Drug Administration Law of the PRC

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Chapter I — General Provisions

Article 1 — This Law is enacted for the purposes of strengthening the supervision and administration of drugs, ensuring drug quality, safeguarding the safety of drug use by the people, protecting the health of the people, and promoting the healthy development of the pharmaceutical industry.

Article 2 — This Law applies to activities of drug research and development, production, distribution, use, supervision and administration, and other drug-related activities within the territory of the People's Republic of China.

Article 3 — Drug administration shall be centered on the health of the people, shall adhere to the principles of risk management, whole-process control, and social co-governance, shall establish scientific and rigorous supervision and administration systems, shall comprehensively enhance drug quality, and shall safeguard the safety, efficacy, and accessibility of drugs.

Article 4 — The state shall encourage the research, development, and creation of new drugs and shall protect the lawful rights and interests of citizens, legal persons, and other organizations in the research, development, and creation of new drugs.

Article 5 — The state shall establish a drug traceability system. Drug marketing authorization holders, drug manufacturers, drug distributors, and medical institutions shall establish and implement a drug traceability system, provide traceability information in accordance with the provisions, and ensure the traceability of drugs.

Article 6 — The state shall establish a system for the reporting and monitoring of adverse drug reactions. Drug marketing authorization holders shall conduct surveillance of adverse drug reactions in accordance with the law, and shall report and evaluate adverse drug reactions.

Chapter II — Research, Development and Registration of Drugs

Article 7 — The research and development of drugs shall comply with the provisions of laws, regulations, rules, standards, and norms and shall ensure that the relevant data and materials are truthful, complete, and reliable. The non-clinical safety evaluation study and clinical trial of drugs shall comply with the relevant good practices.

Article 8 — The State Council's drug regulatory department shall organize the pharmaceutical, medical, and other scientific and technical personnel to evaluate new drugs and shall approve the clinical trials and marketing of new drugs.

Article 9 — The application for drug registration shall be accompanied by sufficient research data demonstrating the safety, efficacy, and quality controllability of the drug. The State Council's drug regulatory department shall review the safety, efficacy, and quality controllability of the drug applied for registration.

Article 10 — Drugs shall comply with the national drug standards. The national drug standards shall include the Pharmacopoeia of the People's Republic of China and the drug standards issued by the State Council's drug regulatory department. The Pharmacopoeia of the People's Republic of China and the drug standards issued by the State Council's drug regulatory department are the national drug standards.

Chapter III — Drug Manufacturers

Article 11 — The establishment of a drug manufacturer shall be subject to the approval of the drug regulatory department of the people's government of the province, autonomous region, or municipality directly under the central government where the enterprise is located, and a Drug Manufacturing Permit shall be issued. Without a Drug Manufacturing Permit, no enterprise shall manufacture drugs.

Article 12 — A drug manufacturer must manufacture drugs in accordance with the Good Manufacturing Practice for Pharmaceutical Products (GMP) formulated by the State Council's drug regulatory department based on this Law. The drug regulatory department shall conduct GMP compliance inspections of drug manufacturers in accordance with the provisions.

Article 13 — Drugs must be manufactured in accordance with the national drug standards and the manufacturing processes approved by the State Council's drug regulatory department, and the manufacturing records must be complete and accurate. Drug manufacturers shall not change the manufacturing process without authorization.

Chapter IV — Drug Distributors

Article 14 — The establishment of a drug wholesaler shall be subject to the approval of the drug regulatory department of the people's government of the province, autonomous region, or municipality directly under the central government where the enterprise is located, and a Drug Distribution Permit shall be issued. The establishment of a drug retailer shall be subject to the approval of the drug regulatory department of the local people's government at or above the county level, and a Drug Distribution Permit shall be issued. Without a Drug Distribution Permit, no enterprise shall distribute drugs.

Article 15 — A drug distributor must distribute drugs in accordance with the Good Supply Practice for Pharmaceutical Products (GSP) formulated by the State Council's drug regulatory department based on this Law.

Chapter V — Drugs for Medical Institutions

Article 16 — Medical institutions must purchase drugs from enterprises holding Drug Manufacturing Permits or Drug Distribution Permits. Medical institutions shall have facilities, equipment, storage conditions, and a hygiene environment commensurate with the types of drugs they use, and shall adopt measures to ensure drug quality.

Article 17 — Medical institutions dispensing pharmaceutical preparations shall be subject to examination by the drug regulatory departments of the people's governments of provinces, autonomous regions, and municipalities directly under the central government, and a Dispensing Permit for Medical Institutions shall be issued upon approval.

Chapter VI — Control over Drugs

Article 18 — The state shall implement a classification management system for prescription drugs and over-the-counter drugs. Specific measures shall be formulated by the State Council's drug regulatory department in conjunction with the State Council's health administrative department.

Article 19 — The importation of drugs shall be subject to the examination and approval of the State Council's drug regulatory department. Only drugs that have passed the examination may be imported. The drugs to be imported must be subject to an import drug registration certificate or a pharmaceutical product registration certificate issued by the State Council's drug regulatory department.

Article 20 — Narcotic drugs, psychotropic substances, toxic drugs for medical use, and radioactive drugs shall be subject to special control measures, and the measures for their control shall be formulated by the State Council.

Source: https://www.danyoungcpa.com/drug-administration-law-prc-1984-amended-2019-english-translation/

Chapter VII — Post-Marketing Management

Article 21 — Drug marketing authorization holders shall take the initiative to carry out post-marketing research of drugs, conduct ongoing evaluation of the safety, efficacy, and quality controllability of drugs, and strengthen the management of the entire life cycle of drugs.

Article 22 — Drug marketing authorization holders shall establish a system for the annual report on post-marketing changes of drugs, and shall report changes in the manufacturing, sale, and post-marketing research of drugs to the drug regulatory departments of provinces, autonomous regions, and municipalities directly under the central government in accordance with the provisions.

Article 23 — Where a drug marketing authorization holder, drug manufacturer, drug distributor, or medical institution discovers or becomes aware of an adverse drug reaction, it shall report the same to the adverse drug reaction monitoring institution in accordance with the provisions. Where the drug regulatory department, in conjunction with the health administrative department, determines through evaluation that a marketed drug has serious adverse reactions or fails to ensure safety, it shall revoke the drug approval document and stop the manufacturing, importation, sale, and use of the drug.

Chapter VIII — Drug Pricing and Advertising

Article 24 — Drugs shall be priced in accordance with the provisions of the Price Law of the People's Republic of China. Drug manufacturers, drug distributors, and medical institutions shall abide by the provisions on price administration and shall provide truthful and accurate pricing information.

Article 25 — Drug advertisements shall be subject to the examination and approval of the drug regulatory department of the people's government of the province, autonomous region, or municipality directly under the central government where the advertiser is located. Without approval, no drug advertisement shall be published. The content of drug advertisements must be truthful and lawful and shall be based on the package insert approved by the State Council's drug regulatory department.

Chapter IX — Supervision and Inspection

Article 26 — Drug regulatory departments shall have the right to conduct supervision and inspection of matters relating to the research and development, manufacturing, distribution, and use of drugs by drug marketing authorization holders, drug manufacturers, drug distributors, and medical institutions in accordance with laws and administrative regulations, and the relevant entities and individuals shall not refuse or obstruct such supervision and inspection.

Article 27 — Drug regulatory departments may take samples of drugs manufactured, distributed, and used by drug marketing authorization holders, drug manufacturers, drug distributors, and medical institutions for testing. The cost of sampling and testing shall be borne by the government in accordance with the provisions of the State Council.

Article 28 — The state shall establish a system for the publication of drug safety information. The State Council's drug regulatory department shall publish information such as the results of drug sampling tests, results of administrative penalties, and drug safety risk warnings on a regular basis.

Chapter X — Legal Liability

Article 29 — Anyone who manufactures or sells counterfeit drugs without obtaining a Drug Manufacturing Permit, Drug Distribution Permit, or Dispensing Permit for Medical Institutions shall be ordered to close down, and the illegally manufactured or sold drugs and the illegal gains shall be confiscated, and a fine of not less than 15 times but not more than 30 times the value of the illegally manufactured or sold drugs shall be imposed concurrently. Where a crime is constituted, criminal liability shall be pursued in accordance with the law.

Article 30 — Where a drug manufacturer, drug distributor, or medical institution purchases drugs in violation of the provisions of this Law, it shall be ordered to make rectification, the illegally purchased drugs and illegal gains shall be confiscated, and a fine of not less than two times but not more than 10 times the value of the illegally purchased drugs shall be imposed concurrently. Where the circumstances are serious, the Drug Manufacturing Permit, Drug Distribution Permit, or Dispensing Permit for Medical Institutions shall be revoked.

Article 31 — Anyone who knows or should have known that a drug is counterfeit or substandard but still provides facilities or conditions such as storage or transportation for the drug shall have the illegal gains confiscated, and a fine of not less than one time but not more than five times the illegal gains shall be imposed concurrently.

Article 32 — Drug marketing authorization holders, drug manufacturers, drug distributors, or medical institutions that violate the provisions of this Law shall, in addition to being subject to administrative penalties in accordance with this Law, be entered into the credit records by the drug regulatory department and announced to the public in accordance with the provisions.

Chapter XI — Supplementary Provisions

Article 33 — For the purposes of this Law, the term "drugs" means articles used for the prevention, treatment, and diagnosis of human diseases, the purposeful regulation of human physiological functions, and for which indications, usage, and dosage are prescribed, including traditional Chinese medicines, chemical drugs, and biological products.

Article 34 — The control of traditional Chinese medicines and medicinal products shall be governed by the provisions of this Law and the Law of the People's Republic of China on Traditional Chinese Medicines.

Article 35 — This Law shall enter into force on December 1, 2019.

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