Drug Administration Law of the People’s Republic of China

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Chapter I — General Provisions

Article 1 — This Law is enacted for the purposes of strengthening drug administration, ensuring drug quality, safeguarding the safety of the people in drug use, and protecting the health and lawful rights and interests of the people.

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Article 2 — This Law shall apply to activities of drug research and development, manufacturing, distribution, use, supervision and administration, and drug price and advertising administration within the territory of the People's Republic of China.

Article 3 — Drug administration shall be centered on the health of the people, adhere to the principles of risk management, full-process control, and social co-governance, establish a scientific and strict supervision and administration system, and comprehensively improve drug quality to ensure the safety, effectiveness, and accessibility of drugs.

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

Chapter II — Drug Research and Registration

Article 5 — The state shall encourage the research and development of new drugs based on clinical value, and shall adopt measures to expedite the review and approval of innovative drugs, drugs for treating serious life-threatening diseases, and drugs urgently needed in clinical practice.

Article 6 — Drug research and development institutions shall have the personnel, facilities, equipment, instruments, and management systems commensurate with the research and development projects, and shall ensure the authenticity and integrity of research data and materials.

Article 7 — Preclinical studies of drugs shall be conducted in accordance with the relevant state provisions, and the safety evaluation research shall meet the requirements of good laboratory practice (GLP).

Article 8 — Clinical trials of drugs shall be conducted in accordance with the relevant state provisions and meet the requirements of good clinical practice (GCP).

Article 9 — Before conducting a clinical trial of a drug, the applicant shall submit an application to the drug regulatory department, truthfully state the clinical trial plan and other relevant materials, and may conduct the clinical trial only after obtaining approval.

Article 10 — Clinical trial institutions shall establish an ethics committee to review the scientific and ethical nature of clinical trial protocols.

Article 11 — Informed consent shall be obtained from subjects or their guardians before conducting a clinical trial.

Article 12 — The drug regulatory department shall establish a drug registration management system. Drug registration applications shall be reviewed and approved in accordance with the relevant state provisions.

Article 13 — The state shall implement a patent linkage system for drugs and a data protection system for drug test data.

Chapter III — Drug Manufacturing

Article 14 — Drug manufacturing shall be subject to a manufacturing license system. Those engaging in drug manufacturing activities shall obtain a Drug Manufacturing License in accordance with law.

Article 15 — The manufacture of drugs shall comply with the Good Manufacturing Practice for Pharmaceutical Products (GMP).

Article 16 — Drug manufacturers shall conduct quality inspection of the drugs they manufacture. Drugs that do not conform to national drug standards shall not leave the factory.

Article 17 — Drug manufacturers shall establish a drug marketing authorization holder system. The drug marketing authorization holder shall be responsible for the safety, effectiveness, and quality control of the

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drug throughout its lifecycle.

Article 18 — The drug marketing authorization holder shall establish a drug quality assurance system and be equipped with specialized personnel to be independently responsible for drug quality management.

Article 19 — The drug marketing authorization holder shall establish a drug traceability system to ensure the traceability of drugs.

Article 20 — The drug marketing authorization holder shall establish an annual reporting system and submit annual reports on drug manufacturing and sales, post-marketing management, risk management, and other information to the drug regulatory department.

Article 21 — The manufacture of drugs such as narcotic drugs, psychotropic substances, toxic drugs for medical use, and radioactive drugs shall comply with the relevant state provisions.

Article 22 — Drug manufacturers shall not accept commission to manufacture drugs without obtaining the corresponding scope of manufacturing license.

Chapter IV — Drug Distribution

Article 23 — Drug distribution shall be subject to a distribution license system. Those engaging in drug wholesale activities shall obtain a Drug Distribution License in accordance with law, and those engaging in drug retail activities shall obtain a Drug Retail License in accordance with law.

Article 24 — Drug distributors shall comply with the Good Supply Practice for Pharmaceutical Products (GSP).

Article 25 — Drug distributors shall purchase drugs from drug marketing authorization holders or drug manufacturers and distributors that are qualified to manufacture or distribute drugs.

Article 26 — Drug distributors shall establish and implement a drug purchase inspection and acceptance system, inspect the certificate of drug quality and labels and other marks, and shall not purchase drugs that do not conform to the prescribed requirements.

Article 27 — Drug distributors shall have the capacity to ensure drug quality during drug storage and transportation.

Article 28 — Drug manufacturers and distributors shall truthfully record information on drug purchase and sale to ensure the accuracy and traceability of records.

Article 29 — Online drug distribution by drug marketing authorization holders, drug manufacturers, and drug distributors shall comply with the provisions of this Law on drug distribution.

Article 30 — The importation of drugs shall be subject to the relevant state provisions. Drugs with no marketing approval in China but urgently needed in clinical practice may be imported in small quantities for specific medical purposes.

Article 31 — The sale of counterfeit and substandard drugs is prohibited.

Chapter V — Drug Administration in Medical Institutions

Article 32 — Medical institutions shall purchase drugs from drug marketing authorization holders, drug manufacturers, and drug distributors that are qualified to manufacture or distribute drugs.

Article 33 — Medical institutions shall establish and implement a drug purchase inspection and acceptance system.

Article 34 — Pharmaceutical preparations dispensed by medical institutions shall be the varieties approved by the drug regulatory department of the people’s government at or above the provincial level.

Article 35 — Medical institutions shall have facilities, equipment, and storage conditions commensurate with the varieties and quantities of drugs they use and shall strengthen drug administration.

Article 36 — Medical institutions shall strengthen the administration of clinical use of drugs and promote rational drug use.

Article 37 — Medical institutions shall establish a system for monitoring and reporting adverse drug reactions.

Article 38 — Medical institutions shall establish a drug recall system for drugs with quality problems.

Chapter VI — Post-Marketing Management of Drugs

Article 39 — The drug marketing authorization holder shall establish a post-marketing drug risk management system and proactively conduct post-marketing drug research.

Article 40 — The drug marketing authorization holder shall carry out post-marketing adverse reaction monitoring of drugs and submit adverse reaction reports.

Article 41 — Where a drug has safety problems or other risks, the drug marketing authorization holder shall take risk control measures such as suspending production, sales, or use, and recalling the drug.

Article 42 — The drug regulatory department shall establish a drug recall system and supervise drug marketing authorization holders in recalling drugs with safety problems.

Article 43 — The drug regulatory department shall organize the evaluation of marketed drugs and re-evaluate the safety, effectiveness, and quality controllability of drugs.

Article 44 — The state shall implement a pharmacovigilance system and monitor, identify, assess, and control adverse or other harmful reactions to drugs.

Article 45 — The drug marketing authorization holder shall establish an information management system for drug safety incidents.

Article 46 — Where major quality problems or safety risks exist, the drug regulatory department shall take emergency control measures.

Article 47 — The state shall establish a shortage drug list management system and a monitoring and early warning mechanism for drug shortages.

Chapter VII — Drug Pricing and Advertising

Article 48 — Drug prices shall be determined primarily by the market. The state shall improve the drug procurement mechanism and regulate drug procurement and pricing.

Article 49 — Drugs covered by medical insurance shall be subject to centralized procurement policies.

Article 50 — Drug marketing authorization holders, drug manufacturers, drug distributors, and medical institutions shall abide by price laws and regulations in accordance with law and shall not engage in unfair pricing practices.

Article 51 — Drug advertising shall be subject to the relevant state provisions and shall not contain false or misleading content.

Article 52 — Advertisement content for prescription drugs shall be limited to professional pharmaceutical journals jointly designated by the drug regulatory department and the health administrative department of the State Council.

Article 53 — Drug marketing authorization holders shall be responsible for the authenticity and lawfulness of drug advertisements.

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Article 54 — Drug advertisements shall not use the names or images of state organs, scientific research institutions, academic institutions, industry associations, experts, scholars, medical personnel, or patients as proof.

Chapter VIII — Supervision and Inspection

Article 55 — The drug regulatory department shall supervise and inspect drug research, manufacturing, distribution, and use in accordance with law.

Article 56 — When performing its supervision and inspection duties, the drug regulatory department may take the following measures:

(1) Conduct on-site inspections;

(2) Access and copy relevant materials;

(3) Take samples for inspection;

(4) Seal up or seize drugs and related materials suspected of having quality problems.

Article 57 — Inspections by the drug regulatory department shall be recorded, and the results shall be published to the public.

Article 58 — The drug regulatory department shall conduct random inspections of drug quality in accordance with law.

Article 59 — The drug regulatory department may adopt measures such as admonishing interviews and circulating notices of criticism against drug marketing authorization holders.

Article 60 — The state shall establish an adverse drug reaction monitoring system.

Article 61 — The drug regulatory department shall establish a credit record system for drug marketing authorization holders, drug manufacturers, drug distributors, and other entities.

Article 62 — The drug regulatory department shall publish information on drug safety risks to the public in a timely manner.

Article 63 — Any entity or individual shall have the right to report drug safety-related illegal activities. The drug regulatory department shall keep confidential the identity of whistleblowers.

Article 64 — The state shall establish a joint disciplinary mechanism for drug safety.

Chapter IX — Legal Liability

Article 65 — Whoever produces or sells counterfeit drugs shall have the illegally produced or sold drugs and illegal gains confiscated, and shall be ordered to cease production and business for rectification; the drug approval documents shall be revoked, and a fine of not less than 15 times but not more than 30 times the value of the illegally produced or sold drugs shall be imposed; where the value of the goods is less than RMB 100,000, it shall be calculated as RMB 100,000.

Article 66 — Whoever produces or sells substandard drugs shall have the illegally produced or sold drugs and illegal gains confiscated, and a fine of not less than 10 times but not more than 20 times the value of the illegally produced or sold drugs shall be imposed; where the circumstances are serious, the drug approval documents shall be revoked.

Article 67 — Where a drug marketing authorization holder violates the drug quality management standards, it shall be ordered to take corrective action and be given a warning; where the circumstances are serious, a fine shall be imposed and the drug approval documents may be revoked.

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Article 68 — Where a drug manufacturer or distributor violates GMP or GSP, it shall be ordered to take corrective action and be given a warning; where it fails to do so, a fine shall be imposed and the drug manufacturing or distribution license may be revoked.

Article 69 — A drug regulatory department may impose an administrative ban on the legal representative, principal responsible person, directly responsible person in charge, and other liable personnel of a drug marketing authorization holder, drug manufacturer, or drug distributor that has committed serious illegal acts.

Article 70 — Where the provisions of this Law on drug importation are violated, sanctions shall be imposed in accordance with law.

Article 71 — Where a medical institution violates the provisions of this Law, the health administrative department or drug regulatory department shall order it to take corrective action and impose sanctions in accordance with law.

Article 72 — Where the law of the People's Republic of China on drug traceability is violated, the drug regulatory department shall order corrective action and may impose a fine.

Article 73 — Where false drug advertising is published, penalties shall be imposed in accordance with the Advertising Law and other laws and administrative regulations.

Article 74 — Where a drug marketing authorization holder, drug manufacturer, drug distributor, or medical institution violates the provisions of this Law, and a crime is constituted, criminal liability shall be pursued in accordance with law.

Article 75 — The state shall implement a punitive compensation system for producing or selling counterfeit drugs or other acts that endanger human life and health.

Article 76 — Where an entity is penalized for drug-related illegal activities, its drug approval documents or drug manufacturing or distribution licenses may be revoked, and the drug regulatory department shall not accept its corresponding applications within five years.

Article 77 — Where a drug regulatory department, health administrative department, or other relevant department fails to perform its drug supervision and administration duties, sanctions shall be imposed on the directly responsible person in charge and other directly liable persons.

Article 78 — Where the drug regulatory department illegally charges fees in the course of supervision and administration, sanctions shall be imposed in accordance with law.

Article 79 — Where a staff member of the drug regulatory department engages in malpractice for personal gain, abuses power, or neglects duty, sanctions shall be imposed in accordance with law; where a crime is constituted, criminal liability shall be pursued.

Article 80 — Entities and individuals may apply for administrative reconsideration or institute administrative lawsuits against specific administrative acts of the drug regulatory department.

Chapter X — Supplementary Provisions

Article 81 — For the purposes of this Law:

(1) "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, usage, and dosage are prescribed, including traditional Chinese medicines, chemical drugs, and biological products;

(2) "Counterfeit drug" means a drug in any of the following circumstances: (a) the ingredients of the drug do not conform to the national drug standards; (b) a non-drug substance is passed off as a drug or one drug is passed off as another; (c) the drug is indicated for a disease for which it is not indicated.

Article 82 — The administration of narcotic drugs, psychotropic substances, toxic drugs for medical use, and radioactive drugs shall be subject to the relevant special state provisions.

Article 83 — The administration of drugs used in traditional Chinese medicine and folk medicines shall be subject to the relevant provisions of this Law.

Article 84 — The administration of veterinary drugs shall be governed by separate provisions.

Article 85 — The specific standards and measures for drug quality management shall be formulated by the drug regulatory department of the State Council.

Article 86 — The state shall establish a professional and technical personnel qualification system for drug administration.

Article 87 — Drug testing institutions shall meet the relevant state provisions and obtain accreditation.

Article 88 — The drug regulatory department shall strengthen the building of a drug information system and improve the level of information technology in drug administration.

Article 89 — The state shall encourage and support drug innovation and provide policy support for the research and development and industrialization of innovative drugs.

Article 90 — The state shall support the development of the traditional Chinese medicine industry and strengthen the protection and development of traditional Chinese medicine resources.

Article 91 — The state shall implement a drug reserve system to ensure the supply of drugs for emergency response to public health incidents and other emergencies.

Article 92 — Drug regulatory departments shall strengthen international exchanges and cooperation and participate in international drug regulatory coordination.

Article 93 — Specific measures for the administration of online drug distribution shall be formulated by the drug regulatory department of the State Council in conjunction with other relevant departments.

Article 94 — The provisions of this Law shall apply, mutatis mutandis, to the supervision and administration of the quality of prepared slices of traditional Chinese medicines.

Article 95 — The provisions of this Law shall apply, mutatis mutandis, to the supervision and administration of the quality of chemical raw materials used for drug manufacturing.

Article 96 — The state shall implement a unified drug classification management system.

Article 97 — The state shall separately prescribe the administration of vaccines.

Article 98 — This Law shall come into force on December 1, 2019. The Drug Administration Law of the People’s Republic of China (2001 Revision) shall be repealed simultaneously.

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