



People's Republic of China Drug Administration Law

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Chapter I General Provisions

Article 1 This Law is enacted for the purpose of strengthening drug management, ensuring the quality of drugs, safeguarding the safety and legal rights of the public, and protecting and promoting public health.

Article 2 This Law applies to the development, production, operation, use and supervision of pharmaceutical products within the territory of the People's Republic of China.

The term "drugs" as used in this Law refers to substances used for the prevention, treatment and diagnosis of human diseases, purposefully regulating human physiology and stipulations of indications or functional indications, usage and dosage, including traditional Chinese medicines, chemical medicines and biological products. Wait.

Article 3 Drug management should focus on people's health, adhere to the principles of risk management, whole process control, and social co-governance, establish a scientific and strict supervision and management system, comprehensively improve the quality of medicines, and ensure the safety, effectiveness, and accessibility of medicines.

Article 4 The State develops modern medicines and traditional medicines to give full play to its role in prevention, medical care and health care.

The state protects wild medicinal materials resources and traditional Chinese medicine varieties, and encourages the cultivation of authentic Chinese herbal medicines.

Article 5 The State encourages the research and creation of new drugs to protect the legitimate rights and interests of citizens, legal persons and other organizations in researching and developing new drugs.

Article 6 The State implements a drug listing permit holder system for drug management. The holder of the drug marketing license is responsible for the safety, effectiveness and quality controllability of the drug during the whole process of drug development, production, management and use.

Article 7 In the development, production, operation and use of pharmaceuticals, laws, regulations, rules, standards and norms shall be observed to ensure that the information in the whole process is true, accurate, complete and traceable.

Article 8 The drug regulatory department of the State Council shall be in charge of the national drug supervision and administration work. The relevant departments of the State Council are responsible for the supervision and administration of drugs in their respective areas of responsibility. The drug regulatory department of the State Council cooperates with relevant departments of the State Council to implement the national pharmaceutical industry development plan and industrial policy.

The drug supervision and administration department of the people's government of the province, autonomous region or municipality directly under the Central Government shall be responsible for drug supervision and administration within its administrative region. The department of the municipal and county-level people's governments that have the responsibility for drug supervision and management (hereinafter referred to as the drug supervision and administration department) shall be responsible for drug supervision and administration within its administrative region. The relevant departments of the local people's governments at or above the county level shall be responsible for the supervision and administration of drugs in their respective areas of responsibility.

Article 9 The local people's governments at or above the county level shall be responsible for the drug supervision and administration work within their respective administrative areas, uniformly lead, organize and coordinate the drug supervision and management work within their respective administrative areas and the response

to drug safety emergencies, and establish and improve the drug supervision and management work. Mechanism and information sharing mechanism.

Article 10 The people's governments at or above the county level shall incorporate drug safety work into their national economic and social development plans, include the funds for drug safety work in the government budget at the same level, strengthen the capacity building of drug supervision and management, and provide protection for drug safety.

Article 11 The pharmaceutical professional technical institutions set up or designated by the drug regulatory authority shall undertake the review, inspection, verification, monitoring and evaluation required for the implementation of drug supervision and management according to law.

Article 12 The State establishes and improves the drug traceability system. The drug regulatory department of the State Council shall formulate uniform drug traceability standards and norms, promote the mutual exchange of drug traceability information, and realize traceability of drugs.

The State establishes a pharmacovigilance system to monitor, identify, evaluate and control adverse drug reactions and other harmful reactions associated with drug use.

Article 13 The people's governments at all levels and their relevant departments, pharmaceutical industry associations, etc. shall strengthen drug safety publicity and education, and carry out the popularization of knowledge such as drug safety laws and regulations.

The news media should carry out public welfare propaganda on knowledge such as drug safety laws and regulations, and conduct public opinion supervision on drug illegal activities. Propaganda reports on drugs should be comprehensive, scientific, objective and fair.

Article 14: Pharmaceutical industry associations shall strengthen self-discipline in the industry, establish and improve industry norms, promote the construction of industry credit system, and guide and urge members to carry out drug production and management activities in accordance with the law.

Article 15 The people's governments at or above the county level and their relevant departments shall commend and reward units and individuals that have made outstanding contributions to the research, production, operation, use, supervision and management of drugs in accordance with relevant state regulations.

Chapter II Drug Development and Registration

Article 16 The State supports drug innovations that are clinically oriented and have clear or special effects on human diseases, and encourage new treatment mechanisms, treatment of serious life-threatening diseases or rare diseases, and multi-targeting systemic effects on humans. Regulate the development of new drugs such as intervention functions, and promote the advancement of pharmaceutical technology.

The state encourages the use of modern science and technology and traditional Chinese medicine research methods to carry out research and drug development of traditional Chinese medicine science and technology, establish and improve a technical evaluation system that conforms to the characteristics of traditional Chinese medicine, and promote the inheritance and innovation of traditional Chinese medicine.

The State adopts effective measures to encourage the development and innovation of children's medicines, supports the development of new varieties, dosage forms and specifications of children's medicines that meet the

physiological characteristics of children, and prioritizes the examination and approval of children's medicines.

Article 17 In conducting drug development activities, it shall abide by the quality management norms for drug non-clinical research and the quality management regulations for drug clinical trials, and ensure that the entire process of drug development continues to meet statutory requirements.

The quality management norms for drug non-clinical research and the quality management regulations for drug clinical trials shall be formulated by the drug regulatory department of the State Council in conjunction with the relevant departments of the State Council.

Article 18 To carry out non-clinical research on drugs, it shall comply with relevant state regulations, and have personnel, sites, equipment, instruments and management systems appropriate to the research projects to ensure the authenticity of relevant data, materials and samples.

Article 19 In carrying out clinical trials of drugs, relevant data, materials and samples such as development methods, quality indicators, pharmacological and toxicological test results shall be truthfully submitted in accordance with the provisions of the drug regulatory authority under the State Council, and approved by the drug regulatory authority under the State Council. The drug regulatory department of the State Council shall, within 60 working days from the date of accepting the application for clinical trial, decide whether to agree and notify the clinical trial sponsor. If it is overdue, it shall be deemed as consent. Among them, if the bioequivalence test is carried out, it shall be reported to the drug regulatory department of the State Council for the record.

Conducting clinical trials of drugs should be carried out in clinical trial institutions with appropriate conditions. The drug clinical trial institution shall implement the record management. The specific measures shall be formulated jointly by the drug regulatory department of the State Council and the health and health department of the State Council.

Article 20 The clinical trial of drugs shall be conducted in accordance with ethical principles and a clinical trial plan shall be formulated and approved by the ethics committee.

The ethics committee should establish an ethical review work system to ensure that the ethical review process is independent, objective and fair, supervise and standardize drug clinical trials, protect the legitimate rights and interests of the subjects, and safeguard the public interest.

Article 21 In implementing a clinical trial of a drug, the subject or his or her guardian shall truthfully explain and explain the details and risks of the clinical trial, obtain the informed consent form voluntarily signed by the subject or his guardian, and take effective measures. Protect the legal rights of the subjects.

Article 22 During the clinical trial of a drug, if there are safety problems or other risks, the clinical trial sponsor shall timely adjust the clinical trial plan, suspend or terminate the clinical trial, and report to the drug regulatory department of the State Council. When necessary, the drug regulatory department of the State Council may order adjustment of clinical trial protocols, suspension or termination of clinical trials.

Article 23: Drugs that are undergoing clinical trials for the treatment of diseases that are seriously life-threatening and have no effective treatment means may benefit from medical observation and are ethical. After examination and informed consent, they may be carried out. Clinically tested institutions are used for other patients with the same condition.

Article 24 Drugs listed in China shall obtain the drug registration certificate upon approval of the drug regulatory

authority under the State Council; however, Chinese herbal medicines and Chinese herbal medicines that have not been subject to examination and approval shall be excluded. The catalogue of Chinese herbal medicines and traditional Chinese medicine decoction pieces subject to examination and approval shall be formulated by the drug regulatory department of the State Council in conjunction with the competent department of Chinese medicine under the State Council.

To apply for drug registration, you should provide true, sufficient and reliable data, data and samples to prove the safety, effectiveness and quality controllability of the drug.

Article 25 For drugs that are applied for registration, the drug regulatory department of the State Council shall organize pharmaceutical, medical and other technical personnel to conduct a review, control the safety, effectiveness and quality of the drug, as well as the quality management and risks of the applicant. The ability to prevent and control damages and liability is reviewed; if the conditions are met, the drug registration certificate is issued.

When the drug regulatory authority under the State Council examines and approves drugs, it shall review and approve the chemical raw materials, review the relevant auxiliary materials, packaging materials and containers directly contacting the drugs, and compare the quality standards, production processes, labels and specifications of the drugs. And approved.

Excipients referred to in this Law refer to the excipients and additives used in the production of pharmaceuticals and formulation.

Article 26: For the treatment of diseases that are seriously life-threatening and have no effective treatment means, as well as drugs that are urgently needed for public health, the clinical trials of drugs have shown that the clinical efficacy of the drug can predict the clinical value, and can be conditionally approved and in the drug The relevant matters are stated in the registration certificate.

Article 27 The drug regulatory department of the State Council shall improve the drug review and approval work system, strengthen capacity building, establish and improve mechanisms for communication and expert consultation, optimize the review and approval process, and improve the efficiency of review and approval.

The conclusions and basis for the approval of the listed drugs shall be disclosed in accordance with the law and accepted by the social supervision. The business secrets known in the review and approval shall be kept confidential.

Article 28 Drugs shall conform to the national drug standards. Where the quality standard of drugs approved by the drug regulatory department of the State Council is higher than the national drug standard, it shall be implemented in accordance with the approved drug quality standards; if there is no national drug standard, it shall comply with the approved drug quality standards.

The Pharmacopoeia of the People's Republic of China and the drug standard promulgated by the drug regulatory department of the State Council are national drug standards.

The drug regulatory department of the State Council, in conjunction with the State Council department in charge of health and health, organizes the Pharmacopoeia Commission to be responsible for the formulation and revision of national drug standards.

The drug inspection agency set up or designated by the drug regulatory department of the State Council shall be responsible for the calibration of national drug standards and reference materials.

Article 29 The name of a drug listed in the national drug standard is the generic name of the drug. Already a generic name for a drug, the name may not be used as a pharmaceutical trademark.

Chapter III Holders of Drug Listing License

Article 30 The holder of a drug marketing license refers to an enterprise or a drug development institution that has obtained a drug registration certificate.

Holders of drug marketing licenses shall be responsible for non-clinical research, clinical trials, production operations, post-marketing studies, adverse reaction monitoring, reporting and handling of drugs in accordance with the provisions of this Law. Other units and individuals engaged in the research, production, operation, storage, transportation and use of pharmaceuticals shall bear corresponding responsibilities according to law.


The legal representative and principal responsible person of the drug marketing license holder shall be fully responsible for the quality of the drug.

Article 31 The holder of a drug marketing license shall establish a drug quality assurance system and be equipped with specialized personnel to independently be responsible for drug quality management.


The holder of the drug marketing license shall conduct regular audits on the quality management system of the drug manufacturing enterprises and drug business enterprises, and supervise their continuous quality assurance and control capabilities.

Article 32 The holder of a drug marketing permit may produce the drug by himself or may entrust the pharmaceutical production enterprise to produce it.

Where the holder of a drug marketing license produces a drug by himself, he shall obtain a drug production license in accordance with the provisions of this Law; if the production is entrusted, he shall entrust a qualified pharmaceutical production enterprise. The drug marketing license holder and the entrusted production enterprise shall sign the entrustment agreement and the quality agreement, and strictly fulfill the obligations stipulated in the agreement.

The drug regulatory department of the State Council shall formulate guidelines for the quality of drug entrusted production, guide and supervise the drug listing permit holders and the entrusted production enterprises to fulfill the drug quality assurance obligations. 

Blood products, narcotic drugs, psychotropic drugs, medical toxic drugs, and pharmaceutical precursor chemicals shall not be entrusted to production; however, unless otherwise stipulated by the drug regulatory authority under the State Council.

Article 33 The holder of a drug marketing permit shall establish a drug listing release procedure, and review the drug released by the drug manufacturer, and release it after being signed by the quality attorney. Those that do not meet the national drug standards shall not be released. 

Article 34 The holder of a drug marketing license may sell the drug that has obtained the drug registration certificate by itself, or may entrust the drug business enterprise to sell it. If the holder of the drug marketing license is engaged in the retail business of drugs, he shall obtain a drug business license.

Where a holder of a drug marketing license sells a drug by himself, he shall have the conditions stipulated in Article 52 of this Law; if the agent is engaged in sales, he shall entrust a qualified pharmaceutical business enterprise.

The holder of the drug marketing license and the entrusted business enterprise shall sign the entrustment agreement and strictly perform the obligations stipulated in the agreement.

Article 35 If a drug marketing permit holder, a pharmaceutical production enterprise or a pharmaceutical business enterprise entrusts storage or transportation of drugs, it shall evaluate the quality assurance capability and risk management capability of the trustee, and sign a commission agreement with the drug quality responsibility, operating procedures, etc., and supervise the trustee.

Article 36 Drug listing license holders, pharmaceutical production enterprises, pharmaceutical trading enterprises and medical institutions shall establish and implement a drug traceability system, and provide traceability information in accordance with regulations to ensure traceability of drugs.

Article 37 The holder of a drug marketing permit shall establish an annual reporting system, and report the production, sales, post-marketing research, risk management, etc. of the drug to the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government every year.

Article 38 Where the holder of a drug marketing license is an overseas enterprise, the enterprise legal person designated by the company shall perform the obligations of the holder of the drug listing permit and bear joint and several liability with the holder of the drug marketing license.

Article 39 Chinese medicine decoction pieces production enterprises shall fulfill the relevant obligations of the holders of drug marketing licenses, implement the whole process management of the production and sale of traditional Chinese medicine decoction pieces, establish a trace system of traditional Chinese medicine decoction pieces, and ensure that Chinese medicine decoction pieces are safe, effective and traceable.

Article 40 With the approval of the drug regulatory authority under the State Council, the holder of a drug marketing license may transfer the drug marketing permission. The transferee shall have the ability to ensure quality control, risk prevention and control, and liability compensation for the safety, effectiveness and quality control of the drug, and fulfill the obligations of the holder of the drug marketing permit.

Chapter IV Pharmaceutical Production

Article 41 In the case of drug production activities, the drug production license shall be obtained upon approval of the drug regulatory authority of the people's government of the province, autonomous region or municipality directly under the Central Government. If there is no drug production license, no drugs may be produced.

The drug production license shall indicate the validity period and production scope, and re-examine and issue the certificate upon expiration.

Article 42 The following conditions shall be met for engaging in the production of pharmaceuticals:


(1) Pharmacy technicians, engineering and technical personnel and corresponding skilled workers who have been qualified according to law;

(2) Plants and facilities that are compatible with the production of pharmaceuticals And the sanitation environment;

(3) having institutions, personnel and necessary equipment and equipment capable of quality management and quality inspection of the drugs produced;

(4) having rules and regulations for ensuring the quality of medicines, and complying with the law of the drug regulatory authority under the State Council Established requirements for quality management of pharmaceutical production.

Article 43 In engaging in pharmaceutical production activities, it shall abide by the standards for the management of pharmaceutical production quality, establish and improve the quality management system for pharmaceutical production, and ensure that the entire process of pharmaceutical production continues to meet statutory requirements.

The legal representative and principal responsible person of the pharmaceutical production enterprise shall be fully responsible for the pharmaceutical production activities of the enterprise. 

Article 44 Drugs shall be produced in accordance with the national drug standards and the production processes approved by the drug regulatory authorities. Production and inspection records shall be complete and accurate and shall not be fabricated.


Traditional Chinese medicine decoction pieces shall be prepared in accordance with the national drug standards; if there are no provisions in the national drug standards, they shall be processed in accordance with the processing standards formulated by the drug regulatory authorities of the people's governments of provinces, autonomous regions and municipalities directly under the Central Government. The processing regulations formulated by the drug regulatory authorities of the people's governments of provinces, autonomous regions and municipalities directly under the Central Government shall be reported to the drug regulatory department of the State Council for the record. Those that do not conform to the national drug standards or are not manufactured in accordance with the processing regulations formulated by the drug regulatory authorities of the people's governments of provinces, autonomous regions or municipalities directly under the Central Government shall not be manufactured or sold.


Article 45 The raw materials and auxiliary materials required for the production of pharmaceuticals shall meet the relevant requirements of the medicinal requirements and the quality management standards for pharmaceutical production.

For the production of pharmaceuticals, the suppliers of raw materials and auxiliary materials shall be examined in accordance with the regulations to ensure that the raw materials and auxiliary materials purchased and used meet the requirements of the preceding paragraph.

Article 46 Packaging materials and containers that are in direct contact with drugs shall meet the requirements for medicinal purposes and meet the standards for the protection of human health and safety.

The packaging materials and containers for unqualified direct contact with drugs shall be ordered to stop using by the drug regulatory authority.

Article 47 A pharmaceutical production enterprise shall conduct quality inspections on pharmaceuticals. If it does not meet the national drug standards, it may not leave the factory. 

Pharmaceutical production enterprises shall establish procedures for the release of pharmaceutical products, and clarify the standards and conditions for factory release. If it meets the standards and conditions, it can be released after being signed by the quality attorney. 

Article 48 Pharmaceutical packaging shall be suitable for the requirements of quality of medicines, and convenient for storage, transportation and medical use.

Chinese herbal medicines should be packaged. On each package, the product name, place of origin, date, and supplier should be indicated, along with a mark of acceptable quality.

Article 49 Pharmaceutical packaging shall be printed or labeled with instructions in accordance with the regulations.

The label or instructions should indicate the generic name, composition, specifications, license holder and its address, manufacturer and its address, approval number, product batch number, date of manufacture, expiration date, indications or functional indications, usage, Dosage, contraindications, adverse reactions and precautions. The words in the label and the manual should be clear, and the date of production, expiration date, etc. should be marked clearly and easily recognized.

Labels and instructions for narcotic drugs, psychotropic drugs, medical toxic drugs, radioactive drugs, external drugs and non-prescription drugs shall be printed with the prescribed marks.

Article 50 Workers who directly contact drugs in drug listing license holders, drug production enterprises, drug trading enterprises and medical institutions shall conduct annual health checks. Those who suffer from infectious diseases or other diseases that may contaminate drugs shall not engage in direct contact with drugs.

Chapter V Drug Management

Article 51 In the case of pharmaceutical wholesale activities, it shall obtain approval from the drug regulatory authority of the people's government of the province, autonomous region or municipality directly under the Central Government to obtain a drug business license. To engage in drug retail activities, it shall obtain approval from the drug regulatory department of the local people's government at or above the county level to obtain a drug business license. If there is no drug business license, no drugs may be operated.

The drug business license shall indicate the validity period and business scope, and re-examine and issue the certificate upon expiration.

The drug regulatory authority shall, in addition to the conditions stipulated in Article 52 of this Law, follow the principle of facilitating the purchase of medicines by the people.

Article 52 The following conditions shall be met for engaging in pharmaceutical business activities:

- (1) Pharmacists or other pharmacy technicians who have been qualified according to law;
- (2) Business premises, equipment, storage facilities and sanitation that are compatible with the drugs they operate environment;
- (c) quality management agencies or personnel suitable for the pharmaceuticals business;
- (4) to have rules and regulations to ensure the quality of drugs, and in line with the drug regulatory department under the State Drug quality management specification requirements established under this Act.

Article 53 In carrying out pharmaceutical business activities, it shall abide by the quality management rules for pharmaceutical products, establish and improve the quality management system for pharmaceutical products, and ensure that the entire process of drug operations continues to meet statutory requirements.

The state encourages and guides drug retail chain operations. The headquarters of a company engaged in the retail chain business of pharmaceuticals shall establish a unified quality management system and perform management responsibility for the business activities of its retail enterprises.

The legal representative and principal responsible person of the pharmaceutical business enterprise shall be fully responsible for the pharmaceutical business activities of the enterprise.

Article 54 The State implements a classification management system for prescription drugs and non-prescription drugs for drugs. The specific measures shall be formulated by the drug regulatory department of the State Council in conjunction with the competent health department of the State Council.

Article 55: Drug listing license holders, pharmaceutical production enterprises, pharmaceutical trading enterprises and medical institutions shall purchase medicines from holders of drug marketing licenses or enterprises with qualifications for drug production and operation; however, purchases have not been approved. Except for the management of Chinese herbal medicines.

Article 56 A pharmaceutical trading enterprise that purchases drugs shall establish and implement a system for inspection and acceptance of incoming goods, and verify the certificate of conformity of drugs and other marks; those that do not meet the requirements shall not be purchased or sold.

Article 57 A pharmaceutical business enterprise that purchases and sells drugs shall have a true and complete record of purchase and sales. The purchase and sales records shall indicate the generic name, dosage form, specifications, product batch number, expiration date, holder of the listing license, manufacturer, purchase and sale unit, purchase and sale quantity, purchase and sale price, purchase and sale date, and other contents as stipulated by the drug regulatory authority under the State Council.

Article 58 The retail drug of a pharmaceutical business enterprise shall be accurate and correct, and correctly explain the usage, dosage and precautions; the prescription shall be checked and the drugs listed in the prescription shall not be altered or substituted. For prescriptions with incompatibility or overdose, the allocation should be refused; if necessary, the prescription should be corrected or re-signed by the prescribing physician.

The sales of Chinese herbal medicines by pharmaceutical companies shall be marked with the place of origin.

The pharmacist or other pharmacy technicians who have been qualified according to law are responsible for the drug management, prescription review and deployment, and rational drug use guidance of the enterprise.

Article 59 A pharmaceutical trading enterprise shall formulate and implement a drug storage system and take necessary measures such as refrigeration, antifreeze, moisture proof, insect control and rodent control to ensure the quality of the drug.

The inspection system should be implemented for drug storage and delivery.

Article 60 The Chinese and American medicinal materials may be sold in the urban and rural market trade market, unless otherwise stipulated by the State Council.

Article 61 The holders of drug marketing licenses and pharmaceutical enterprises that sell drugs through the Internet shall abide by the relevant provisions of the drug business of this Law. The specific management measures shall be formulated by the drug regulatory department of the State Council in conjunction with the department in charge of health and health of the State Council.

Drugs specially administered in countries such as vaccines, blood products, narcotic drugs, psychotropic drugs, medical toxic drugs, radioactive drugs, and pharmaceutical precursor chemicals shall not be sold on the Internet.

Article 62 The provider of a third-party platform for drug network transactions shall, in accordance with the provisions of the drug regulatory authority under the State Council, file with the drug regulatory authority of the

people's government of the province, autonomous region or municipality directly under the Central Government.

The third-party platform provider shall, in accordance with the law, review the qualifications of the drug listing license holders and drug business enterprises that apply to enter the platform to ensure that they meet the statutory requirements and manage the drug business operations that occur on the platform.

If the third-party platform provider discovers that the drug listing license holder or drug business enterprise that enters the platform operation violates the provisions of this Law, it shall promptly stop and immediately report to the drug regulatory department of the county-level people's government; if serious illegal activities are found, The provision of online trading platform services should be stopped immediately.

Article 63 Newly discovered and imported medicinal materials from overseas may only be sold after approval by the drug regulatory authority of the State Council.

Article 64 Drugs shall be imported from the ports where the drugs are allowed to be imported, and the enterprises that import the drugs shall file with the drug supervision and administration department at the port. The Customs shall go through customs clearance procedures with the import drug clearance form issued by the drug supervision and administration department. If there is no customs clearance form for imported drugs, the customs shall not release it.

The drug supervision and administration department at the port of the port shall notify the drug inspection agency to conduct spot checks on imported drugs in accordance with the provisions of the drug regulatory authority under the State Council.

The port that allows the import of drugs shall be submitted by the drug regulatory department of the State Council in conjunction with the General Administration of Customs and submitted to the State Council for approval.

Article 65 If a medical institution urgently needs to import a small amount of drugs, it may be imported after approval by the drug regulatory authority under the State Council or the people's government of the province, autonomous region or municipality directly under the Central Government authorized by the State Council. Imported drugs should be used for specific medical purposes within a designated medical facility.

Individuals carrying small quantities of drugs for personal use shall be handled in accordance with relevant state regulations.

Article 66 Import and export of narcotic drugs and psychotropic drugs within the scope of state regulations shall be subject to the import permit and export permit issued by the drug regulatory authority under the State Council.

Article 67. It is forbidden to import drugs that have inaccurate curative effects, have large adverse reactions, or endanger human health for other reasons.

Article 68 The drug regulatory department of the State Council shall designate the drug inspection agency to conduct inspections before or during the sale of the following drugs; if it is not tested or fails to pass the inspection, it shall not be sold or imported:

- (1) Drugs sold in China for the first time;
- (2) Biological products prescribed by the drug regulatory authority under the State Council ;
- (3) Other drugs prescribed by the State Council.

Chapter VI Pharmaceutical Administration of Medical Institutions

Article 69 A medical institution shall be equipped with a pharmacist or other pharmacy technician who has been qualified according to law, and is responsible for the drug management, prescription review and deployment, and rational drug use guidance of the unit. Non-pharmaceutical technicians may not directly engage in pharmaceutical technology work.

Article 70 If a medical institution purchases drugs, it shall establish and implement a system for inspection and acceptance of incoming goods, and verify the certificate of conformity of drugs and other marks; if it does not meet the requirements, it shall not be purchased or used.

Article 71 Medical institutions shall have places, equipment, storage facilities and sanitary environment that are compatible with the drugs used, formulate and implement drug storage systems, and take necessary measures such as refrigeration, antifreeze, moisture, insects and rodents to ensure that The quality of the drug.

Article 72 Medical institutions shall adhere to the principles of safe, effective, economic and rational use of drugs, follow the guidelines for the clinical application of drugs, clinical diagnosis and treatment guidelines and drug instructions, and review the suitability of physicians' prescriptions and medication orders.

Other drug use units other than medical institutions shall abide by the provisions of this Law concerning the use of drugs by medical institutions.

Article 73 A prescription of a pharmacist or other pharmacy technician who has been qualified according to law shall be checked and the drugs listed in the prescription shall not be altered or substituted. For prescriptions with incompatibility or overdose, the allocation should be refused; if necessary, the prescription should be corrected or re-signed by the prescribing physician.

Article 74 Medical institutions that prepare preparations shall obtain approval from the drug regulatory authority of the people's government of the local province, autonomous region or municipality directly under the Central Government to obtain a medical institution's preparation license. If there is no medical institution preparation license, the preparation shall not be formulated.

The medical institution preparation license shall be marked with a valid period, and the certificate shall be re-examined upon expiration.

Article 75 For the preparation of preparations by medical institutions, there shall be facilities, management systems, inspection instruments and sanitary environment that can guarantee the quality of the preparations.

The preparation of preparations by medical institutions shall be carried out in accordance with the approved process, and the required raw materials, auxiliary materials and packaging materials shall meet the requirements for medicinal purposes.

Article 76 The preparations formulated by a medical institution shall be the varieties that are not required for clinical use by the unit and shall be approved by the drug regulatory authority of the people's government of the local province, autonomous region or municipality directly under the Central Government; however, the law shall be formulated for the preparation of traditional Chinese medicines. Except as provided.

The preparations prepared by the medical institution shall be tested for quality according to the regulations; if they are qualified, they shall be used in the unit by the doctor's prescription. Approved by the drug regulatory department of the State Council or the drug regulatory authority of the people's government of the province, autonomous region or municipality directly under the Central Government, the preparations formulated by the

medical institutions may be transferred between designated medical institutions.

Preparations prepared by medical institutions may not be marketed.

Chapter VII Management of Drugs After Listing

Article 77 The holder of a drug marketing license shall formulate a post-marketing risk management plan, take the initiative to conduct post-marketing research, further confirm the safety, effectiveness and quality controllability of the drug, and strengthen the drug-listed drugs. Continuous management.

Article 78 For drugs with conditional approval, holders of drug marketing licenses shall take corresponding risk management measures and complete relevant research as required within the prescribed time limit; fail to complete the research as required within the time limit or fail to prove that the benefits outweigh the risks The drug regulatory department of the State Council shall handle the matter until the drug registration certificate is cancelled.

Article 79 The classification and management shall be carried out on the changes in the production process of drugs in accordance with their risks and the degree of control over the safety, effectiveness and quality controllability of drugs. If it is a major change, it shall be approved by the drug regulatory department of the State Council, and other changes shall be filed or reported in accordance with the provisions of the drug regulatory authority under the State Council.

The holder of the drug marketing license shall, in accordance with the provisions of the drug regulatory authority under the State Council, comprehensively evaluate and verify the impact of the changed items on the safety, effectiveness and quality controllability of the drug.

Article 80 Holders of drug marketing licenses shall carry out monitoring of adverse reactions after drug listing, actively collect, track and analyze information on suspected adverse drug reactions, and take timely risk control measures for drugs with identified risks.

Article 81 The holders of drug marketing licenses, pharmaceutical production enterprises, pharmaceutical trading enterprises and medical institutions shall regularly inspect the quality, efficacy and adverse reactions of the drugs produced, operated and used by their own units. If a suspected adverse reaction is found, it shall promptly report to the drug regulatory authority and the competent health authority. The specific measures shall be formulated by the drug regulatory department of the State Council in conjunction with the competent health department of the State Council.

For drugs that have been confirmed to have serious adverse reactions, the drug regulatory authorities of the State Council or the drug regulatory authorities of the people's governments of provinces, autonomous regions, and municipalities directly under the Central Government shall, in accordance with actual conditions, adopt emergency control measures such as stopping production, sales, and use, and shall organize the appraisal within five days. The administrative decision shall be made within 15 days from the date of the conclusion of the appraisal.

Article 82 If a drug has quality problems or other potential safety hazards, the holder of the drug marketing permit shall immediately stop selling, inform the relevant drug business enterprises and medical institutions to stop selling and using, recall the drugs that have been sold, and promptly publicly recall the information. If necessary, production should be stopped immediately, and the recall and handling of drugs should be reported to the drug regulatory authorities and health authorities of the people's governments of provinces, autonomous regions, and

municipalities directly under the Central Government. Pharmaceutical manufacturers, pharmaceutical companies and medical institutions should cooperate.

Where the holder of a drug marketing permit shall recall the drug according to law and has not recalled it, the drug supervision and administration department of the people's government of the province, autonomous region or municipality directly under the Central Government shall order it to recall it.

Article 83 The holder of a drug marketing permit shall conduct post-marketing evaluations on the safety, effectiveness and quality controllability of the listed drugs on a regular basis. When necessary, the drug regulatory authority of the State Council may order the drug listing license holder to conduct post-marketing evaluation or directly organize post-marketing evaluation.

It has been evaluated that for drugs that are inaccurate in efficacy, have large adverse reactions, or endanger human health due to other reasons, the drug registration certificate should be cancelled.

Drugs that have been cancelled for drug registration certificates may not be produced or imported, sold or used.

Drugs that have been cancelled for drug registration certificates and have expired, etc., shall be supervised by the drug supervision and administration department or other measures such as harmless treatment shall be taken according to law.

Chapter VIII Drug Prices and Advertising

Article 84 The State shall improve the drug procurement management system, monitor drug prices, conduct cost and price surveys, strengthen drug price supervision and inspection, investigate and punish price violations such as price monopoly and price increases, and maintain drug price order.

Article 85: Drugs that are subject to market-adjusted prices according to law, drug-licensing license holders, drug-producing enterprises, drug-operated enterprises, and medical institutions shall, in accordance with the principles of fairness, reasonableness, honesty, credit, and quality, set prices for drug users. Provide affordable medicines.

Drug listing license holders, pharmaceutical production enterprises, pharmaceutical trading enterprises and medical institutions shall abide by the regulations of the drug price department of the State Council on drug price management, formulate and mark the retail price of drugs, and prohibit profits, price monopoly and price fraud.

Article 86 The holders of drug marketing licenses, pharmaceutical production enterprises, pharmaceutical trading enterprises and medical institutions shall provide the drug price authorities with the actual purchase and sale prices and purchase and sales quantities of their drugs.

Article 87 Medical institutions shall provide patients with a list of prices of drugs used, truthfully announce the prices of their commonly used drugs in accordance with regulations, and strengthen the management of rational drug use. The specific measures shall be formulated by the competent health department of the State Council.

Article 88: Drug export license holders, pharmaceutical production enterprises, pharmaceutical trading enterprises and medical institutions are prohibited from giving or receiving kickbacks or other improper benefits in the purchase and sale of drugs.

It is forbidden for the drug listing license holder, the pharmaceutical production enterprise, the pharmaceutical business enterprise or the agent to give the person in charge of the medical institution using the drug, the drug

purchaser, the physician, the pharmacist and other related persons property or other illegitimate interests in any name. It is forbidden for the person in charge of the medical institution, the drug purchaser, the physician, the pharmacist and other relevant personnel to accept the property or other illegitimate interests given by the drug listed license holder, the drug manufacturer, the drug business enterprise or the agent in any name.

Article 89: Drug advertisements shall be approved by the advertising review authority determined by the people's government of the province, autonomous region or municipality directly under the Central Government where the advertiser is located; no approval may be issued.

Article 90 The content of drug advertisements shall be true and lawful. The drug specifications approved by the drug regulatory authority under the State Council shall prevail and shall not contain false contents.

Drug advertisements may not contain assertions or guarantees indicating efficacy or safety; they shall not be recommended or certified by the state or image of state organs, scientific research units, academic institutions, industry associations, experts, scholars, physicians, pharmacists, patients, etc.

Non-pharmaceutical advertisements may not have propaganda involving drugs.

Article 91 For drug prices and advertisements, if there is no provision in this Law, the "Price Law of the People's Republic of China", the "Anti-Monopoly Law of the People's Republic of China", the "Anti-Unfair Competition Law of the People's Republic of China", and the "People's Republic of China" shall apply. Advertising Law, etc.

Chapter IX Drug Reserves and Supplies

Article 92 The State implements a drug reserve system and establishes drug reserves at the central and local levels.

In the event of a major disaster, epidemic or other unexpected incident, the drug may be urgently invoked in accordance with the provisions of the Law of the People's Republic of China on Emergency Response.

Article 93 The State implements the basic drug system, selects appropriate quantities of essential drugs, strengthens organizational production and reserves, improves the supply of essential drugs, and meets the basic drug needs for disease prevention and treatment.

Article 94 The State establishes a drug supply and demand monitoring system, collects and aggregates information on the supply and demand of shortage drugs in a timely manner, and applies early warnings to the shortage of drugs to take countermeasures.

Article 95 The State implements a management system for shortage of drug lists. The specific measures shall be formulated by the competent health department of the State Council in conjunction with the drug regulatory department of the State Council and other departments.

If the holder of a drug marketing license stops producing a shortage of drugs, it shall report to the drug regulatory department of the State Council or the drug regulatory authority of the people's government of the province, autonomous region or municipality directly under the Central Government in accordance with the regulations.

Article 96 The State encourages the development and production of shortages of drugs, and prioritizes the examination and approval of new drugs that are in urgent need of clinically needed shortages of drugs, diseases such as major infectious diseases and rare diseases.


Article 97 The State Council may restrict or prohibit exports for shortages of drugs. When necessary, the relevant departments of the State Council may adopt measures such as organizing production, price intervention and expanding imports to ensure the supply of medicines.

Holders of drug marketing licenses, pharmaceutical production enterprises, and pharmaceutical trading enterprises shall guarantee the production and supply of drugs in accordance with regulations.

Chapter X Supervision and Management

Article 98 Prohibition of production (including preparation, the same below), sales, use of counterfeit drugs, inferior drugs.

In one of the following circumstances, it is a counterfeit drug:


(1) The ingredients contained in the drug do not conform to the ingredients specified in the national drug standard; 

(2) the drug is impersonated by a non-pharmaceutical or impersonated with another drug;

(3) Deteriorating Drugs;

(4) The indications or functional indications indicated by the drugs are outside the prescribed scope.

In one of the following circumstances, it is a bad drug:

(1) the content of the drug component does not meet the national drug standard; 

(2) the drug that is contaminated;

(3) the drug that is not marked or changed in validity;

(4) change the product lot number of the drug;

(v) expired medicines;

(vi) without added preservatives, pharmaceutical excipients;

(7) other drugs do not meet the standards of drugs.

It is forbidden to produce and import drugs without obtaining the drug approval certificate; it is forbidden to use drugs of raw materials, packaging materials and containers that have not been reviewed and approved in accordance with regulations.

Article 99 The drug supervision and administration department shall, in accordance with the provisions of laws and regulations, supervise and inspect the activities of drug development, production, operation and use of drugs by drug users, and if necessary, provide products for the development, production, operation and use of drugs. Or the units and individuals of the service shall conduct an extension inspection, and the relevant units and individuals shall cooperate with them and shall not refuse or conceal them.

The drug supervision and administration department shall implement key supervision and inspection of high-risk drugs.

Where there is evidence to prove that there may be potential safety hazards, the drug supervision and administration department shall, according to the supervision and inspection, take measures such as warning, interview, rectification within a time limit, and suspension of production, sales, use, import, etc., and publish the inspection and processing results in a timely manner.

When the drug supervision and administration department conducts supervision and inspection, it shall produce

a certification document, and the business secrets known in the supervision and inspection shall be kept confidential.

Article 100 The drug supervision and administration department may conduct random inspections on the quality of drugs according to the needs of supervision and management. Sampling inspections shall be sampled in accordance with regulations and no fees shall be charged; samples shall be purchased for sampling. The required expenses are subject to the provisions of the State Council.

For drugs and related materials that have evidence to prove that they may endanger human health, the drug supervision and administration department may seal up and detain and make administrative decisions within seven days; if the drugs need to be inspected, they shall be within 15 days from the date of issuance of the inspection report. Make administrative decisions.

Article 101 The drug regulatory department of the State Council and the people's governments of provinces, autonomous regions and municipalities directly under the Central Government shall regularly announce the results of random inspections of drug quality; if the announcement is improper, it shall be corrected within the scope of the original announcement.

Article 102 If a party disagrees with the results of a drug inspection, it may, within seven days from the date of receipt of the drug inspection result, apply for re-inspection to the drug inspection agency set up or designated by the original drug inspection agency or the higher-level drug regulatory authority. It is also possible to apply for re-inspection directly to the drug inspection agency set up or designated by the drug regulatory authority under the State Council. The drug inspection agency that accepts the re-inspection shall make a re-inspection conclusion within the time specified by the drug regulatory authority under the State Council.

Article 103 The drug regulatory authority shall comply with the drug production quality management regulations and drug management for drug listing license holders, drug production enterprises, drug management enterprises, non-clinical safety evaluation research institutions, and drug clinical trial institutions. Quality management practices, drug non-clinical research quality management practices, drug clinical trial quality management practices, etc. are inspected and monitored to continue to meet statutory requirements.

Article 104 The State establishes a team of professional and specialized drug inspectors. Inspectors should be familiar with drug laws and regulations and have pharmaceutical expertise.

Article 105 The drug supervision and administration department shall establish a drug marketing license holder, a pharmaceutical production enterprise, a drug management enterprise, a non-clinical safety evaluation research institution for drugs, a drug clinical trial institution, and a drug safety credit file of a medical institution, and record permission shall be issued. The results of daily supervision and inspection, investigation of illegal acts, etc. shall be announced to the public in accordance with the law and updated in a timely manner; for those with bad credit records, the frequency of supervision and inspection shall be increased, and joint punishment may be implemented in accordance with state regulations.

Article 106 The drug regulatory authority shall publish the e-mail address and telephone number of the department, accept consultation, complaints, and reports, and promptly reply, verify, and handle it according to law. Reports that are true to the investigation are rewarded to the reporter in accordance with relevant regulations.

The drug supervision and administration department shall keep the information of the reporter confidential and protect the legitimate rights and interests of the reporter. If the whistleblower reports the unit, the unit shall not

retaliate against the whistle-blower by dismissing or changing the labor contract or other means.

Article 107 The State implements a unified system for the publication of drug safety information. The overall situation of national drug safety, drug safety risk warning information, major drug safety incidents and their investigation and handling information, and other information that the State Council determines to be uniformly announced shall be uniformly announced by the drug regulatory department of the State Council. The impact of drug safety risk warning information and major drug safety incidents and their investigation and processing information is limited to specific regions, and may also be announced by the drug regulatory authorities of the people's governments of relevant provinces, autonomous regions, and municipalities directly under the Central Government. The above information may not be released without authorization.

The publication of drug safety information shall be timely, accurate and comprehensive, and shall be accompanied by necessary explanations to avoid misleading.

No unit or individual may fabricate or distribute false drug safety information.

Article 108 The people's government at or above the county level shall formulate an emergency plan for drug safety incidents. Drug listing license holders, pharmaceutical production enterprises, pharmaceutical trading enterprises and medical institutions shall formulate their own drug safety incident handling plans and organize training and emergency drills.

In the event of a drug safety incident, the people's government at or above the county level shall immediately organize the response work in accordance with the emergency plan; the relevant units shall immediately take effective measures to prevent the damage from expanding.

Article 109 If the drug supervision and administration department fails to discover the systemic risks of drug safety in a timely manner and fails to eliminate the hidden dangers of drug safety in the supervision and management area in a timely manner, the people's government at the same level or the drug supervision and administration department of the higher-level people's government shall conduct the main responsible persons. Interview.

If the local people's government fails to perform its drug safety duties and fails to eliminate potential major drug safety hazards in a timely manner, the higher-level people's government or the drug supervision and administration department of the higher-level people's government shall conduct an interview with its principal responsible person.

The departments and local people's governments that have been interviewed should immediately take measures to rectify the drug supervision and management work.

The situation of the interview and the rectification situation shall be included in the appraisal and assessment records of the drug supervision and management work of the relevant departments and local people's governments.

Article 110 The local people's government and its drug supervision and administration department shall not restrict or exclude drugs produced by non-local drug listing license holders or pharmaceutical production enterprises from entering the region by means of drug testing and examination and approval.

Article 111 The drug supervision and administration department and its designated or designated pharmaceutical professional and technical institutions shall not participate in the production and operation of drugs, and may not recommend or supervise or supervise drugs in their name.

The drug supervision and administration department and its staff set up or designated by the pharmaceutical

professional technical organization shall not participate in the drug production and operation activities.

Article 112 If the State Council has other special administrative regulations on narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs, and precursor chemicals, it shall be in accordance with its provisions.

Article 113 If the drug supervision and administration department finds that a drug illegal act is suspected of committing a crime, it shall promptly transfer the case to the public security organ.


The public security organ, the people's procuratorate, and the people's court shall promptly transfer the case to the drug supervision and administration department if it is not required to pursue criminal responsibility or exempt from criminal punishment according to law.

The public security organs, the people's procuratorates, and the people's courts request the drug regulatory authorities, the competent departments of ecological environment, and other departments to provide inspection conclusions, confirmation opinions, and harmless treatment of the drugs involved, and relevant departments shall provide them in time for assistance.

Chapter XI Legal Liability

Article 114 Whoever violates the provisions of this Law and constitutes a crime shall be investigated for criminal responsibility according to law.

Article 115 If a drug production license, a drug business license or a medical institution's preparation license is not produced or sold, it shall be ordered to close, the illegally produced and sold drugs and illegal proceeds shall be confiscated, and illegally produced and sold. The drug value (including the sold and unsold drugs, the same below) is a fine of 15 times to 30 times the value of the goods; if the value of the goods is less than 100,000 yuan, it is calculated at 100,000 yuan.

Article 116 Whoever produces or sells counterfeit drugs shall be confiscated illegally produced and sold drugs and illegal gains, ordered to suspend production and suspend business for rectification, revoke the drug approval documents, and be fifteen times the amount of drugs illegally produced and sold. If the amount of goods is less than 100,000 yuan, the calculation shall be based on 100,000 yuan; if the circumstances are serious, the drug production license, drug business license or medical institution preparation license shall be revoked, and the corresponding shall not be accepted within 10 years. Application; if the holder of the drug marketing license is an overseas enterprise, its drug imports are prohibited within 10 years. 

Article 117 Anyone who produces or sells inferior drugs shall be confiscated illegally produced and sold drugs and illegal gains, and shall be fined not less than ten times and twenty times less than the value of the drug produced or sold illegally; illegal production and wholesale If the value of the drug value is less than 100,000 yuan, it shall be calculated at 100,000 yuan. If the value of the illegal retail drug is less than 10,000 yuan, it shall be calculated at 10,000 yuan. If the circumstances are serious, the production shall be suspended and the drug shall be rectified until the drug approval certificate is revoked. , drug production license, drug business license or medical institution preparation license.

The Chinese medicine decoction pieces produced and sold do not meet the drug standards, and they do not affect the safety and effectiveness. They are ordered to make corrections within a time limit and give warnings; they

can be fined between 100,000 yuan and 500,000 yuan.

Article 118: The production or sale of counterfeit drugs, or the production or sale of inferior drugs, if the circumstances are serious, the legal representative, the principal responsible person, the directly responsible person in charge and other responsible personnel shall be confiscated during the period of the violation. The income earned by the unit shall be a fine of 30% or more and 3 times or less of the income obtained by the unit. It is forbidden to engage in the production and business operations of the drug for life, and may be detained by the public security organ for more than five days and less than fifteen days.

The raw materials, auxiliary materials, packaging materials and production equipment specially used by the producers for the production of counterfeit drugs and inferior drugs shall be confiscated.

Article 119 Where a drug use unit uses counterfeit or inferior drugs, it shall be punished according to the provisions of selling counterfeit drugs or retail inferior drugs; if the circumstances are serious, the legal representative, the principal responsible person, the directly responsible person in charge and other responsibilities If a person has a medical and health personnel practicing certificate, the practice certificate shall also be revoked.

Article 120 It is known or should be known that it is a counterfeit or inferior drug or a drug specified in Items 1 to 5 of Paragraph 1 of Article 124 of this Law, and provides convenient conditions for storage and transportation. , confiscation of all storage and transportation income, and a fine of more than one time and five times the illegal income; if the circumstances are serious, and impose a fine of not less than five times and fifteen times the illegal income; if the illegal income is less than 50,000 yuan, according to five Million yuan calculation.

Article 121 The decision on the punishment of counterfeit drugs and inferior drugs shall state the conclusions of the quality inspection of the drug inspection agency according to law.

Article 122 Anyone who forges, alters, leases, lends, or sells a license or a certificate of approval of a drug shall confiscate the illegal income and impose a fine of not less than one time but not more than five times the illegal income; if the circumstances are serious, a fine of not less than five times and fifteen times the illegal income, and the drug production license, drug business license, medical institution preparation license or drug approval certificate shall be revoked, and the legal representative, principal responsible person, directly responsible person in charge and others shall be revoked. The responsible person shall be fined not less than 20,000 yuan but not more than 200,000 yuan. It is forbidden to engage in drug production and business activities within ten years, and may be detained by the public security organ for more than five days and less than fifteen days; if the illegal income is less than 100,000 yuan, 100,000 yuan calculation.

Article 123 If a false certificate, data, data, sample or other means is provided to defraud a clinical trial license, a drug production license, a drug business license, a medical institution's preparation license or a drug registration, etc., the relevant license is revoked. During the year, the corresponding application will not be accepted, and a fine of not less than 500,000 yuan but not more than 5 million yuan will be imposed. If the circumstances are serious, the legal representative, the principal responsible person, the directly responsible person in charge and other responsible personnel shall be charged more than 20,000 yuan. A fine of less than 200,000 yuan is forbidden to engage in drug production and business activities within 10 years, and may be detained by the public security organs for more than five days and less than fifteen days.

Article 124 Anyone who commits any of the following acts in violation of the provisions of this Law shall

confiscate illegally produced, imported and sold drugs and illegal proceeds, as well as raw materials, auxiliary materials, packaging materials and production equipment specially used for illegal production, and shall order the suspension of production. Shut down and rectify, and impose a fine of 15 times or more and 30 times less than the value of illegally produced, imported, and sold drugs; if the value of goods is less than 100,000 yuan, it shall be calculated at 100,000 yuan; if the circumstances are serious, the drug approval certificate shall be revoked. Documents until the drug production license, drug business license or medical institution preparation license is revoked, the legal representative, the principal responsible person, the directly responsible person in charge and other responsible personnel shall be confiscated from the income of the unit during the period of the illegal act. gained more than thirty percent and impose a fine of three times the income of a decade until the lifetime ban engage in drug production and business activities, and may consist of more than five days than 15 days detained by the police at:

- without obtaining drugs (a) approval documents produced, imported drugs;
- (b) the use of approved drugs taken fraudulently obtained documents Production, imported drugs;
- (c) used without the review and approval of the drug raw material drug production;
- (iv) shall be without being tested, namely drug sales;
- (e) production and sale of the drug regulatory department of the State Council, prohibited drug use;
- (6) Fabricating production and inspection records;
- (7) Making major changes in the pharmaceutical production process without approval.

If the drugs specified in Items 1 to 3 of the preceding paragraph or the drugs used by the drug use units are used in accordance with the provisions of the first paragraph to the fifth paragraph, the penalties shall be imposed in accordance with the provisions of the preceding paragraph; if the circumstances are serious, the legal representative of the drug use unit If the principal person in charge, the directly responsible person in charge, and other responsible personnel have a certificate of practice for medical and health personnel, the certificate of practice shall also be revoked.

Without the approval to import a small number of drugs that have been legally listed overseas, if the circumstances are relatively minor, they may be mitigated or exempted from punishment according to law.

Article 125 Anyone who commits any of the following acts in violation of the provisions of this Law shall confiscate illegally produced and sold drugs and illegal proceeds, as well as packaging materials and containers, order them to suspend production and suspend business for rectification, and impose a fine of more than 500,000 yuan and 5 million yuan. If the circumstances are serious, the drug approval certificate, drug production license, and drug business license shall be revoked. The legal representative, the principal responsible person, the directly responsible person in charge and other responsible personnel shall be 20,000 yuan or more. A fine of not more than 10,000 yuan, for 10 years until life is prohibited from engaging in drug production and management activities:

- (1) conducting drug clinical trials without approval;
- (2) using unreviewed packaging materials or containers for direct contact with drugs to produce drugs, or selling Such drugs;
- (3) the use of unapproved labels, instructions.

Article 126 In addition to the circumstances stipulated in this Law, drug listing license holders, pharmaceutical

production enterprises, pharmaceutical enterprises, non-clinical safety evaluation research institutions, drug clinical trial institutions, etc. do not comply with drug production. Quality management practices, quality management practices for pharmaceuticals, quality management norms for drug non-clinical research, quality management practices for drug clinical trials, etc., shall be ordered to correct within a time limit and given a warning; if the overdue period is not corrected, it shall be less than 100,000 yuan and less than 500,000 yuan. If the circumstances are serious, a fine of not less than RMB 500,000 and not more than RMB 2 million shall be imposed, and the company shall suspend production and suspend business for rectification until the drug approval certificate, drug production license, drug business license, etc., and non-clinical safety evaluation research institutions are revoked. The drug clinical trial institution shall not conduct drug non-clinical safety evaluation research or drug clinical trial within five years, and the legal representative, principal responsible person, directly responsible person in charge and other responsible personnel shall be confiscated from the unit during the period of the illegal act. Earned income and earned more than 10% of the income The following fines, banned for life until a decade engaged in pharmaceutical production and business activities.

Article 127 Anyone who violates the provisions of this Law and has one of the following acts shall be ordered to make corrections within a time limit and be given a warning; if the overdue period is not corrected, a fine of not less than 100,000 yuan but not more than 500,000 yuan shall be imposed:

- (1) Carrying out biological activities, etc. The effectiveness test was not filed;
- (2) During the clinical trial of the drug, it was found that there were safety problems or other risks. The clinical trial sponsor did not timely adjust the clinical trial plan, suspend or terminate the clinical trial, or did not report to the drug regulatory authority under the State Council;
- (3) Failure to comply with the regulations the establishment and implementation of the drug tracing system;
- (4) failing to submit annual reports in accordance with the provisions;
- (5) Failing to pharmaceutical production process to change the record or report in accordance with the provisions;
- (f) not established after-marketing risk management plan;
- (vii) Post-marketing research or post-marketing evaluation of drugs was not carried out in accordance with regulations.

Article 128 In addition to the punishment according to law for counterfeit or inferior drugs, the packaging of the drug is not printed, labeled or accompanied by instructions. The label and the instructions do not indicate relevant information or are printed in accordance with the regulations. Marked, ordered to correct, give warning; if the circumstances are serious, the drug registration certificate is revoked.

Article 129 In violation of the provisions of this Law, holders of drug marketing licenses, pharmaceutical manufacturing enterprises, pharmaceutical trading enterprises or medical institutions have not purchased drugs from holders of drug marketing licenses or enterprises with pharmaceutical production and business qualifications. Ordered to correct, confiscate illegally purchased drugs and illegal gains, and impose a fine of more than two times and ten times the amount of illegally purchased drugs; if the circumstances are serious, the fines of the value of goods shall be less than ten times and less than thirty times. The drug approval certificate, drug production license, drug business license or medical institution practice license shall be revoked; if the value of the goods is less than

50,000 yuan, it shall be calculated at 50,000 yuan.

Article 130 In violation of the provisions of this Law, drugs purchased and sold by pharmaceutical business enterprises are not recorded in accordance with the regulations. If the retail drugs do not correctly explain the usage and dosage, or if the prescriptions are not prepared according to the regulations, they shall be ordered to make corrections and give warnings; , the drug business license is revoked.

Article 131 In violation of the provisions of this Law, if the third-party platform provider of drug network transactions fails to perform the qualification review, report, or stop providing the services of the online trading platform, it shall be ordered to make corrections, the illegal income shall be confiscated, and 200,000 yuan shall be imposed. A fine of not more than two million yuan; if the circumstances are serious, the company shall be ordered to suspend business for rectification and impose a fine of not less than 2 million yuan but not more than 5 million yuan.

Article 132 If a drug that has obtained a drug registration certificate has not been filed in accordance with the regulations to the drug regulatory authority at the port where the drug is allowed to be imported, it shall be ordered to make corrections within a time limit and given a warning; if it is not corrected within the time limit, the drug registration certificate shall be revoked.

Article 133 In violation of the provisions of this Law, if a medical institution sells its prepared preparations on the market, it shall be ordered to correct, confiscate the illegally sold preparations and illegal proceeds, and be at least five times the value of the illegally sold preparations. The following fines; if the circumstances are serious, and the amount of the goods is less than five times and fifteen times the fine; if the value of the goods is less than 50,000 yuan, it is calculated at 50,000 yuan.

Article 134 If the holder of a drug marketing permit fails to carry out monitoring of adverse drug reactions or reports suspected adverse drug reactions in accordance with the regulations, it shall be ordered to make corrections within a time limit and be given a warning; if it fails to make corrections within the time limit, it shall be ordered to suspend production and suspend business for rectification, and shall be placed at 100,000. A fine of not more than one million yuan.

If a pharmaceutical business enterprise fails to report suspected adverse drug reactions in accordance with the regulations, it shall be ordered to make corrections within a time limit and be given a warning; if it fails to make corrections within the time limit, it shall be ordered to suspend production and suspend business for rectification, and impose a fine of not less than 50,000 yuan but not more than 500,000 yuan.

If a medical institution fails to report suspected adverse drug reactions in accordance with the regulations, it shall be ordered to make corrections within a time limit and be given a warning; if it fails to make corrections within the time limit, it shall be imposed a fine of not less than 50,000 yuan but not more than 500,000 yuan.

Article 135 If a drug marketing permit holder refuses to recall after the drug regulatory authority of the people's government of a province, autonomous region or municipality directly under the Central Government has ordered his recall, he shall be fined a fine of not less than five times and ten times the value of the drug. If the value of the goods is less than 100,000 yuan, it shall be calculated at 100,000 yuan; if the circumstances are serious, the drug approval certificate, drug production license, drug business license shall be revoked, and the legal representative, principal responsible person and directly responsible person in charge shall be revoked. And other responsible personnel, a fine of not less than 20,000 yuan but not more than 200,000 yuan. If a pharmaceutical production

enterprise, a pharmaceutical business enterprise or a medical institution refuses to cooperate with the recall, it shall impose a fine of not less than 100,000 yuan but not more than 500,000 yuan.

Article 136 Where the holder of a drug listing permit is an overseas enterprise, if the enterprise legal person designated in China does not perform the relevant obligations in accordance with the provisions of this Law, the provisions of this Law concerning the legal liability of the holder of the drug listing permit shall apply. .

Article 137 Any of the following acts shall be severely punished within the scope of punishment provided for in this Law:

(1) posing as an anesthetic drug, a psychotropic drug, a medical toxic drug, a radioactive drug, a drug-based precursor chemical, or impersonating another drug with other drugs;

(2) Producing and selling pregnant women and children as the main using the object's counterfeit or substandard drugs;

(c) the production and sale of biological products belong to counterfeit or substandard drugs;

(iv) production and sale of counterfeit or substandard drugs, injury consequences;

(e) production and sale of counterfeit drugs substandard drugs, after treatment recidivism;

(6) Refusing to evade supervision and inspection, forgery, destruction, concealing evidence material, or unauthorized use of seizure, seizure of items.

Article 138 Where a drug inspection agency issues a false inspection report, it shall be ordered to make corrections, give a warning, and impose a fine of not less than 200,000 yuan but not more than 1 million yuan on the unit; directly responsible persons and other directly responsible personnel Declassification, dismissal, dismissal, confiscation of illegal income, and a fine of less than 50,000 yuan; if the circumstances are serious, the qualification for inspection shall be revoked. If the inspection result issued by the drug inspection agency is untrue, and the loss is caused, it shall bear the corresponding liability for compensation.

Article 139 The administrative penalties stipulated in Articles 115 to 138 of this Law shall be decided by the drug supervision and administration department of the people's government at or above the county level in accordance with the division of responsibilities; the licenses shall be revoked and the licenses shall be revoked. The decision is made by the department that originally approved and issued the certificate.

Article 140 If a drug marketing permit holder, a pharmaceutical production enterprise, a drug trading enterprise or a medical institution violates the provisions of this Law, the drug supervision and administration department or the health and health department shall order it to be dismissed, and shall be 50,000 yuan or more. A fine of less than 100,000 yuan.

Article 141 Where a drug marketing permit holder, a pharmaceutical production enterprise, a pharmaceutical trading enterprise or a medical institution gives, receives or receives any undue advantage in the purchase and sale of a drug, the drug marketing license holder, the pharmaceutical production enterprise, Where the pharmaceutical business enterprise or agent gives the person in charge of the medical institution using the drug, the drug purchaser, the physician, the pharmacist, etc., or other illegitimate interests, the market supervision and management department shall confiscate the illegal income and pay 300,000 yuan. If the circumstances are serious, the business license of the drug listing permit holder, the drug manufacturer, or the drug business enterprise shall be revoked, and the drug regulatory authority shall revoke the drug approval certificate, drug production license, and drug

business. license.

Where a drug marketing license holder, a pharmaceutical production enterprise, or a pharmaceutical business enterprise pays bribes to a state employee during drug development, production, or operation, the legal representative, the principal responsible person, the directly responsible supervisor, and other responsible personnel shall be prohibited from engaging in life. Pharmaceutical production and operation activities.

Article 142. The holders of drug marketing licenses, pharmaceutical production enterprises, responsible persons of pharmaceutical enterprises, procurement personnel and other relevant personnel shall accept other drug marketing license holders, pharmaceutical production enterprises and pharmaceutical enterprises in the purchase and sale of drugs. Or the property or other improper benefits given by the agent, the illegal income shall be confiscated, and the punishment shall be imposed according to law; if the circumstances are serious, the drug production and operation activities shall be prohibited within five years.

If the person in charge of the medical institution, the drug purchaser, the physician, the pharmacist, etc. accepts the property or other illegitimate benefits granted by the drug listing permit holder, the drug manufacturer, the drug business enterprise or the agent, the health and health department or The unit shall impose disciplinary action and confiscate the illegal income; if the circumstances are serious, it shall also revoke its practice certificate.

Article 143 Anyone who violates the provisions of this Law by fabricating or distributing false drug safety information constitutes a violation of public security management shall be punished by public security organs according to law.

Article 144 Where a drug marketing permit holder, a pharmaceutical production enterprise, a pharmaceutical trading enterprise or a medical institution violates the provisions of this Law and causes damage to the drug users, it shall be liable for compensation according to law.

If the quality of the drug is damaged, the victim may request damages from the drug listing license holder or the drug manufacturer, or may request damages from the drug business enterprise or medical institution. If a victim's claim for compensation is received, the first responsible system shall be implemented, and the first payment shall be made; after the first payment, the claim may be recovered according to law.

The production of counterfeit drugs, inferior drugs or knowing that fake drugs or inferior drugs are still sold or used, the victim or his close relatives may request compensation for the loss of ten times or three times the loss in addition to the claim for damages; If the amount is less than one thousand yuan, it is one thousand yuan.

Article 145 Where the drug supervision and administration department or its designated or designated drug professional technical institution participates in the drug production and management activities, its superior competent authority shall order it to make corrections and confiscate the illegal income; if the circumstances are serious, the person directly responsible shall be directly responsible. And other directly responsible personnel are given disciplinary action according to law.

Where the drug supervision and administration department or the staff of its designated or designated pharmaceutical professional technical organization participate in the drug production and management activities, it shall be punished according to law.

Article 146 Where the drug supervision and administration department or its designated or designated drug inspection agency illegally collects the inspection fee during the drug supervision and inspection, the relevant

government department shall order it to be returned, and the directly responsible person in charge and other directly responsible personnel shall be legally responsible. If the circumstances are serious, the qualification for the inspection shall be revoked.

Article 147 In case of violation of the provisions of this Law, if the drug supervision and administration department has one of the following acts, it shall revoke the relevant license and punish the directly responsible person in charge and other directly responsible personnel according to law:

- (1) Failure to meet the conditions Approved for clinical trials of drugs;
- (2) Issue drug registration certificates for drugs that do not meet the requirements;
- (3) Issue drug production licenses, drug business licenses or medical institution preparation licenses for units that do not meet the requirements.

Article 148 In case of violation of the provisions of this Law, if the local people's government at or above the county level has one of the following acts, the directly responsible person in charge and other directly responsible personnel shall be given a record or a greater punishment; if the circumstances are serious, the case shall be downgraded. Dismissal or dismissal:

- (1) Reporting, misreporting, delaying, or missing drug safety incidents;
- (2) Failure to eliminate regional major drug safety hazards in a timely manner, resulting in special major drug safety incidents within the administrative region, or continuous major drug safety incidents;
- (3) Poor performance of duties, causing serious adverse effects or major losses.

Article 149 In case of violation of the provisions of this Law, if the drug supervision and administration department has one of the following acts, the directly responsible person in charge and other directly responsible personnel shall be given a record or a greater punishment; if the circumstances are serious, the case shall be downgraded. Or dismissal; if the circumstances are serious, the dismissal shall be given:

- (1) Reporting, false reporting, delaying of reporting, or underreporting of drug safety incidents;
- (2) Failure to promptly investigate and punish the discovered drug safety violations;
- (3) Failure to discover drugs in time Safety systemic risks, or failure to eliminate potential chemical safety hazards in the area under supervision and management, have serious impacts;
- (4) Others fail to perform drug supervision and management duties, causing serious adverse effects or major losses.

Article 150 If drug supervision and management personnel abuse their powers, engage in malpractices for personal gains, or neglect their duties, they shall be punished according to law.

Those who are responsible for dereliction of duty or dereliction of duty in the investigation of counterfeit drugs or inferior drugs shall be given a serious punishment according to the competent personnel directly responsible for the drug supervision and administration department and other persons directly responsible.

Article 151 The amount of goods specified in this Chapter shall be calculated at the price of illegally producing and selling drugs; if there is no price, it shall be calculated according to the market price of similar drugs.

Chapter 12 Supplementary Provisions

Article 152 The management of planting, collecting and raising Chinese herbal medicines shall be carried out in accordance with the provisions of relevant laws and regulations.

Article 153 The administrative measures for regional folk medicinal materials shall be formulated by the drug regulatory department of the State Council in conjunction with the competent department of Chinese medicine under the State Council.

Article 154 The specific measures for the implementation of this Law by the Chinese People's Liberation Army and the Chinese People's Armed Police Force shall be formulated by the State Council and the Central Military Commission in accordance with this Law.

Article 155 This Law shall come into force on December 1, 2019.

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- Graphic policy: The newly revised "Drug Administration Law of the People's Republic of China" came to the full text (1)

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