing principles for price management, granting the SDA sole authority to approve drugs, prohibiting the erection of local trade barriers, prohibiting regulators. from engaging in commerce and strengthening penalties for violations.

Other aspects of the amended Law of particular interest to foreign investors are the creation of basis for toll manufacturing, the requirement that drugs be imported at designated ports, and the prohibition on mass advertising of prescription drugs. As China’s pharmaceutical industry continues to grow in size and sophistication, global pharmaceutical companies drawn. to the market will find that it is governed by an increasingly comprehensive regulatory structure.

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¹ Although the definition of “drug” in Article 102 of the Law includes TCMs, many provisions of the amended Law do not apply to TCMs. Although importing TCM materials into China is a very substantial business, TCMs are not addressed here except to the extent that they are covered by the general provisions of the Law.

² China reportedly has more than 311,000 medical institutions, of which 16,678 are classified as hospitals, 3,200 of which can be found in urban areas. See *A Guide to Interpretation and Application of the PRC Drug Administration Law*, Hu Jihua and Zhang Guilong, eds. (2001), page 95.

³ *Notice Concerning Regulations Related to Manufacturing Drugs in Different Localities and Entrusted Processing*, SDA, October 8, 1999.

⁴ *Provisional Administrative Measures on the Classification of Prescription and Non-Prescription Medicines*, SDA Order #10, June 18, 1999; *Interim Rules on the*

- Distribution of Prescription and Non-Prescription Drugs*, SDA, December 28, 1999.
- ⁵ *Notice Concerning Strengthening Prescription Drug Advertisement Examination and Investigation Work*, SDA and SAIC, January 12, 2001; *Explanation Concerning the Cessation of Mass-Media Advertising of Prescription Drugs*, SDA, January 23, 2001.
- ⁶ *Provisional Measures on Administration of Drug Prices*, (SDPC), September 15, 1966 and *Supplementary Provisions on the Provisional Measures on Administration of Drug Prices*, SDPC, February 2, 1997. The price control mechanism was revised in 2000. See *Opinions Concerning the Reform of Administration of Drug Prices*, SDPC, July 20, 2000; *Catalogue of Drugs Subject to Price Determination*, SDPC, December 21, 2000, *Measures for Government to Determine Drug Prices*, SDPC, December 21, 2000; *Circular Concerning Issues on Determination and Adjustment of Category 'B' Drug Prices*, SDPC, December 21, 2000; *Measures for Examination and Approval of Government Determination of Drug Price Applications*, SDPC, December 21, 2000; and *Measures on Drug Price Monitoring*, SDPC, December 21, 2000.
- ⁷ Article 9; SDA, *Administration of Pharmaceutical Production Quality Guidelines* June 18, 1999 and SDA, *New Pharmaceuticals Examination and Approval Procedures*, April 21, 1999.
- ⁸ Hu and Zhang, page 8.
- ⁹ SDA, *Administration of Imported Pharmaceuticals Procedures*, effective May 1, 1999.
- ¹⁰ *Circular on Implementation Opinions Concerning Correcting Malpractice In Pharmaceutical Sales*, State Council, August 1999 and March 2000; *Implementing Opinions Concerning Vigorous Measure to Break Malpractice in Pharmaceutical Sales*, MOH 1999; *Circular Concerning the Strict Prohibition of Providing Sales Commissions Such as Clinical Promotion Fees, Prescription Fees And Others*, MOH September 7, 1998.