Drug Administration Law of the People's Republic of China (2019 Revision)[1]

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The "Drug Administration Law of the People's Republic of China" was revised and adopted at the 12th meeting of the Standing Committee of the 13th National People's Congress of the People's Republic of China on August 26, 2019. It is hereby promulgated and shall come into effect on December 1, 2019.

President of the People's Republic of China

Xi Jinping

August 26, 2019

Drug Administration Law of the People's Republic of China (Promulgated by the 7th meeting of the Standing Committee of the 6th National People's Congress on September 20, 1984; first amendment at the 20th meeting of the Standing Committee of the 9th National People's Congress on February 28, 2001; first revision according to the decision on amending seven laws including the "Marine Environmental Protection Law of the People's Republic of China" at the 6th meeting of the Standing Committee of the 12th National People's Congress on December 28, 2013; second revision according to the decision on amending the "Drug Administration Law of the People's Republic of China" at the 14th meeting of the Standing Committee of the 12th National People's Congress on April 24, 2015; second revision at the 12th meeting of the Standing Committee of the 13th National People's Congress on August 26, 2019)

[1] Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

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Chapter I: General Provisions

Article 1

This law is enacted to strengthen drug administration, ensure drug quality, safeguard public safety and legitimate rights in drug use, and to protect and promote public health.

Article 2

This Law applies to drug research, production, distribution, use, and supervision within the territory of the People's Republic of China. Drugs refer to substances used for preventing, treating, or diagnosing human diseases, intentionally regulating human physiological functions, with specified indications or functions, usage, and dosage, including traditional Chinese medicines, chemical drugs, and biological products.

Article 3

Drug administration shall prioritize public health, adhere to principles of risk management, full-process control, and social co-governance, and establish a scientific and strict supervisory system to comprehensively enhance drug quality and ensure safety, efficacy, and accessibility.

Article 4

The State promotes the development of modern and traditional medicines, leveraging their roles in prevention, treatment, and healthcare. The State protects wild medicinal resources and varieties of traditional Chinese medicines and encourages the cultivation of authentic traditional Chinese medicines.

Article 5

The State encourages research and development of new drugs and protects the legitimate rights of citizens, legal persons, and other organizations in researching and developing new drugs.

Article 6

The State implements a drug marketing authorization holder system. Holders are legally responsible for the safety, efficacy, and quality control of drugs throughout their research, production, distribution, and use.

Article 7

All activities involving drug research, production, distribution, and use must comply with relevant laws, regulations, rules, standards, and guidelines, ensuring that all information throughout the process is authentic, accurate, complete, and traceable.

Article 8

The medicinal product regulatory department of the State Council shall be responsible for the national supervision and administration of medicinal products. The other relevant departments of the State Council shall be responsible for supervision and administration related to medicinal products within their respective functions. The medicinal product regulatory department of the State Council shall cooperate with the relevant departments of the State Council in implementing national general plans for pharmaceutical industry development and industry policies.

The medicinal product regulatory departments of the people's governments of provinces, autonomous regions, and municipalities directly under the central government shall be responsible for the supervision and administration of medicinal products within their respective administrative regions. The department of a people's government at or above the districted city or the county level charged with the function of supervision and administration of medicinal products ("medicinal product regulatory department") shall be responsible for the supervision and administration of medicinal products within its administrative region. The relevant departments of a local people's government at or above the county level shall be responsible for supervision and administration related to medicinal products within their respective functions.

Article 9

Local people's governments at or above the county level are responsible for drug supervision in their jurisdictions, leading, organizing, and coordinating drug supervision and responses to drug safety emergencies, and establishing robust mechanisms for drug supervision and information sharing.

Article 10

People's governments at or above the county level shall incorporate drug safety work into their economic and social development plans, allocate funding for drug safety in their budgets, and strengthen drug supervisory capacity to support drug safety work.

Article 11

Drug regulatory departments or their designated professional technical institutions conduct necessary evaluations, inspections, verifications, monitoring, and assessments for drug supervision.

Article 12

The State establishes a drug traceability system. The State Council's drug regulatory department shall formulate unified traceability standards and norms to promote information sharing and ensure drug traceability. The State establishes a pharmacovigilance system to monitor, identify, evaluate, and control adverse drug reactions and other drug-related harmful reactions.

Article 13

People's governments at all levels, their departments, and drug industry associations shall enhance drug safety education and promote knowledge of drug safety laws and regulations. News media shall conduct public-interest promotion of drug safety laws and regulations and supervise drug-related violations. Drug-related reports shall be comprehensive, scientific, objective, and fair.

Article 14

Drug industry associations shall strengthen self-discipline, establish industry norms, promote integrity systems, and supervise members to conduct drug production and distribution lawfully.

Article 15

People's governments at or above the county level and their departments shall commend and reward units and individuals making outstanding contributions to drug research, production, distribution, use, and supervision, in accordance with national regulations.

Chapter II: Drug Research and Registration

Article 16

The State supports drug innovation oriented toward clinical value with clear or special therapeutic effects, encourages drugs with new mechanisms, treatments for life-threatening or rare diseases, or multi-target systemic regulation, and promotes drug technology advancement.

The State encourages using modern science and traditional Chinese medicine research methods for drug development, establishing evaluation systems suited to traditional Chinese medicines to promote their inheritance and innovation. The State takes effective measures to encourage pediatric drug research, supporting the development of new pediatric drug varieties, formulations, and specifications, with priority review and approval.

Article 17

Drug research activities shall comply with Good Laboratory Practices (GLP) and Good Clinical Practices (GCP) to ensure continuous compliance with legal requirements. GLP and GCP standards are formulated by the State Council's drug regulatory department in collaboration with relevant departments.

Article 18

Non-clinical drug research shall comply with national regulations, with personnel, facilities, equipment, instruments, and management systems appropriate to the research project, ensuring the authenticity of data, materials, and samples.

Article 19

Clinical drug trials shall submit research methods, quality standards, pharmacological and toxicological results, and other data, materials, and samples to the State Council's drug regulatory department for approval. The department shall decide within 60 working days of receiving the application; failure to notify within this period is deemed approval. Bioequivalence trials require filing with the department. Clinical trials shall be conducted in qualified institutions, which are subject to filing management, with specific measures formulated by the State Council's drug regulatory and health departments.

Article 20

Clinical drug trials shall adhere to ethical principles, develop trial protocols, and obtain ethics committee approval. Ethics committees shall establish independent, objective, and fair review systems to supervise trials, protect participants' rights, and safeguard public interest.

Article 21

Clinical drug trials shall truthfully explain and clarify trial purposes and risks to participants or their guardians, obtain voluntary informed consent, and take effective measures to protect participants' rights.

Article 22

During clinical trials, if safety issues or other risks are identified, the trial sponsor shall promptly adjust the trial protocol, suspend, or terminate the trial and report to the State Council's drug regulatory department. The department may order adjustments, suspension, or termination if necessary.

Article 23

For drugs in clinical trials for life-threatening diseases with no effective treatments, if medical observation suggests potential benefits and ethical principles are met, they may be used in the trial institution for other patients with similar conditions after review and informed consent.

Article 24

Drugs marketed in China must obtain a drug registration certificate from the State Council's drug regulatory department, except for traditional Chinese medicinal materials and decoctions not subject to approval management. The list of approved traditional Chinese medicines is formulated by the State Council's drug regulatory and traditional Chinese medicine departments. Drug registration applications must provide authentic, sufficient, and reliable data, materials, and samples proving safety, efficacy, and quality control.

Article 25

For drug registration applications, the drug regulatory department under the State Council shall organize a review panel of pharmaceutical, medical, and technical experts to evaluate the drug's safety, efficacy, quality control, as well as the applicant's quality management, risk control, and liability compensation capabilities. If all requirements are met, a drug registration certificate will be issued.

During the approval process, active pharmaceutical ingredients, excipients, packaging materials that come into direct contact with the drug, containers, quality standards, manufacturing processes, labels, and instructions are reviewed and approved simultaneously.

Article 26

For drugs treating life-threatening diseases with no effective treatments or urgently needed for public health, if clinical trial data show efficacy and predictable clinical value, conditional approval may be granted, with relevant matters specified in the registration certificate.

Article 27

The State Council's drug regulatory department shall improve drug review and approval systems, enhance capacity, establish communication and expert consultation mechanisms, optimize review processes, and improve efficiency. Approval conclusions and bases shall be disclosed lawfully for public supervision, with commercial secrets kept confidential.

Article 28

Drugs shall comply with the national drug standards. If the drug quality standards approved by the drug regulatory department of the State Council are higher than the national drug standards, the approved drug quality standards shall be followed; if there are no national drug standards, the approved drug quality standards shall be complied with the Pharmacopoeia of the People's Republic of China and drug standards promulgated by the drug regulatory department of the State Council constitute the national drug standards.

The drug regulatory department of the State Council, together with the health authority of the State Council, organizes the Pharmacopoeia Committee, which is responsible for the formulation and revision of national drug standards. Drug testing institutions established or designated by the drug regulatory department of the State Council are responsible for the calibration of national drug reference standards and reference materials.

Article 29

The drug names included in the national drug standards are called generic drug names. Once a name is established as a generic drug name, it cannot be used as a drug trademark.

Chapter III: Drug Marketing Authorization Holder (MAH)

Article 30

The Drug Marketing Authorization Holder (MAH) refers to the enterprise or drug research institution that obtains the drug registration certificate. The MAH shall be responsible, according to the law, for non-clinical research, clinical trials, production and operation, post-marketing research, adverse reaction monitoring, reporting, and handling. Other entities or individuals engaged in drug research, production, operation, storage, transportation, or use shall assume corresponding responsibilities according to law. The MAH's legal representative and principal leaders are fully responsible for drug quality.

Article 31

The MAH must establish a drug quality assurance system and appoint dedicated personnel independently responsible for drug quality management.The MAH must regularly audit the quality management systems of entrusted drug manufacturers and distributors, ensuring they continuously maintain quality assurance and control capabilities.

Article 32

The MAH may produce drugs by itself or entrust qualified drug manufacturers to produce. If producing drugs themselves, the MAH must obtain a drug production license according to law. If entrusting production, it must be to qualified manufacturers. The MAH and entrusted

manufacturers must sign entrustment and quality agreements and strictly fulfill their obligations.

The State Council drug regulatory department issues guidelines for quality agreements in entrusted production to guide and supervise the MAH and manufacturers in fulfilling quality assurance obligations.

Blood products, narcotics, psychotropic drugs, toxic medical drugs, and precursor chemicals for drug production may not be entrusted for production, except as otherwise regulated by the State Council drug regulatory department.

Article 33

The MAH must establish a drug release procedure to review drugs released by manufacturers. Only after signature by an authorized quality person can drugs be released. Drugs not meeting national standards must not be released.

Article 34

The MAH may sell the registered drugs themselves or entrust qualified drug distributors to sell them. If the MAH engages in retail, it must obtain a drug business license. MAHs selling directly must meet conditions specified in Article 52 of this law. If entrusting sales, they must use qualified distributors. The MAH and distributors must sign entrustment agreements and strictly follow their terms.

Article 35

When MAHs, manufacturers, or distributors entrust drug storage or transportation, they must assess the entrusted party's quality assurance and risk management capabilities, sign entrustment agreements detailing quality responsibilities and operational procedures, and supervise the entrusted party.

Article 36

MAHs, manufacturers, distributors, and medical institutions must establish and implement a drug traceability system, provide traceability information as required, and ensure drugs can be traced.

Article 37

MAHs must establish an annual reporting system and report drug production, sales, post-marketing research, risk management, and other related information to provincial-level drug regulatory departments every year.

Article 38

For MAHs that are foreign enterprises, they must designate a domestic legal entity in China to fulfill the MAH obligations, who will bear joint liability with the foreign MAH.

Article 39

Enterprises producing traditional Chinese medicine (TCM) decoction pieces must fulfill MAH obligations for TCM decoction pieces, implement full-process management over production and sales, establish a traceability system, and ensure the safety, efficacy, and traceability of TCM decoction pieces. Production and inspection records must be authentic, complete, and traceable.

Article 40

With approval from the drug regulatory department of the State Council, the Drug Marketing Authorization Holder (MAH) may transfer the drug marketing authorization. The transferee must have the capabilities to ensure drug safety, efficacy, quality control, risk management, and liability compensation, and must fulfill the obligations of the MAH.

Chapter IV: Drug Production

Article 41

Any entity engaging in drug production must obtain approval from the drug regulatory department of the provincial-level government where it is located and obtain a drug production license. No drug production is allowed without this license. The drug production license shall specify its validity period and scope of production and must be renewed upon expiration.

Article 42

Entities engaged in drug production must meet the following conditions:

1-Have qualified pharmaceutical technicians, engineering technicians, and corresponding skilled workers;

2-Have factories, facilities, and sanitary environments suitable for drug production;

3-Have institutions, personnel, and necessary instruments and equipment capable of conducting quality management and testing of the produced drugs;

4-Have regulations ensuring drug quality and comply with Good Manufacturing Practices (GMP) as stipulated by the drug regulatory department of the State Council.

Article 43

Drug producers must comply with GMP, establish and improve a drug production quality management system, and ensure continuous compliance with legal requirements throughout the entire production process. The legal representative and principal leaders of the drug production enterprise bear full responsibility for the production activities.

Article 44

Drugs must be produced according to national drug standards and approved production processes. Production and inspection records must be complete and accurate, and fabrication is prohibited. Traditional Chinese medicine (TCM) pieces must be processed according to national drug standards.

Where no national standard exists, provincial or municipal drug regulatory departments shall issue processing standards, which must be filed with the State Council drug regulatory department. Drugs or TCM pieces that do not meet these standards shall not be released or sold.

Article 45

Raw materials and excipients used in drug production must meet pharmaceutical requirements and comply with GMP. Suppliers of raw materials and excipients must be audited to ensure the materials meet these requirements.

Article 46

Packaging materials and containers that directly contact drugs must meet pharmaceutical standards and ensure safety for human health. The drug regulatory department will order cessation of use of any non-compliant packaging materials or containers.

Article 47

Drug manufacturers must conduct quality inspections on drugs. Drugs not meeting national standards must not be released. Manufacturers shall establish drug release procedures

specifying standards and conditions. Only drugs meeting these criteria and signed off by authorized quality personnel may be released.

Article 48

Drug packaging must meet drug quality requirements and facilitate storage, transportation, and medical use. Transported TCM raw materials must be packaged, with each package labeled with product name, origin, date, supplier, and quality certification marks.

Article 49

Drug packaging must have labels or attached instructions that clearly state the generic name, ingredients, specifications, MAH and manufacturer addresses, approval number, batch number, production date, expiry date, indications or functions, usage and dosage, contraindications, adverse reactions, and precautions. Labels and instructions must be clear, with production and expiry dates prominently marked for easy identification.

Special drugs such as narcotics, psychotropics, toxic drugs, radioactive drugs, topical drugs, and OTC drugs must have specific regulatory marks on their labels and instructions.

Article 50

Personnel directly involved in drug contact at MAHs, production, distribution enterprises, and medical institutions must undergo annual health checks. Those with infectious diseases or other conditions that may contaminate drugs are prohibited from working in direct drug contact.

Chapter V: Drug Distribution

Article 51

Engaging in drug wholesale activities shall require approval from the drug regulatory department of the provincial, autonomous regional, or municipal government where the entity is located, along with obtaining a drug distribution license. Engaging in drug retail activities shall require approval from the drug regulatory department of the local government at or above the county level where the entity is located, along with obtaining a drug distribution license. Without a drug distribution license, no entity may distribute drugs.

The drug distribution license shall specify its validity period and business scope, and it shall be re-examined and reissued upon expiration.

When implementing drug distribution licensing, drug regulatory departments shall, in addition to meeting the conditions stipulated in Article 52 of this Law, adhere to the principle of facilitating public access to medications.

Article 52

Entities engaged in drug distribution activities shall meet the following conditions:

1-Employ legally qualified pharmacists or other pharmaceutical technical personnel;

2-Have business premises, equipment, storage facilities, and sanitary conditions suitable for the drugs being distributed;

3-Have a quality management agency or personnel suitable for the drugs being distributed;

4-Establish quality assurance rules and comply with the requirements of the Good Supply Practice for Pharmaceutical Products (GSP) formulated by the drug regulatory department of the State Council under this Law.

Article 53

Entities engaged in drug distribution activities shall comply with the GSP, establish and improve a drug distribution quality management system, and ensure that the entire distribution process consistently meets legal requirements.

The state encourages and guides chain retail operations for drugs. The headquarters of enterprises engaged in chain retail drug distribution shall establish unified quality management systems and assume management responsibilities for the distribution activities of their affiliated retail enterprises.

The legal representative and primary responsible person of a drug distribution enterprise shall bear overall responsibility for the enterprise's drug distribution activities.

Article 54

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

Article 55

Drug marketing authorization holders, drug manufacturers, drug distributors, and medical institutions shall purchase drugs from drug marketing authorization holders or enterprises with drug production or distribution qualifications, except for the purchase of non-regulated traditional Chinese medicinal materials.

Article 56

Drug distributors shall establish and implement a drug procurement inspection and acceptance system to verify drug quality certifications and other identifiers. Drugs that do not meet regulatory requirements shall not be purchased or sold.

Article 57

Drug distributors shall maintain truthful and complete records of drug purchases and sales. These records shall include the drug's generic name, dosage form, specification, batch number, validity period, marketing authorization holder, manufacturer, purchasing and selling entities, quantities, prices, dates, and other information required by the drug regulatory department of the State Council.

Article 58

Drug retailers shall dispense drugs accurately and provide correct instructions on usage, dosage, and precautions. Prescriptions shall be verified before dispensing, and no unauthorized substitutions or alterations are permitted. Prescriptions with incompatible combinations or excessive dosages shall be refused; adjustments may only be made after consultation with the prescribing physician.

When selling traditional Chinese medicinal materials, drug distributors shall indicate the place of origin. Legally qualified pharmacists or other pharmaceutical technical personnel shall oversee drug management, prescription review and dispensing, and rational drug use guidance.

Article 59

Drug distributors shall establish and implement drug storage systems, taking necessary measures such as refrigeration, freeze protection, moisture prevention, pest control, and rodent prevention to ensure drug quality. Drugs shall be inspected upon receipt and dispatch.

Article 60

Traditional Chinese medicinal materials may be sold in rural and urban trade fairs, unless otherwise stipulated by the State Council.

Article 61

Drug marketing authorization holders and drug distributors selling drugs online shall comply with this Law's provisions on drug distribution. Specific measures shall be formulated by the drug regulatory department of the State Council in conjunction with the health administration department and other relevant authorities.

Vaccines, blood products, narcotics, psychotropic substances, toxic drugs for medical use, radioactive drugs, and precursor chemicals for drug production that are subject to special state control shall not be sold online.

Article 62

The provider of a third-party platform for online trading in medicinal products shall, in accordance with the rules of the medicinal product regulatory department of the State Council, undergo recordation with the medicinal product regulatory department of the people's government of the province, autonomous region, or municipality directly under the Central Government where it is located.

The provider of the third-party platform shall, in accordance with the law, examine the qualifications, among others, of marketing authorization holders and distributors of medicinal products which apply for distribution on the platform to ensure their compliance with the statutory requirements, and manage the acts of distribution of medicinal products which occur on the platform.

Where the provider of the third-party platform discovers that any marketing authorization holder or distributor of medicinal products engaged in distribution on the platform violates the provisions of this Law, it shall cease in a timely manner and report immediately the violation to the medicinal product regulatory department of the local people's government at the county level; and if any illegal conduct discovered is serious, cease immediately the provision of online trading platform services to the violator.

Article 63

Newly discovered or imported medicinal materials from abroad may only be sold after approval by the drug regulatory department of the State Council.

Article 64

Drugs imported into China must enter through designated ports. The importing enterprise is required to file a record with the drug regulatory authority at the port of entry. Customs clearance shall be granted only upon presentation of an import drug clearance certificate issued by the drug regulatory authority. Without this certificate, Customs shall not release the drugs.

The drug regulatory authority at the port of entry shall coordinate with drug testing institutions to conduct sampling and inspections, in accordance with the requirements set by the State Council's drug regulatory department.

Designated drug import ports shall be proposed jointly by the State Council's drug regulatory department and the General Administration of Customs and submitted to the State Council for approval.

Article 65

Medical institutions may import small quantities of drugs urgently needed for clinical use, subject to approval by the drug regulatory department of the State Council or authorized provincial, autonomous regional, or municipal governments. Such drugs shall only be used for specific medical purposes within designated medical institutions.

Individuals carrying small quantities of drugs for personal use shall comply with relevant national regulations.

Article 66

Import or export of narcotics and psychotropic substances within state-specified categories shall require import or export permits issued by the drug regulatory department of the State Council.

Article 67

The import of drugs with unproven efficacy, significant adverse effects, or other risks to human health is prohibited.

Article 68

The drug regulatory department of the State Council shall designate drug testing institutions to inspect the following drugs before sale or import. Drugs that are uninspected or fail inspection shall not be sold or imported:

1-Drugs sold in China for the first time;

2-Biological products specified by the drug regulatory department of the State Council;

3-Other drugs specified by the State Council.

Chapter VI: Pharmaceutical Affairs Management in Medical Institutions

Article 69

Medical institutions shall employ legally qualified pharmacists or other pharmaceutical technical personnel to oversee drug management, prescription review and dispensing, and rational drug use guidance. Non-pharmaceutical technical personnel shall not directly engage in pharmaceutical technical work.

Article 70

Medical institutions shall establish and implement a drug procurement inspection and acceptance system to verify drug quality certifications and other identifiers. Drugs that do not meet regulatory requirements shall not be purchased or used.

Article 71

Medical institutions shall have premises, equipment, storage facilities, and sanitary conditions suitable for the drugs they use, establish and implement drug storage systems, and take necessary measures such as refrigeration, freeze protection, moisture prevention, pest control, and rodent prevention to ensure drug quality.

Article 72

Medical institutions shall adhere to safe, effective, and economic principles for drug use, follow clinical drug use guidelines, diagnostic and treatment standards, and drug instructions, and review the appropriateness of physician prescriptions and medication orders. Other drug users outside medical institutions shall comply with this Law's provisions on drug use by medical institutions.

Article 73

Legally qualified pharmacists or other pharmaceutical technical personnel dispensing prescriptions shall verify them and shall not alter or substitute prescribed drugs without authorization. Prescriptions with incompatible combinations or excessive dosages shall be refused; adjustments may only be made after consultation with the prescribing physician.

Article 74

To be engaged in pharmaceutical compounding, a medical institution shall be subject to the approval of the medicinal product regulatory department of the province, autonomous region, or municipality directly under the central government where it is located and obtain a medical institution compounding permit. No pharmaceutical compounding may be conducted without a medical institution compounding permit.

The medical institution preparation license shall specify its validity period and shall be re-examined and reissued upon expiration.

Article 75

A medical institution engaged in pharmaceutical compounding shall have the facilities, management system, testing instruments, and hygienic environment capable of assuring quality of the preparations created.

A medical institution shall conduct pharmaceutical compounding according to the processes reviewed and approved, and the needed raw materials, inactive ingredients, and packaging materials, among others, shall satisfy the requirements for medicinal use.

Article 76

The preparations created from pharmaceutical compounding by a medical institution shall be the varieties clinically needed by the institution but not available on the market and be subject to the approval of the medicinal product regulatory department of the province, autonomous region, or municipality directly under the central government where it is located; except as otherwise required by laws regarding traditional Chinese medicinal preparations.

The quality of preparations created by pharmaceutical compounding by a medical institution shall be inspected as required; and compliant preparations may be used upon a doctor's prescription within the institution. With the approval of the medicinal product regulatory department of the State Council or the medicinal product regulatory department of the people's government of a province, autonomous region, or municipality directly under the central government, the preparations created from pharmaceutical compounding by medical institutions may be shared among the designated medical institutions.

Preparations created by pharmaceutical compounding and medical institutions may not be sold on the market.

Chapter VII: Post-Marketing Drug Management

Article 77

Drug marketing authorization holders shall develop post-marketing risk management plans, actively conduct post-marketing studies, further confirm drug safety, efficacy, and quality controllability, and strengthen ongoing management of marketed drugs.

Article 78

For a conditionally approved drug, the marketing authorization holder must implement risk management measures and complete the required studies within the specified timeframe. If the studies are not completed on time, or if the benefits of the drug cannot be demonstrated to outweigh its risks, the drug regulatory department under the State Council shall take appropriate legal action, including revoking the drug registration certificate.

Article 79

Modifications in the process of manufacture of medicinal products shall be managed by classification according to the risks posed by them to the safety, efficacy, and quality controllability of medicinal products and the degrees of their impacts. Significant modifications shall be subject to the approval of the medicinal product regulatory department of the State Council, and any other modification shall undergo recordation or be reported in accordance with the rules of the medicinal product regulatory department of the State Council.

A marketing authorization holder shall, in accordance with the rules of the medicinal product regulatory department of the State Council, comprehensively assess and verify the impact of any modification on the safety, efficacy, and quality controllability of medicinal products.

Article 80

Drug marketing authorization holders shall monitor post-marketing adverse drug reactions, actively collect and analyze suspected adverse reaction information, and promptly implement risk control measures for identified risks.

Article 81

Drug marketing authorization holders, manufacturers, distributors, and medical institutions shall regularly evaluate the quality, efficacy, and adverse reactions of drugs they produce, distribute, or use. Suspected adverse reactions shall be promptly reported to drug regulatory and health authorities.

For medicinal products with confirmed occurrences of severe adverse reactions, the medicinal product regulatory department of the State Council or the medicinal product regulatory department of the people's government of a province, autonomous region, or municipality directly under the Central Government shall adopt emergency control measures such as ceasing manufacture, sale, or use based on the actual circumstances, organize an appraisal within five days, and in accordance with the law, make an administrative disposition decision within 15 days from the date of appraisal conclusion.

Article 82

If a drug has quality issues or other safety risks, the marketing authorization holder shall immediately halt sales, notify relevant distributors and medical institutions to stop sales and use, recall sold drugs, disclose recall information, and, if necessary, halt production. The recall and handling shall be reported to provincial-level drug regulatory and health departments. Drug manufacturers, distributors, and medical institutions shall cooperate.

If a marketing authorization holder fails to recall drugs as required, provincial-level drug regulatory departments shall order the recall.

Article 83

Drug marketing authorization holders shall conduct periodic post-marketing evaluations of drug safety, efficacy, and quality controllability. The drug regulatory department of the State Council may order or directly conduct such evaluations if necessary.

Drugs with unproven efficacy, significant adverse effects, or other risks to human health shall have their registration certificates canceled. Canceled or expired drugs shall not be produced, imported, sold, or used. Such drugs shall be destroyed under regulatory supervision or otherwise disposed of safely.

Chapter VIII: Drug Pricing and Advertising

Article 84

The state shall improve drug procurement management, monitor drug prices, conduct cost-price investigations, strengthen price supervision, and crack down on monopolistic or inflated pricing to maintain price order.

Article 85

Drugs under market-based pricing shall be priced fairly, reasonably, and in good faith by marketing authorization holders, manufacturers, distributors, and medical institutions, ensuring affordability for users.

These entities shall comply with state pricing regulations, clearly mark retail prices, and prohibit profiteering, price monopolies, or fraud.

Article 86

Marketing authorization holders, manufacturers, distributors, and medical institutions shall provide actual purchase and sales prices and quantities to pricing authorities as required.

Article 87

Medical institutions shall provide patients with price lists for drugs used, publicly disclose prices of commonly used drugs, and strengthen rational drug use management. Specific measures shall be formulated by the health administration department of the State Council.

Article 88

Bribery or other improper benefits in drug transactions are prohibited. Marketing authorization holders, manufacturers, distributors, or their agents are prohibited from offering money or

benefits to medical institution personnel, including leaders, purchasers, physicians, or pharmacists. Medical personnel are prohibited from accepting such benefits.

Article 89

Medicinal product advertisements shall be subject to the approval of 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; and no medicinal product advertisement may be published without such approval.

Article 90

The contents of medicinal product advertisements shall be true, lawful, based on the package leaflet reviewed and approved by the medicinal product regulatory department of the State Council, and free of falsehood.

Medicinal product advertisements shall not contain any assertion or guarantee pertaining to efficacy or safety; and shall not use the names or images of state authorities, scientific research entities, academic organizations, industry associations, experts, scholars, doctors, pharmacists, and patients, among others, for recommendation or testimonial purposes.

The advertisements of non-medicinal products shall not have any content involving medicinal products.

Article 91

Drug pricing and advertising not covered by this Law shall comply with the Price Law, Anti-Monopoly Law, Anti-Unfair Competition Law, Advertising Law, and other relevant laws.

Chapter IX: Drug Reserve and Supply

Article 92

The state implements a drug reserve system with central and local reserves. During major disasters, epidemics, or emergencies, drugs may be requisitioned under the Emergency Response Law.

Article 93

The state shall implement an essential drug system, selecting essential drugs to enhance production and reserve capacity and meet basic medication needs for disease prevention and treatment.

Article 94

The state establishes a drug supply-demand monitoring system to collect and analyze shortage information, issue warnings, and take responsive measures.

Article 95

The state implements a shortage drug list management system. Specific measures shall be formulated by the health administration department of the State Council in conjunction with the drug regulatory department and other authorities.

Marketing authorization holders halting production of shortage drugs shall report to the drug regulatory department of the State Council or provincial-level drug regulatory departments.

Article 96

The state encourages the development and production of shortage drugs and prioritizes review and approval of new drugs for urgent clinical needs, major infectious diseases, and rare diseases.

Article 97

The State Council may restrict or prohibit the export of shortage drugs. If necessary, relevant departments may organize production, intervene in pricing, or expand imports to ensure supply.

Marketing authorization holders, manufacturers, and distributors shall ensure drug production and supply as required.

Chapter X: Supervision and Administration

Article 98 The production (including preparation), sale, or use of counterfeit or substandard drugs is prohibited.

The following are considered counterfeit drugs:

1-Drugs with ingredients not matching national standards;

2-Non-drugs or other drugs misrepresented as the intended drug;

3-Deteriorated drugs;

4-Drugs with indications or functions exceeding approved scope.

The following are considered substandard drugs:

1-Drugs with ingredient quantities not meeting national standards;

2-Contaminated drugs;

3-Drugs with unmarked or altered expiration dates;

4-Drugs with unmarked or altered batch numbers;

5-Expired drugs;

6-Drugs with unauthorized additives or excipients;

7-Other drugs failing to meet standards.

Producing or importing drugs without approval documents or using unapproved raw materials, packaging, or containers is prohibited.

Article 99

Drug regulatory departments shall supervise drug research, production, distribution, and use in accordance with laws and regulations. If necessary, inspections may extend to entities providing products or services to these activities, who shall cooperate and not conceal information.

High-risk drugs shall be subject to focused supervision.

If evidence suggests potential safety hazards, regulatory departments may issue warnings, conduct interviews, order rectifications, or suspend production, sales, use, or imports, and publicly disclose inspection results.

Inspectors shall present credentials and protect trade secrets learned during inspections.

Article 100

Drug regulatory departments may conduct random drug quality inspections as needed. Sampling shall follow regulations and be free of charge; samples shall be purchased. Costs shall be covered as stipulated by the State Council.

For drugs suspected of endangering health, regulatory departments may seize or detain the drugs and related materials, making administrative decisions within seven days (or fifteen days if testing is required).

Article 101

The State Council and provincial-level drug regulatory departments shall regularly announce drug quality inspection results. Incorrect announcements shall be corrected within the original scope.

Article 102

Parties disputing drug inspection results may apply for re-inspection within seven days to the original or higher-level drug testing institution or directly to a State Council-designated institution. Re-inspection conclusions shall be issued within the timeframe set by the State Council's drug regulatory department.

Article 103

Drug regulatory departments shall inspect compliance with Good Manufacturing Practice (GMP), GSP, Good Laboratory Practice (GLP), and Good Clinical Practice (GCP) by marketing authorization holders, manufacturers, distributors, non-clinical research institutions, and clinical trial institutions to ensure ongoing legal compliance.

Article 104

The state shall establish a professional and specialized drug inspection team. Inspectors shall be familiar with drug laws and possess pharmaceutical expertise.

Article 105

Drug regulatory departments shall establish drug safety credit records for marketing authorization holders, manufacturers, distributors, non-clinical research institutions, clinical trial institutions, medical institutions, documenting licenses, inspection results, and violations. Records shall be publicly updated, and entities with poor credit may face increased inspections or joint penalties.

Article 106

Drug regulatory departments shall publish contact information for inquiries, complaints, and reports, responding promptly and verifying claims. Whistleblowers shall be rewarded as stipulated.

Whistleblower confidentiality and rights shall be protected. Employers shall not retaliate against whistleblowers.

Article 107

The state implements a unified drug safety information release system. National drug safety status, risk warnings, major incidents, and other State Council-designated information shall be released uniformly by the State Council's drug regulatory department. Regional information may be released by provincial-level drug regulatory departments. Unauthorized releases are prohibited.

Released information shall be timely, accurate, and comprehensive, with necessary explanations to avoid misinterpretation.

Fabricating or spreading false drug safety information is prohibited.

Article 108

Governments at or above the county level shall formulate drug safety emergency plans. Marketing authorization holders, manufacturers, distributors, and medical institutions shall develop response plans and conduct training and drills.

During drug safety incidents, governments shall activate emergency responses, and relevant entities shall take immediate measures to mitigate harm.

Article 109

If the drug regulatory department fails to promptly identify systemic risks to drug safety or to timely eliminate drug safety hazards within its supervision area, the local government at the same level or the higher-level drug regulatory department shall conduct an official interview with its principal responsible persons.

If a local government fails to fulfill its drug safety responsibilities or to promptly eliminate significant regional drug safety hazards, the higher-level government or the higher-level drug regulatory department shall conduct an official interview with its principal responsible persons.

The interviewed departments and local governments shall immediately take measures to rectify the drug supervision and administration work.

The interview and rectification situations shall be included in the evaluation and assessment records of the relevant departments and local governments' drug supervision and administration work.

Article 110

Local governments and their drug regulatory departments shall not use drug testing, approval procedures, or other measures to restrict or exclude drugs produced by marketing authorization holders or drug manufacturers from other regions from entering their jurisdiction.

Article 111

The drug regulatory authorities and the specialized technical institutions they establish or designate shall not participate in drug production or business activities, nor recommend or supervise drugs in their name. Additionally, staff of these regulatory authorities and institutions are prohibited from engaging in drug production or business activities.

Article 112

The State Council shall impose special management regulations on narcotic drugs, psychotropic drugs, toxic medical drugs, radioactive drugs, and precursor chemicals for drugs in accordance with relevant provisions.

Article 113

If the drug regulatory department discovers drug-related illegal activities suspected of criminal offenses, it shall promptly transfer the case to the public security authorities. If the case does not require criminal prosecution or is exempt from criminal punishment but administrative responsibility should be pursued, the public security authorities, procuratorate, and courts shall promptly transfer the case to the drug regulatory department.

When the public security authorities, procuratorate, or courts request the drug regulatory department, environmental protection authorities, or other relevant departments to provide inspection results, identification opinions, or assist with harmless disposal of the involved drugs, the relevant departments shall provide timely assistance.

Chapter XI: Legal Liability

Article 114

Those who violate the provisions of this law and constitute a crime shall be investigated for criminal responsibility according to law.

Article 115

Those who produce or sell drugs without obtaining a drug production license, drug business license, or medical institution preparation license shall be ordered to close, have the illegally produced or sold drugs and illegal gains confiscated, and be fined between 15 and 30 times the value of the illegal drugs (including drugs sold and unsold). If the value is less than 100,000 yuan, it shall be calculated as 100,000 yuan.

Article 116

Those who produce or sell counterfeit drugs shall have the illegally produced or sold drugs and illegal gains confiscated, be ordered to suspend production and business for rectification, have their drug approval documents revoked, and be fined between 15 and 30 times the value of the illegal drugs; if the value is less than 100,000 yuan, it shall be calculated as 100,000 yuan. In serious cases, the drug production license, drug business license, or medical institution preparation license shall be revoked, and corresponding applications shall not be accepted for 10 years. If the drug marketing authorization holder is a foreign enterprise, its drug importation shall be prohibited for 10 years.

Article 117

Those who produce or sell inferior drugs shall have the illegally produced or sold drugs and illegal gains confiscated and be fined between 10 and 20 times the value of the illegal drugs; if the value of the illegal production or wholesale drugs is less than 100,000 yuan, it shall be calculated as 100,000 yuan; if the retail value is less than 10,000 yuan, it shall be calculated as 10,000 yuan. In serious cases, they shall be ordered to suspend production and business for rectification, or even have their drug approval documents, production license, business license, or medical institution preparation license revoked.

For the production and sale of traditional Chinese medicine decoction pieces that do not meet drug standards but do not affect safety and efficacy, they shall be ordered to make corrections within a time limit and given a warning; a fine between 100,000 and 500,000 yuan may be imposed.

Article 118

For serious cases of producing or selling counterfeit or inferior drugs, the legal representatives, main responsible persons, directly responsible supervisors, and other responsible personnel shall have the income obtained during the illegal acts confiscated and be fined between 30% and 300% of the income, be banned for life from engaging in drug production and business activities, and may be detained by the public security organs for 5 to 15 days.

Materials, auxiliaries, packaging materials, and production equipment used specifically for producing counterfeit or inferior drugs shall be confiscated.

Article 119

Drug-using units that use counterfeit or inferior drugs shall be punished according to the provisions on selling counterfeit drugs and retailing inferior drugs; in serious cases, legal representatives, main responsible persons, directly responsible supervisors, and other responsible personnel with medical and health practitioner certificates shall have their practitioner certificates revoked.

Article 120

Those who know or should know that drugs belong to counterfeit or inferior drugs or those specified in Article 124, paragraph 1, items 1 to 5, and provide storage, transportation, or other convenience conditions shall have all storage and transportation income confiscated and be fined between one and five times the illegal income; in serious cases, be fined between five and fifteen times the illegal income; if the illegal income is less than 50,000 yuan, it shall be calculated as 50,000 yuan.

Article 121

Administrative penalties for counterfeit and inferior drugs shall be based on quality inspection conclusions issued by drug inspection institutions.

Article 122

Those who forge, alter, rent, lend, or illegally buy and sell licenses or drug approval documents shall have illegal income confiscated and be fined between one and five times the illegal income; in serious cases, be fined between five and fifteen times the illegal income, have drug production licenses, business licenses, medical institution preparation licenses, or drug approval documents revoked; legal representatives, main responsible persons, directly responsible supervisors, and other responsible personnel shall be fined between 20,000 and 200,000 yuan, banned from engaging in drug production and business activities for 10 years, and may be detained by public security organs for 5 to 15 days; if illegal income is less than 100,000 yuan, it shall be calculated as 100,000 yuan.

Article 123

Those who provide false certificates, data, materials, samples, or use other means to fraudulently obtain clinical trial permits, drug production permits, drug business permits, medical institution preparation permits, or drug registration permits shall have related permits revoked, not accept related applications for 10 years, and be fined between 500,000 and

5,000,000 yuan; in serious cases, legal representatives, main responsible persons, directly responsible supervisors, and other responsible personnel shall be fined between 20,000 and 200,000 yuan, banned from drug production and business activities for 10 years, and may be detained by public security organs for 5 to 15 days.

Article 124

Those who violate this law in any of the following ways shall have illegally produced, imported, or sold drugs and illegal gains confiscated, as well as raw materials, auxiliaries, packaging materials, and production equipment used specifically for illegal production; be ordered to suspend production and business for rectification; and be fined between 15 and 30 times the value of the illegal drugs; if the value is less than 100,000 yuan, it shall be calculated as 100,000 yuan; in serious cases, have drug approval documents revoked or even drug production, business, or medical institution preparation licenses revoked. Legal representatives, main responsible persons, directly responsible supervisors, and other responsible personnel shall have income obtained during the illegal acts confiscated and be fined between 30% and 300% of the income, be banned for 10 years to life from engaging in drug production and business activities, and may be detained by public security organs for 5 to 15 days:

1- Producing or importing drugs without drug approval documents;

2- Producing or importing drugs using drug approval documents obtained by fraud;

3- Producing drugs using active pharmaceutical ingredients not reviewed or approved;

4- Selling drugs without required inspection;

5- Producing or selling drugs prohibited by the State Drug Administration;

6- Fabricating production or inspection records;

7- Making major unapproved changes during drug production.

Selling drugs as per items (1) to (3), or drug-using units using drugs as per items (1) to (5), shall be punished according to the above. In serious cases, the legal representatives, main responsible persons, directly responsible supervisors, and other responsible personnel of drug-using units with medical practitioner certificates shall have those certificates revoked.

Importing small quantities of legally marketed foreign drugs without approval, if the case is minor, may be exempted or mitigated.

Article 125

Whoever violates the provisions of this law by engaging in any of the following acts shall be subject to confiscation of the illegally produced or sold drugs and the illegal gains, as well as packaging materials and containers; be ordered to suspend production or business for rectification; and be fined not less than 500,000 yuan and not more than 5 million yuan. If the circumstances are serious, the drug approval certificate, drug production license, and drug business license shall be revoked, and a fine of not less than 20,000 yuan and not more than 200,000 yuan shall be imposed on the legal representative, principal person in charge, directly responsible supervisors, and other responsible personnel, who shall also be prohibited from engaging in drug production and business activities for a period ranging from ten years up to a lifetime ban:

1-Conducting drug clinical trials without approval;

2-Using packaging materials or containers that have not undergone review and approval and that directly contact drugs to produce drugs, or selling such drugs;

3-Using unapproved labels or instructions.

Article 126

Except where otherwise provided by this Law, if a marketing authorization holder of drugs, drug manufacturing enterprise, drug distribution enterprise, non-clinical safety evaluation institution, clinical trial institution, or similar entity fails to comply with the Good Manufacturing Practices (GMP), Good Distribution Practices (GDP), Good Laboratory Practices (GLP) for non-clinical research, or Good Clinical Practices (GCP), it shall be ordered to make corrections within a time limit and be given a warning.

If the entity fails to make corrections within the prescribed time, it shall be fined not less than 100,000 yuan and not more than 500,000 yuan.

If the circumstances are serious, a fine of not less than 500,000 yuan and not more than 2 million yuan shall be imposed, and it may be ordered to suspend production or business for rectification, up to and including revocation of the drug approval certificate, drug production license, or drug distribution license.

In addition, non-clinical safety evaluation institutions and clinical trial institutions shall be prohibited from conducting related activities for five years.

The legal representative, principal person in charge, directly responsible supervisors, and other responsible personnel shall have the income obtained during the period of the violation confiscated, and be fined between 10% and 50% of that income. They may also be prohibited from engaging in drug production, distribution, or related activities for a period of ten years up to life.

Article 127

Whoever violates the provisions of this Law by engaging in any of the following acts shall be ordered to make corrections within a specified time limit and be given a warning; if the corrections are not made within the time limit, a fine of not less than 100,000 yuan and not more than 500,000 yuan shall be imposed:

1-Conducting a bioequivalence study without filing the necessary record;

2-During a clinical drug trial, upon discovering safety issues or other risks, the sponsor fails to promptly adjust the trial protocol, suspend or terminate the clinical trial, or fails to report to the drug regulatory authority under the State Council;

3-Failing to establish and implement a drug traceability system as required;

4-Failing to submit annual reports as required;

5-Failing to file or report changes in the drug manufacturing process as required;

6-Failing to formulate a post-marketing risk management plan;

7-Failing to carry out post-marketing studies or post-marketing evaluations of drugs as required.

Article 128

Except for cases where punishment should be imposed under the provisions for counterfeit or substandard drugs, where the packaging of a drug does not bear or affix labels or is not accompanied by an instruction leaflet as required, or where the label or leaflet fails to indicate the required information or prescribed mark, the responsible party shall be ordered to correct and be given a warning; if the circumstances are serious, the drug registration certificate shall be revoked.

Article 129

Any marketing authorization holder, drug manufacturing enterprise, drug distribution enterprise, or medical institution that purchases drugs from entities other than holders of drug marketing authorizations or enterprises duly qualified for drug manufacturing or distribution, in violation of this Law, shall be ordered to rectify the violation. The illegally procured drugs and any unlawful gains shall be confiscated. A fine shall be imposed amounting to no less than twice and no more than ten times the value of the illegally purchased drugs. In cases of serious circumstances, a fine of no less than ten times and no more than thirty times the value shall be imposed, and the drug approval certificates, drug production licenses, drug distribution licenses, or medical institution practice licenses shall be revoked. Where the value of the drugs involved is less than 50,000 yuan, the value shall be deemed as 50,000 yuan for the purposes of penalty calculation.

Article 130

Where a drug distribution enterprise fails to record drug purchase and sales transactions as prescribed, retails drugs without properly explaining their usage and dosage, or dispenses drugs without adhering to prescribed prescription requirements, it shall be ordered to make corrections and issued a warning. In cases of serious violations, the drug distribution license shall be revoked.

Article 131

Where a third-party online drug trading platform provider fails to fulfill obligations such as qualification verification, reporting, or ceases to provide online trading platform services in violation of this Law, it shall be ordered to rectify the violation, illegal gains shall be confiscated, and a fine ranging from no less than 200,000 yuan to no more than 2 million yuan shall be imposed. In cases of serious circumstances, the provider shall be ordered to suspend operations for rectification, and a fine ranging from no less than 2 million yuan to no more than 5 million yuan shall be imposed.

Article 132

Imported drugs that have obtained drug registration certificates but are not filed with the drug supervision and administration department at the port of entry as required shall be ordered to make corrections within a time limit and be given a warning; if overdue and not corrected, the drug registration certificate will be revoked.

Article 133

A medical institution which, in violation of the provisions of this Law, places its preparations created from pharmaceutical compounding on the market shall be ordered to take corrective action, and in addition to confiscation of the preparations illegally sold and illegal proceeds, fined not less than two times nor more than five times the value of goods of the preparations illegally sold; or if the circumstances are serious, fined not less than five times nor more than 15 times the value of goods of the preparations illegally sold; and if the value of goods is under 50,000 yuan, the fine shall be calculated on the basis of 50,000 yuan.

Article 134

Where a marketing authorization holder fails to conduct monitoring of adverse drug reactions or to report suspected adverse reactions as mandated by law, they shall be ordered to rectify the violation within a prescribed time frame and issued a formal warning. Should the violation remain uncorrected beyond the stipulated period, the authority shall impose suspension of

production or business operations for rectification and levy a fine ranging from no less than 100,000 yuan to no more than 1,000,000 yuan.

Where a drug distribution enterprise fails to report suspected adverse reactions as required, it shall be ordered to make corrections within a specified time limit and receive a formal warning. In the event of failure to comply within the prescribed period, suspension of business operations for rectification shall be enforced, accompanied by a fine of not less than 50,000 yuan and not exceeding 500,000 yuan.

Where a medical institution neglects to report suspected adverse drug reactions in accordance with legal requirements, it shall be ordered to correct the breach within a set deadline and issued a warning. If the institution fails to comply within the given timeframe, a fine ranging from 50,000 yuan to 500,000 yuan shall be imposed.

Article 135

Where a marketing authorization holder refuses to recall drugs as ordered by the drug supervision and administration department of the provincial, autonomous region, or municipality government, they shall be fined no less than five times and no more than ten times the value of the recalled drugs; if the value is less than 100,000 yuan, it shall be calculated as 100,000 yuan; if the circumstances are serious, the drug approval documents, drug production license, and drug distribution license shall be revoked; the legal representative, principal person in charge, directly responsible person, and other responsible personnel shall be fined no less than 20,000 yuan and no more than 200,000 yuan. Where drug manufacturing enterprises, drug distribution enterprises, or medical institutions refuse to cooperate with a recall, they shall be fined no less than 100,000 yuan and no more than 500,000 yuan.

Article 136

Where a corporate enterprise in China designated by a marketing authorization holder which is an overseas enterprise fails to perform the relevant obligations in accordance with the provisions of this Law, the provisions of this Law on the legal liability of marketing authorization holders shall apply.

Article 137

Where any of the following acts occur, penalties shall be imposed more severely within the limits provided by this Law:

1-Using narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs, or precursor chemicals for controlled substances to impersonate other drugs, or using other drugs to impersonate the aforementioned drugs;

2-Producing or selling counterfeit or substandard drugs primarily intended for pregnant women, postpartum women, or children;

3-Producing or selling biological products that are counterfeit or substandard drugs;

4-Producing or selling counterfeit or substandard drugs that result in personal injury;

5-Producing or selling counterfeit or substandard drugs and reoffending after being penalized;

6-Refusing or evading supervision and inspection, forging, destroying, or concealing relevant evidence materials, or unlawfully using sealed or confiscated items.

Article 138

Where a drug testing institution issues a false testing report, it shall be ordered to correct, be given a warning, and fined no less than 200,000 yuan and no more than 1 million yuan; for the unit, responsible personnel shall be demoted, removed from posts, or dismissed in accordance with law, illegal gains shall be confiscated, and a fine of no more than 50,000 yuan shall be imposed; if circumstances are serious, testing qualifications shall be revoked. Where results found by the testing institution are false and cause losses, it shall bear corresponding compensation liability.

Article 139

Administrative penalties prescribed in Articles 115 to 138 of this Law shall be decided by drug supervision and administration departments at or above the county level according to their respective duties; license revocation or cancellation shall be decided by the original approving or issuing authority.

Article 140

Where a marketing authorization holder, manufacturing enterprise, distribution enterprise, or medical institution hires personnel in violation of this Law, the drug supervision and administration department or the health authority shall order dismissal and impose a fine of no less than 50,000 yuan and no more than 200,000 yuan.

Article 141

Where a marketing authorization holder, drug manufacturing enterprise, drug distribution enterprise, or medical institution offers, solicits, or accepts kickbacks or other improper benefits in the course of drug procurement and sales, the market supervision authority shall confiscate any unlawful gains and impose a fine ranging from no less than 300,000 yuan to no more than 3 million yuan. In cases of severe violations, the relevant business licenses shall be revoked, and the drug approval certificates, production licenses, and distribution licenses shall be revoked by the drug regulatory authority.

Where a marketing authorization holder, drug manufacturing enterprise, or drug distribution enterprise provides bribes to state personnel in relation to drug development, production, or trade, the legal representative, principal person in charge, directly responsible individuals, and other responsible personnel shall be permanently prohibited from engaging in drug production and distribution activities.

Article 142

Where the person in charge, procurement personnel, or other relevant staff of a marketing authorization holder, manufacturing enterprise, or distribution enterprise receive property or other improper benefits from another authorization holder, manufacturer, enterprise, or agent in connection with the purchase and sale of drugs, any unlawful gains shall be confiscated and appropriate penalties imposed. In cases of serious violations, a prohibition from engaging in drug production and distribution activities for a period of five years shall be enforced.

Where personnel of medical institutions, including heads, procurement staff, physicians, and pharmacists, receive property or other improper benefits, the relevant health authority or the institution itself shall impose disciplinary measures and confiscate the unlawful gains. In instances of serious infractions, the revocation of professional practice certificates shall be mandated.

Article 143

Where any person fabricates or spreads false drug safety information in violation of this Law, and it constitutes a violation of public security management, the public security organ shall impose penalties in accordance with such regulations.

Article 144

Where a marketing authorization holder, manufacturing enterprise, distribution enterprise, or medical institution violates this Law and causes damage to the user, they shall bear civil compensation responsibility in accordance with law. Where damage is caused by drug quality issues, the injured party may claim compensation from the marketing authorization holder or manufacturing enterprise, or from the distribution enterprise or medical institution; upon receipt of the claim, the responsible party shall take primary liability and make advance compensation, after which they may seek recourse in accordance with the law.

Where counterfeit or substandard drugs are knowingly produced, sold, or used, the injured party or their close relative may, in addition to claiming compensation for losses, request payment of ten times the price or three times the loss; if the additional compensation amount is less than 1,000 yuan, it shall be 1,000 yuan.

Article 145

Where drug supervision and administration departments, or their established or designated professional technical institutions, engage in drug production or distribution activities, their superior authorities shall order rectification and confiscate any illegal income. In cases of serious violations, responsible personnel shall be subject to disciplinary actions in accordance with the law.

Where personnel of drug supervision and administration departments, or their established or designated technical institutions, participate in drug production or distribution activities, they shall be disciplined in accordance with applicable legal provisions.

Article 146

Where drug supervision and administration departments or their established or designated testing institutions illegally collect testing fees in drug supervision, they shall be ordered by relevant governmental departments to refund, and responsible personnel shall be disciplined in accordance with law; if circumstances are serious, testing qualifications shall be revoked.

Article 147

Where drug supervision and administration departments violate this Law by any of the following acts, the relevant licenses shall be revoked and responsible personnel disciplined accordingly:

1-Approving clinical trials without meeting conditions;

2-Issuing drug registration certificates for unqualified drugs;

3-Issuing manufacturing, distribution, or medical institution formulation licenses to unqualified entities.

Article 148

Where any of the following acts are committed by the local people's governments at or above the county level in violation of the provisions of this Law, the directly responsible supervisory personnel and other directly responsible individuals shall be subject to demerit or serious demerit penalties; in cases of serious circumstances, demotion, removal from office, or dismissal shall be imposed:

1-Concealing, falsifying, delaying reporting, or omitting the report of drug safety incidents;

2-Failing to promptly eliminate regional major drug safety hazards, resulting in the occurrence of extraordinarily serious drug safety incidents within the administrative region, or the repeated occurrence of major drug safety incidents;

3-Negligence in the performance of duties, causing serious adverse effects or significant losses.

Article 149

Where drug supervision and other departments violate this Law by any of the following, responsible personnel shall be given demerit or major demerit; if the circumstances are relatively serious, demotion or removal shall apply; if the circumstances are serious, dismissal shall apply:

1-Concealing, false reporting, delaying reporting, or omitting drug safety incidents;

2-Failing to promptly address discovered drug safety violations;

3-Failing to promptly identify or eliminate systematic drug safety risks or oversight blind spots causing serious impact;

4-Other failures in performing drug supervision duties causing serious adverse impact or significant losses.

Article 150

Where any medicinal product regulatory staff member abuses his or her powers, makes falsification for personal gain, or neglects his or her duties, he or she shall be disciplined in accordance with the law.

Where dereliction of duty or malfeasance in office is committed during the investigation of illegal conduct related to counterfeit medicinal products or medicinal products of inferior quality, the directly liable executive in charge and other liable persons of the medicinal product regulatory department shall be disciplined in a heavier manner in accordance with the law.

Article 151

The “value of goods” referred to in this chapter shall be calculated based on the labeled price of the illegally produced or sold drugs; if no labeled price exists, the market price of similar drugs shall be used.

Chapter XII: Supplementary Provisions

Article 152

Management of planting, collecting, and breeding of traditional Chinese medicine materials shall be implemented in accordance with relevant laws and regulations.

Article 153

Methods for managing regionally used folk drugs shall be formulated by the drug supervision administration department of the State Council in conjunction with the national traditional Chinese medicine administration.

Article 154

Specific measures for the People's Liberation Army and the People's Armed Police in implementing this Law 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.