Regulations for the Implementation of the Drug Administration Law of the PRC

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Chapter I — General Provisions

Article 1 — These Implementing Regulations are formulated in accordance with the Drug Administration Law of the People's Republic of China (hereinafter referred to as the "Drug Administration Law").

Article 2 — The pharmaceutical regulatory department of the State Council shall establish a national pharmaceutical inspection institution. The pharmaceutical regulatory departments of the people's governments of provinces, autonomous regions and municipalities directly under the Central Government may establish local pharmaceutical inspection institutions within their respective administrative regions.

The pharmaceutical inspection institutions established by the State Council and local pharmaceutical regulatory departments shall be responsible for the quality inspection of pharmaceuticals required by the State in accordance with the law.

Article 3 — The State shall implement a classified protection system for traditional Chinese medicines (TCM), and specific measures shall be formulated by the pharmaceutical regulatory department of the State Council in conjunction with the competent department of traditional Chinese medicine of the State Council.

Chapter II — Administration of Pharmaceutical Manufacturing Enterprises

Article 4 — To establish a pharmaceutical manufacturing enterprise, an applicant shall make an application to the pharmaceutical regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government at the place where the enterprise is to be located, and the application shall be examined and approved by the pharmaceutical regulatory department of the State Council. A Pharmaceutical Manufacturing Permit shall be issued to the enterprise upon approval.

The Pharmaceutical Manufacturing Permit shall specify the term of validity and the scope of production. Any change in the licensed matters shall be subject to re-examination and approval in accordance with the law.

Article 5 — A pharmaceutical manufacturing enterprise shall, in accordance with the requirements of the Good Manufacturing Practice (GMP) for Pharmaceutical Products formulated by the pharmaceutical regulatory department of the State Council, organize production. The pharmaceutical regulatory department shall conduct GMP certification for pharmaceutical manufacturing enterprises in accordance with the prescribed standards.

Article 6 — The pharmaceutical regulatory department of the State Council or the pharmaceutical regulatory department of the people's government of a province, autonomous region or municipality directly under the Central Government authorized by the pharmaceutical regulatory department of the State Council shall organize GMP certification for pharmaceutical manufacturing enterprises.

Article 7 — Pharmaceutical manufacturing enterprises shall, in accordance with the provisions of the Drug Administration Law and these Regulations, re-apply for GMP certification before the expiration of the certification.

Chapter III — Administration of Pharmaceutical Trading Enterprises

Article 8 — To establish a pharmaceutical wholesale enterprise, an applicant shall make an application to the pharmaceutical regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government at the place where the proposed enterprise is to be located. To establish a pharmaceutical retail enterprise, an applicant shall make an application to the pharmaceutical regulatory department of the local people's government at the level of a city divided into districts or at the county level.

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A Pharmaceutical Trading Permit shall specify the term of validity, scope of trading and registered address. Any change in the licensed matters shall be subject to re-examination and approval.

Article 9 — Pharmaceutical trading enterprises shall, in accordance with the requirements of the Good Supply Practice (GSP) for Pharmaceutical Products formulated by the pharmaceutical regulatory department of the State Council, conduct pharmaceutical trading activities.

Article 10 — Urban and rural market fairs may sell Chinese herbal medicines, unless otherwise provided by the State Council.

Article 11 — A pharmaceutical trading enterprise shall purchase pharmaceuticals from pharmaceutical manufacturing enterprises or other pharmaceutical trading enterprises that have obtained the Pharmaceutical Manufacturing Permit or Pharmaceutical Trading Permit in accordance with the law.

Article 12 — Imported pharmaceuticals sold by a pharmaceutical trading enterprise shall have an Import Drug License and an Import Drug Inspection Report.

Chapter IV — Administration of Medical Institutions' Pharmaceutical Preparations

Article 13 — To prepare pharmaceutical preparations, a medical institution shall apply to the pharmaceutical regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government at the place where the institution is located for approval. A Pharmaceutical Preparation Permit for Medical Institutions shall be issued to the institution upon approval.

Article 14 — Medical institutions shall be equipped with the facilities, equipment, inspection instruments and health conditions suitable for the pharmaceutical preparations they prepare, so as to ensure the quality of the preparations.

Article 15 — The pharmaceutical preparations prepared by a medical institution shall be varieties that are clinically needed and not supplied in the market, and shall be used within the institution within the prescribed time limit.

Where a medical institution needs to allocate or use its preparations in other medical institutions under special circumstances, it shall obtain the approval of the pharmaceutical regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government.

Article 16 — The labels of the pharmaceutical preparations issued by a medical institution to patients shall specify the name of the preparation, indications, usage and dosage, contraindications and precautions, and the name, address and preparation date of the medical institution.

Chapter V — Administration of Pharmaceuticals

Article 17 — A drug regulatory department shall, in accordance with the provisions, review new drug applications and issue drug registration numbers to those that comply with the prescribed requirements.

Pharmaceutical manufacturing enterprises may only produce pharmaceuticals after obtaining a drug registration number.

Article 18 — The research, development, production, import and distribution of narcotic drugs, psychotropic substances and toxic drugs for medical use shall be subject to the relevant laws and administrative regulations.

Article 19 — The pharmaceutical regulatory department shall, in accordance with the provisions, conduct inspections of pharmaceuticals and re-evaluate the pharmaceuticals that have been examined and approved for production or import. Those that fail to pass the re-evaluation shall have their drug registration number withdrawn.

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Article 20 — The State shall implement a national essential drugs system. Specific measures shall be formulated by the pharmaceutical regulatory department of the State Council in conjunction with the relevant departments of the State Council.

Article 21 — The State shall encourage the cultivation of Chinese herbal medicines and the development of new varieties of Chinese herbal medicines, protect wild medicinal resources, and promote the development of the modern traditional Chinese medicine industry.

Article 22 — The import of pharmaceuticals shall comply with the provisions of the Drug Administration Law and shall be subject to the examination and approval of the pharmaceutical regulatory department of the State Council. An Import Drug License shall be issued to those that pass the examination. Customs shall release the goods based on the Import Drug License.

Upon arrival at the port, imported pharmaceuticals shall be registered with the pharmaceutical regulatory department at the place of the port. Customs shall release the goods based on the Drug Import Customs Clearance Form issued by the pharmaceutical regulatory department.

Article 23 — Imported pharmaceuticals shall be subject to import pharmaceutical inspection by the port pharmaceutical inspection institution. Where sampling inspection is required, the sampling inspection fee shall be paid by the purchaser. Pharmaceuticals that fail to pass the inspection may not be sold or used.

Chapter VI — Administration of Pharmaceutical Packaging

Article 24 — The packaging of directly contacting pharmaceuticals shall comply with the requirements for the use of pharmaceuticals and shall comply with the standards for pharmaceutical packaging materials. Pharmaceutical packaging materials shall be subject to the administration of registration.

Article 25 — Pharmaceutical manufacturing enterprises may not use pharmaceutical packaging materials that have not been approved for registration.

Article 26 — The labels and instructions of pharmaceuticals shall comply with the provisions of the pharmaceutical regulatory department of the State Council. The text on the labels shall be printed in characters that are regular, clear and easy to identify, and shall not contain any content that misleads or deceives consumers.

Article 27 — The labels and instructions of traditional Chinese medicine pieces shall comply with the provisions of the pharmaceutical regulatory department of the State Council.

Chapter VII — Administration of Pharmaceutical Pricing and Advertising

Article 28 — For pharmaceuticals whose prices are set or guided by the government in accordance with the law, the government pricing department shall, in accordance with the provisions of the Price Law, rationally set and adjust the prices based on the principles of social average cost, market supply and demand situation, and social affordability.

Article 29 — The prices of pharmaceuticals shall be set by the market, and the production enterprises, trading enterprises and medical institutions shall comply with the provisions on price administration.

Article 30 — Pharmaceutical manufacturing enterprises, trading enterprises and medical institutions shall indicate the retail price of the pharmaceuticals in accordance with the provisions, and shall not increase the price without authorization.

Article 31 — Pharmaceutical advertisements shall be subject to the examination and approval of the pharmaceutical regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government at the place where the enterprise is located, and an approval number for pharmaceutical advertisement shall be issued. The content of the advertisement shall

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be based on the instructions approved by the pharmaceutical regulatory department of the State Council, and shall not contain false content.

Article 32 — Prescription drugs may only be introduced in pharmaceutical professional newspapers and periodicals designated by the health administrative department of the State Council and the pharmaceutical regulatory department of the State Council, and may not be advertised through the mass media or in other ways.

Chapter VIII — Supervision and Inspection of Pharmaceuticals

Article 33 — Pharmaceutical regulatory departments shall conduct supervision and inspection of the pharmaceuticals manufactured and traded by pharmaceutical manufacturing and trading enterprises and the pharmaceuticals purchased and used by medical institutions in accordance with the law, and shall have the right to take samples for inspection.

Article 34 — The pharmaceutical regulatory department shall, in accordance with the provisions, conduct tracking inspections of pharmaceuticals that have passed the examination and approval or certification, and shall take corresponding measures for those that fail to meet the requirements.

Article 35 — The pharmaceutical regulatory department shall, in accordance with the provisions, conduct periodic quality sampling inspections on pharmaceuticals in the links of production, trading and use, and shall publish the results of the quality sampling inspections in accordance with the law.

Article 36 — Where a pharmaceutical inspection institution conducts sampling inspections of pharmaceuticals in accordance with the provisions, it shall issue an inspection report. The fees for sampling inspections shall be borne by the State Treasury in accordance with the provisions.

Article 37 — Where a pharmaceutical regulatory department takes administrative enforcement measures such as sealing up or detaining the pharmaceuticals and related materials involved in a case in accordance with the law, it shall have the approval of the principal person in charge of the pharmaceutical regulatory department.

Article 38 — The State Council and the pharmaceutical regulatory departments of the people's governments of provinces, autonomous regions and municipalities directly under the Central Government shall publish information on the results of pharmaceutical quality sampling inspections and the handling of illegal acts in accordance with the law.

Chapter IX — Legal Liability

Article 39 — Where a pharmaceutical manufacturing enterprise or a pharmaceutical trading enterprise produces or trades counterfeit pharmaceuticals, or produces or trades substandard pharmaceuticals, the pharmaceutical regulatory department shall impose penalties in accordance with the provisions of the Drug Administration Law.

Article 40 — Where a pharmaceutical manufacturing enterprise or a pharmaceutical trading enterprise engages in production or trading activities without obtaining a Pharmaceutical Manufacturing Permit, a Pharmaceutical Trading Permit or a Pharmaceutical Preparation Permit for Medical Institutions, the pharmaceutical regulatory department shall ban the enterprise, confiscate the illegally produced or traded pharmaceuticals and the illegal income, and impose a fine in accordance with the law.

Article 41 — Where a pharmaceutical manufacturing enterprise or a pharmaceutical trading enterprise fails to conduct production or trading in accordance with the Good Manufacturing Practice or Good Supply Practice, the pharmaceutical regulatory department shall issue a warning and order it to make corrections within a prescribed time limit; where it fails to make corrections within the time limit, it shall be ordered to suspend production or trading for rectification and a fine of not less than RMB 5,000 but not more than RMB

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20,000 shall be imposed; where the circumstances are serious, the Pharmaceutical Manufacturing Permit or Pharmaceutical Trading Permit shall be revoked.

Article 42 — Where an imported pharmaceutical does not have an Import Drug License, it shall be treated as a counterfeit drug. Where the quality of an imported pharmaceutical fails to meet the prescribed standards, it shall be treated as a substandard drug.

Article 43 — Where a medical institution uses counterfeit or substandard pharmaceuticals, it shall be penalized in accordance with the provisions on the penalties for the use of counterfeit or substandard pharmaceuticals.

Article 44 — Where a pharmaceutical manufacturing enterprise uses pharmaceutical packaging materials that have not been approved for registration, the pharmaceutical regulatory department shall order it to cease use, and impose a fine in accordance with the law.

Article 45 — Where a pharmaceutical regulatory department or a pharmaceutical inspection institution violates the provisions of these Regulations and commits any of the following acts, the directly responsible person in charge and other directly responsible persons shall be given administrative sanctions in accordance with the law; where a crime is constituted, criminal liability shall be pursued in accordance with the law:

(1) Failing to perform the duties of supervision and inspection in accordance with the law;

(2) Issuing permits, certificates or approval documents in violation of the prescribed conditions;

(3) Committing fraud or malpractice for personal gain in law enforcement activities;

(4) Disclosing trade secrets known during supervision and inspection.

Chapter X — Supplementary Provisions

Article 46 — The meanings of the following terms as used in these Regulations:

"New drug" means a pharmaceutical product that has not been marketed in China.

"Prescription drug" means a pharmaceutical product that may be dispensed, purchased and used only with the prescription of a licensed physician or assistant licensed physician.

"Non-prescription drug" means a pharmaceutical product that may be purchased and used by consumers themselves without the prescription of a licensed physician or assistant licensed physician in accordance with the drug instructions.

Article 47 — The pharmaceutical regulatory department of the State Council shall be responsible for interpreting these Regulations.

Article 48 — These Regulations shall enter into force on September 15, 2002.

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