# Pharmaceutical 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 pharmaceuticals, ensuring the quality of pharmaceuticals, safeguarding the safety of the public in the use of pharmaceuticals, and protecting the health and lawful rights and interests of the public.

Article 2 — This Law shall apply to entities and individuals engaged in the research and development, production, distribution, use, and supervision and administration of pharmaceuticals within the territory of the People's Republic of China.

Article 3 — The administration of pharmaceuticals shall be centered on the health of the people, adhere to the principles of risk management, whole-process control, and social co-governance, and shall establish a scientific and strict supervision and administration system.

Article 4 — The state shall encourage the research and creation of new drugs and protect the lawful rights and interests of entities and individuals in the research and development of new drugs. The state shall promote the development of the pharmaceutical industry.

Article 5 — The pharmaceutical supervisory and administrative department under the State Council shall be in charge of the supervision and administration of pharmaceuticals nationwide. The relevant departments under the State Council shall be responsible for supervision and administration related to pharmaceuticals within their respective functions.

## Chapter II — Research and Development

Article 6 — The state shall support pre-clinical research and clinical trials of drugs. Drug pre-clinical research and clinical trials shall comply with the relevant national regulations and technical guidelines.

Article 7 — The conduct of clinical trials of drugs shall comply with ethical principles, subject to the approval of the pharmaceutical supervisory and administrative department under the State Council, and be conducted at qualified clinical trial institutions.

Article 8 — The sponsors of clinical trials shall ensure that clinical trials are conducted in accordance with the approved protocols and shall be responsible for the safety and efficacy of the drugs under investigation.

Article 9 — Participants in clinical trials shall give informed consent and be informed of the purpose and methodology of the trial, the potential risks, and the protective measures available to them.

## Chapter III — Drug Registration

Article 10 — Drugs marketed in China shall be subject to registration and shall obtain a drug registration certificate, except for drugs not required to be registered for marketing authorization. The application for drug registration shall include sufficient research data.

Article 11 — When evaluating applications for drug registration, the pharmaceutical supervisory and administrative department shall conduct a comprehensive review of the safety, efficacy, and quality controllability of the drug and shall make a decision on whether to grant registration.

Article 12 — Drugs that have obtained registration shall be issued a drug registration number. The drug registration certificate shall be valid for five years. The holder of the certificate shall apply for re-registration six months before the expiration of the certificate.

Article 13 — The state shall establish a drug marketing authorization holder system. The drug marketing authorization holder shall be responsible for the safety, efficacy, and quality controllability of the drug throughout the lifecycle of the drug.

## Chapter IV — Drug Production

Article 14 — Entities engaged in drug production activities shall obtain a drug production license in accordance with the law. No drug shall be produced without a drug production license.

Article 15 — Drug production shall comply with the Good Manufacturing Practice for Pharmaceutical Products (GMP) and establish a sound quality management system.

Article 16 — Drug manufacturers shall inspect the drugs they produce in accordance with the drug standards and shall not release substandard drugs. Drugs shall be accompanied by instructions for use and labels that conform to the relevant provisions.

Article 17 — Active pharmaceutical ingredients, excipients, and pharmaceutical packaging materials and containers used in drug production shall comply with the requirements for pharmaceutical use and the relevant national standards.

## Chapter V — Drug Distribution

Article 18 — Entities engaged in drug wholesale or retail activities shall obtain a drug distribution license in accordance with the law. No drug shall be distributed without a drug distribution license.

Article 19 — Drug distribution entities shall comply with the Good Supply Practice for Pharmaceutical Products (GSP) and establish a sound quality management system for drug distribution.

Article 20 — Drug distribution entities shall purchase drugs from drug manufacturers or drug distribution entities holding legal qualifications. They shall conduct acceptance inspections on the drugs purchased and maintain complete purchase and sale records.

Article 21 — The sale of drugs shall be accurate and the explanations shall be correct. Prescription drugs shall be dispensed with a physician’s prescription. Over-the-counter drugs may be purchased by consumers without a prescription.

Article 22 — Drug distribution entities shall not sell counterfeit or inferior drugs. The importation of drugs shall comply with the provisions of this Law, and imported drugs shall be accompanied by an import drug registration certificate.

## Chapter VI — Drug Use in Medical Institutions

Article 23 — Medical institutions shall allocate pharmaceutical technical personnel appropriate to the level and scope of their medical services. Non-pharmaceutical technical personnel shall not directly engage in pharmaceutical technical work.

Article 24 — Medical institutions shall formulate a drug formulary based on the national essential drugs list and clinical treatment guidelines, and shall purchase drugs through centralized procurement platforms.

Article 25 — Medical institutions shall conduct acceptance inspections of drugs purchased and shall have facilities, equipment, and storage conditions commensurate with the types and quantities of drugs in use.

Article 26 — When dispensing drugs, pharmacists in medical institutions shall check the prescriptions and shall not change or substitute drugs without authorization. Where a prescription contains a contraindication



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or an unreasonable combination, the pharmacist shall refuse to dispense the drug.

## Chapter VII — Post-Marketing Management

Article 27 — The drug marketing authorization holder shall formulate a post-marketing risk management plan for the drug and shall take the initiative to carry out post-marketing research on the drug.

Article 28 — The state shall implement a reporting system for adverse drug reactions. Drug manufacturers, drug distributors, and medical institutions shall regularly monitor and report adverse drug reactions.

Article 29 — Where a drug presents safety risks, the drug marketing authorization holder shall take measures such as revising the drug label and package insert, suspending production, sale, or use, or recalling the drug.

Article 30 — The state shall establish a drug recall system. Where a drug manufacturer discovers that a drug presents safety risks, it shall recall the drug on its own initiative. The pharmaceutical supervisory and administrative department may also order a recall.

## Chapter VIII — Drug Pricing and Advertising

Article 31 — The price of drugs shall be formulated in accordance with the principles of fair and reasonable pricing, honesty and credibility, and quality-price consistency. Drug price information shall be disclosed and subject to public supervision.

Article 32 — The advertisement of drugs shall be subject to approval by the pharmaceutical supervisory and administrative department. The content of the advertisement shall be truthful and lawful and shall be based on the instructions approved by the pharmaceutical supervisory and administrative department.

Article 33 — The advertisement of prescription drugs shall be published only in medical and pharmaceutical professional journals jointly designated by the health administrative department and the pharmaceutical supervisory and administrative department under the State Council. The mass media shall not publish advertisements for prescription drugs.

## Chapter IX — Drug Reserve and Supply

Article 34 — The state shall implement a drug reserve system. In the event of a major disaster, epidemic, or other emergency, the State Council may urgently mobilize drugs.

Article 35 — The state shall establish a supply guarantee system for drugs in short supply, monitor the supply of drugs, and adopt measures to ensure the supply and stabilize the prices of drugs in short supply.

Article 36 — The state shall encourage the production of drugs for rare diseases and pediatric drugs in short supply and shall provide policy support to drugs that meet the relevant conditions.

## Chapter X — Supervision and Administration

Article 37 — The pharmaceutical supervisory and administrative departments shall, in accordance with the law, supervise and inspect the compliance of drug research and development, production, distribution, and use with the drug laws and regulations.

Article 38 — When conducting supervision and inspections, pharmaceutical supervisory and administrative personnel shall have the authority to enter the production, distribution, and use sites of drugs for inspection, consult and reproduce relevant materials, and seal and seize drugs and relevant materials.

Article 39 — The state shall implement a system of regular public announcements of the results of drug quality inspections. The pharmaceutical supervisory and administrative department shall, in accordance with the law, disclose information on drug administrative permits, drug quality inspections, drug recalls, and



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administrative penalties.

## Chapter XI — Legal Liability

Article 40 — Where a drug is produced or sold without a license, the pharmaceutical supervisory and administrative department shall ban the production or sale, confiscate the illegally produced or sold drugs and the illegal gains, and impose a fine. Where the circumstances are serious, the person in charge shall be prohibited from engaging in drug production or distribution activities for life.

Article 41 — Where counterfeit drugs are produced or sold, the pharmaceutical supervisory and administrative department shall confiscate the illegally produced or sold drugs and the illegal gains, order the suspension of production or operations for rectification, revoke the drug approval documents, and impose a fine of not less than 15 times but not more than 30 times the value of the drugs.

Article 42 — Where inferior drugs are produced or sold, the pharmaceutical supervisory and administrative department shall confiscate the illegally produced or sold drugs and the illegal gains and impose a fine of not less than 10 times but not more than 20 times the value of the drugs.

Article 43 — Where a violation of the provisions of this Law constitutes a crime, criminal liability shall be pursued in accordance with the law.

## Chapter XII — Supplementary Provisions

Article 44 — For the purposes of this Law: “drug” means articles used for the prevention, treatment, and diagnosis of human diseases, for the purposeful regulation of human physiological functions, and for which indications or functions and uses, usage, and dosage are specified, including traditional Chinese medicines, chemical drugs, and biological products. “Counterfeit drug” means a drug whose ingredients do not conform to the national drug standards, or a non-drug substance passed off as a drug or one drug passed off as another drug. “Inferior drug” means a drug whose ingredients do not conform to the national drug standards in respect of their content.

Article 45 — The administration of Chinese herbal medicines and prepared slices of Chinese herbal medicines shall be governed by this Law. Where there are special provisions, such provisions shall apply.

Article 46 — This Law shall come into force on December 1, 2019.

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