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

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Unofficial English translation prepared for reference only. The official Chinese text prevails.

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Chapter I — General Provisions

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

Article 2 — Activities involving the research and development, manufacturing, distribution, use, and supervision and administration of drugs shall be conducted with people's health as the central concern, follow scientific principles and ethical norms, and comprehensively prevent and control risks.

Article 3 — The State shall improve the drug innovation system, support clinically value-oriented drug research, development and innovation, encourage the research and creation of new drugs, and support the clinical promotion and use of new drugs; promote the inheritance and innovation of traditional Chinese medicine (TCM), and give full play to the role of TCM in prevention, medical treatment and health care; and promote the research, development and innovation of generic drugs, and improve the quality and efficacy of generic drugs.

Article 4 — The department of the people's government at or above the county level that performs drug regulatory duties (hereinafter referred to as the "drug regulatory department") shall be responsible for drug supervision and administration. Other relevant departments of the people's government at or above the county level shall be responsible for the supervision and administration work related to drugs within their respective scope of duties.

Article 5 — The competent industry and information technology department of the State Council, the competent commerce department of the State Council and other departments shall, according to the division of duties, formulate plans and industrial policies related to the development of the national drug manufacturing, distribution and other industries in accordance with the national economic and social development plans and the development of the drug industry, promote the structural adjustment and technological innovation of the drug industry, enhance the resilience and security of the industrial chain, and promote the high-quality development of the drug industry. The drug regulatory department of the State Council shall cooperate with the competent industry and information technology department, the competent commerce department and other departments of the State Council in implementing the plans and industrial policies related to the development of the national drug industry.

Chapter II — Drug Research, Development and Registration

Article 6 — Drug research and development activities shall comply with the good laboratory practice for non-clinical drug studies and the good clinical practice for drug clinical trials, and ensure that records and data are truthful, accurate, complete and traceable.

Article 7 — Non-clinical safety evaluation studies conducted for the purpose of applying for drug registration shall be carried out by an institution qualified and certified for non-clinical safety evaluation studies. To apply for the qualification certification of a non-clinical safety evaluation institution, an application shall be submitted to the drug regulatory department of the State Council, together with materials proving compliance with the good laboratory practice for non-clinical studies. The drug regulatory department of the State Council shall organize and conduct the review and make a decision within 20 working days from the date of acceptance of the application. Where the prescribed conditions are met, the license shall be granted and a qualification certificate shall be issued; where the prescribed conditions are not met, the license shall not be granted and the reasons shall be explained in writing.

A qualification certificate for a non-clinical safety evaluation institution shall be valid for five years. Upon expiration of the validity period, where it is necessary to continue to conduct non-clinical safety evaluation studies, an application shall be made for the re-issuance of the qualification certificate.

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Article 8 — A drug clinical trial sponsor shall select drug clinical trial institutions and investigators with the corresponding capabilities, and perform the responsibilities of protecting subjects, managing drugs used in clinical trials, managing clinical trial data, and risk management, among other matters.

The preparation of drugs used in clinical trials shall comply with the relevant requirements of good manufacturing practice for drugs.

A drug clinical trial sponsor and a drug clinical trial institution shall not charge subjects any fees related to the clinical trial.

Article 9 — Where the sponsor of a drug clinical trial approved pursuant to paragraph 1 of Article 19 of the Drug Administration Law is changed, an application shall be submitted to the drug regulatory department of the State Council. The drug regulatory department of the State Council shall review the application and make a decision within 20 working days from the date of acceptance of the application.

Article 10 — Drug research and development activities conducted overseas for the purpose of applying for drug registration shall comply with the relevant provisions of the Drug Administration Law, these Regulations, and other laws, regulations, rules, standards and norms. Research data obtained overseas that comply with the relevant provisions of the drug regulatory department of the State Council may be used in the application for drug registration.

Article 11 — The import of reference drugs or samples needed for research, development or testing for the purpose of applying for drug registration shall be subject to the approval of the drug regulatory department of the State Council; provided, however, that the drugs for clinical trials specified in the clinical trial approval documents may be imported on the strength of the approval documents. The drug regulatory department of the State Council shall review the application and make a decision within 20 working days from the date of acceptance of the application.

Article 12 — In developing chemical generic drugs, reference drugs shall be scientifically selected for comparative study in accordance with the technical requirements formulated by the drug regulatory department of the State Council; where there is a reference listed drug designated by the drug regulatory department of the State Council, the reference listed drug shall be selected as the reference drug for comparative study.

Article 13 — The development of traditional Chinese medicine drugs shall be guided by traditional Chinese medicine theories, and the safety and efficacy of traditional Chinese medicine drugs shall be comprehensively evaluated on the basis of traditional Chinese medicine theories, human-use experience of traditional Chinese medicine, clinical trial data and other factors. The evaluation of the efficacy of a traditional Chinese medicine drug shall be consistent with its clinical positioning and reflect the characteristics of traditional Chinese medicine.

Article 14 — In developing and manufacturing traditional Chinese medicine drugs, the stability of the source and quality of Chinese medicinal materials and the sustainable use of resources shall be ensured, and adverse impacts on the ecological environment shall be avoided; where wild animals or plants are involved, the relevant provisions of the State shall be complied with.

Article 15 — The drug regulatory department of the State Council shall conduct review and approval of drugs for which registration is applied in accordance with Article 25 of the Drug Administration Law.

In order to support clinically value-oriented drug research, development and innovation, the drug regulatory department of the State Council may apply procedures such as the breakthrough therapy drug procedure, the conditional approval procedure, the priority review and approval procedure, and the special approval procedure to eligible drug registration applications, so as to accelerate the marketing of drugs.

The drug regulatory department of the State Council shall establish and improve the review and approval, inspection and testing, and standard management systems that are consistent with the characteristics of

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traditional Chinese medicine drugs.

Article 16 — When approving a drug, the drug regulatory department of the State Council shall conduct review and approval of the chemical active pharmaceutical ingredient together with the drug; where the conditions are met, it shall issue a drug registration certificate for the drug and an approval certificate for the chemical active pharmaceutical ingredient. For chemical active pharmaceutical ingredients used in the manufacture of registered drugs, an application for review and approval may also be submitted directly to the drug regulatory department of the State Council; where the conditions are met, an approval certificate for the chemical active pharmaceutical ingredient shall be issued. When reviewing and approving a chemical active pharmaceutical ingredient, the drug regulatory department of the State Council shall approve the quality standard, manufacturing process and labeling of the chemical active pharmaceutical ingredient at the same time.

To transfer a drug registration certificate or an approval certificate for a chemical active pharmaceutical ingredient, an application shall be submitted to the drug regulatory department of the State Council. The drug regulatory department of the State Council shall review the application and make a decision within 20 working days from the date of acceptance of the application.

Article 17 — A drug registration certificate and an approval certificate for a chemical active pharmaceutical ingredient shall be valid for five years. Upon expiration of the validity period, where it is necessary to continue marketing, an application for renewal of registration shall be made.

A marketing authorization holder and a chemical active pharmaceutical ingredient manufacturer shall apply to the drug regulatory department of the provincial people's government at the place where they are located for renewal of registration; where the marketing authorization holder or the chemical active pharmaceutical ingredient manufacturer is an overseas enterprise, the application for renewal of registration shall be submitted to the drug regulatory department of the State Council.

Article 18 — Where the circumstances for registration as an over-the-counter drug prescribed by the drug regulatory department of the State Council are met, a drug registration applicant may directly submit an application for over-the-counter drug registration.

For a registered prescription drug, where the marketing authorization holder considers it appropriate to be managed as an over-the-counter drug, it may apply to the drug regulatory department of the State Council for conversion to an over-the-counter drug. For a registered over-the-counter drug, where the marketing authorization holder considers, based on the results of adverse reaction monitoring and post-marketing evaluation, that it is not appropriate to be managed as an over-the-counter drug, it shall apply to the drug regulatory department of the State Council for conversion to a prescription drug. Where the drug regulatory department of the State Council, after organizing and conducting evaluation, considers that the requirements are met, it shall decide to convert a prescription drug into an over-the-counter drug or convert an over-the-counter drug into a prescription drug, and announce the conversion to the public.

The drug regulatory department of the State Council may, based on the need to ensure the safety of public drug use and after organizing and conducting evaluation, decide to convert an over-the-counter drug into a prescription drug.

Article 19 — The State shall promote the improvement of drug standards and continuously enhance the level of drug quality.

The drug quality standard approved by the drug regulatory department of the State Council shall be the drug registration standard. The drug registration standard shall comply with the general technical requirements of the Pharmacopoeia of the People's Republic of China, and shall not be lower than the corresponding national drug standard. A marketing authorization holder shall evaluate its drug registration standard in light of the formulation and revision of national drug standards; where revision is necessary, it shall revise the

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standard in a timely manner and submit an application for change or undergo filing or reporting in accordance with the provisions of the drug regulatory department of the State Council.

Article 20 — National drug reference standards and reference substances shall be used in drug research, development and registration applications. Where there are no national drug reference standards or reference substances, a drug registration applicant shall submit the raw materials and relevant technical data used in the study of the drug quality standard to the drug testing institution established or designated by the drug regulatory department of the State Council, and the drug testing institution shall, in accordance with the law, develop and standardize the national drug reference standards and reference substances.

The drug testing institution established or designated by the drug regulatory department of the State Council shall strengthen its capacity to develop national drug reference standards and reference substances, and ensure the supply of national drug reference standards and reference substances.

Article 21 — The State shall support the research, development and innovation of drugs for pediatric use and drugs for the treatment of rare diseases.

For new varieties of drugs for pediatric use, drugs for pediatric use adopting new dosage forms or new specifications, and drugs with added pediatric indications, where the conditions are met, a market exclusivity period of no more than two years shall be granted.

For drugs for the treatment of rare diseases that meet the conditions, where the marketing authorization holder undertakes to ensure the supply of the drug, a market exclusivity period of no more than seven years shall be granted. Where the marketing authorization holder fails to perform its undertaking to ensure drug supply, the market exclusivity period shall be terminated.

The specific conditions and measures for granting market exclusivity periods shall be formulated by the drug regulatory department of the State Council.

Article 22 — The State shall protect the undisclosed test data and other data obtained by the marketing authorization holder itself and submitted for drugs containing new chemical entities and other eligible drugs, and no one shall make improper commercial use of such undisclosed test data and other data.

The protection period for the data specified in the preceding paragraph shall not exceed six years from the date of drug registration. During the protection period, where another applicant uses the data specified in the preceding paragraph to apply for drug registration without the consent of the marketing authorization holder, the registration shall not be granted; provided, however, that this does not apply where the other applicant submits data obtained by itself.

Except under the following circumstances, the drug regulatory department shall not disclose the data specified in paragraph 1 of this Article:

(1) where the public interest so requires; or

(2) where measures have been taken to ensure that such data will not be improperly used for commercial purposes.

The specific measures for the protection of the data specified in paragraph 1 of this Article shall be formulated by the drug regulatory department of the State Council.

Chapter III — Marketing Authorization Holders

Article 23 — A marketing authorization holder shall establish and improve its drug quality assurance system, set up an independent quality management department, and staff it with a production director, a quality director and a qualified person. The qualified person shall independently perform the duty of drug release for marketing.

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Article 24 — A marketing authorization holder shall comply with the good pharmacovigilance practice, establish and improve its pharmacovigilance system, monitor adverse drug reactions and other harmful reactions related to drug use, and establish risk identification, assessment and control mechanisms. Drug distributors and medical institutions shall cooperate with the marketing authorization holder in carrying out pharmacovigilance work.

The good pharmacovigilance practice shall be formulated by the drug regulatory department of the State Council.

Article 25 — Where a marketing authorization holder is an overseas enterprise, the legal person within the territory of China designated by it in accordance with Article 38 of the Drug Administration Law shall have the corresponding quality management capability and risk control capability, and shall set up the corresponding management departments and staff them with corresponding personnel. The relevant information of the designated legal person within the territory of China shall be specified in the drug instructions.

Article 26 — A marketing authorization holder shall, in accordance with the provisions of the drug regulatory department of the State Council, provide accessible-format versions of drug labels and instructions, such as audio, large-print, Braille or electronic versions, so as to facilitate drug use by persons with disabilities and the elderly.

The contents of the electronic version of drug instructions shall be consistent with the drug instructions approved by the drug regulatory department of the State Council, and shall have the same effect as the paper version of drug instructions; the audio and Braille versions of drug labels and instructions shall be for reference only.

Article 27 — A marketing authorization holder shall comprehensively evaluate and verify the impact of changes during the drug manufacturing process on the safety, efficacy and quality controllability of the drug, and submit an application for change or undergo filing or reporting in accordance with the provisions of the drug regulatory department of the State Council.

The drug regulatory department shall strengthen the supervision and administration of changes during the drug manufacturing process; where it discovers that the evaluation and verification of a change filed or reported by a marketing authorization holder is insufficient to prove that the change is scientific, reasonable and risk-controllable, or discovers that the category of change management selected by the marketing authorization holder is inappropriate, it shall order the marketing authorization holder to make corrections, take corresponding risk control measures, and handle the matter in accordance with the law.

Article 28 — A marketing authorization holder shall continuously monitor the quality, efficacy and adverse reactions of its registered drugs.

A marketing authorization holder shall regularly carry out post-marketing evaluation of its registered drugs, comprehensively analyze and assess the risks and benefits of the drugs, and, based on the results of post-marketing evaluation, take measures such as revising the instructions, improving the quality standard, improving the manufacturing process, suspending manufacturing and sales, implementing drug recalls, and applying for cancellation of the drug registration certificate. Where necessary, the drug regulatory department of the State Council may order the marketing authorization holder to carry out post-marketing evaluation or directly organize and carry out post-marketing evaluation.

Where a marketing authorization holder fails to continuously monitor the quality, efficacy and adverse reactions of its registered drugs in accordance with the provisions, or fails to carry out post-marketing evaluation as required by the drug regulatory department of the State Council, the drug registration certificate shall not be renewed upon expiration of its validity period.

Article 29 — A manufacturer of traditional Chinese medicine decoction pieces and a manufacturer of traditional Chinese medicine formula granules shall perform the relevant obligations of a marketing

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authorization holder, conduct whole-process management of the manufacturing and sales of traditional Chinese medicine decoction pieces and traditional Chinese medicine formula granules, establish a traceability system for traditional Chinese medicine decoction pieces and traditional Chinese medicine formula granules, and ensure the safety, efficacy and traceability of traditional Chinese medicine decoction pieces and traditional Chinese medicine formula granules.

Chapter IV — Drug Manufacturing

Article 30 — To engage in drug manufacturing activities, an application shall be submitted to the drug regulatory department of the provincial people's government at the place where the applicant is located, together with materials proving compliance with the conditions prescribed in Article 42 of the Drug Administration Law; to engage in vaccine manufacturing activities, materials proving compliance with the conditions prescribed in paragraph 3 of Article 22 of the Vaccine Administration Law of the People's Republic of China (hereinafter referred to as the "Vaccine Administration Law") shall also be submitted. The drug regulatory department of the provincial people's government shall organize and conduct the review and make a decision within 30 working days from the date of acceptance of the application. Where the prescribed conditions are met, the license shall be granted and a drug manufacturing license shall be issued; where the prescribed conditions are not met, the license shall not be granted and the reasons shall be explained in writing.

To change the licensed items of a drug manufacturing license, a drug manufacturer shall submit an application to the original license-issuing department. The original license-issuing department shall review the application and make a decision within 15 working days from the date of acceptance of the application.

A drug manufacturing license shall be valid for five years. Upon expiration of the validity period, where it is necessary to continue manufacturing drugs, an application shall be made for the re-issuance of the drug manufacturing license.

Article 31 — A marketing authorization holder that manufactures drugs by itself shall obtain a drug manufacturing license.

A marketing authorization holder that entrusts the manufacturing of drugs shall entrust a drug manufacturer that meets the conditions. The marketing authorization holder shall perform the responsibilities of supplier audit, management of changes during the drug manufacturing process, and drug release for marketing, supervise the entrusted manufacturer, and ensure that the entire drug manufacturing process continuously complies with the statutory requirements. The entrusted manufacturer shall organize manufacturing in accordance with good manufacturing practice and shall not further entrust the manufacturing to another party.

Blood products, narcotic drugs, psychotropic substances, medical toxic drugs, precursor chemicals of the drug category, and drugs containing ingredients of narcotic drugs, psychotropic substances or precursor chemicals of the drug category shall not be entrusted for manufacturing; provided, however, that this does not apply where the drug regulatory department of the State Council provides otherwise.

Article 32 — Where a marketing authorization holder has a genuine need, it may entrust drug manufacturers that meet the conditions to manufacture the following drugs by staged manufacturing:

(1) innovative drugs with special requirements for manufacturing processes, facilities and equipment;

(2) drugs urgently needed for clinical use proposed by the relevant departments of the State Council, drugs urgently needed for responding to public health emergencies, or drugs needed for reserve purposes; or

(3) other drugs prescribed by the drug regulatory department of the State Council.

A marketing authorization holder that entrusts staged manufacturing of drugs shall establish a unified quality assurance system covering the entire drug manufacturing process and all manufacturing sites, so as to

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ensure that the entire drug manufacturing process continuously complies with the statutory requirements.

Article 33 — Under any of the following circumstances, where the manufacturing capacity of a vaccine marketing authorization holder is exceeded, the vaccine marketing authorization holder may, upon approval by the drug regulatory department of the State Council, entrust vaccine manufacturers that meet the conditions to manufacture, or manufacture by stages, vaccines:

(1) manufacturing combined multivalent vaccines;

(2) where the relevant departments of the State Council propose urgent needs for disease prevention and control or reserve needs; or

(3) other circumstances prescribed by the drug regulatory department of the State Council.

Article 34 — In manufacturing biological products such as vaccines and blood products, all data generated during the manufacturing and testing processes shall be truthfully recorded by means of informatization in accordance with the provisions.

Article 35 — Where a drug marketed within the territory of China is manufactured overseas, its manufacturing activities shall comply with the relevant requirements of the Drug Administration Law, these Regulations, and other laws, regulations, rules, standards and norms. Where a drug manufactured overseas is repackaged within the territory of China, after the marketing authorization holder files the matter with the drug regulatory department of the State Council, the drug manufacturer carrying out the repackaging may sell the repackaged drug to drug distributors and medical institutions.

Article 36 — The following drugs manufactured before obtaining the drug approval document may be marketed after obtaining the drug approval document, provided that they meet the requirements for drug release for marketing:

(1) commercial-scale batches that have passed the corresponding good manufacturing practice compliance inspection; and

(2) drugs that are new drugs, drugs for the treatment of rare diseases, drugs in short supply, or other drugs urgently needed for clinical use — commercial-scale batches manufactured after passing the corresponding good manufacturing practice compliance inspection.

A marketing authorization holder shall strengthen the risk management of drugs marketed in accordance with the preceding paragraph.

Article 37 — The State shall encourage the development of standardized cultivation and breeding of Chinese medicinal materials, and encourage the use of genuine Chinese medicinal materials. The provincial people's government shall, in light of local realities, formulate relevant plans, encourage the implementation of good agricultural practice for Chinese medicinal materials, and promote the standardized cultivation and breeding of Chinese medicinal materials.

In light of the characteristics of Chinese medicinal materials, origin processing may be carried out on Chinese medicinal materials. The drug regulatory department of the provincial people's government shall formulate guiding principles for the origin processing of Chinese medicinal materials in accordance with good agricultural practice for Chinese medicinal materials, taking into account the distribution of local Chinese medicinal material resources, the tradition of cultivation and breeding, and the characteristics of genuine Chinese medicinal materials.

Article 38 — Chinese medicinal materials used in drug manufacturing shall comply with the national drug standards and drug registration standards. Where there are no national drug standards or drug registration standards, they shall comply with the standards for regionally and traditionally used medicinal materials formulated by the drug regulatory department of the provincial people's government.

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The first import of Chinese medicinal materials shall be subject to the approval of the drug regulatory department of the State Council. The drug regulatory department of the State Council shall review the application and make a decision within 20 working days from the date of acceptance of the application.

Article 39 — A manufacturer of traditional Chinese medicine decoction pieces shall process traditional Chinese medicine decoction pieces by itself and shall not entrust the processing of traditional Chinese medicine decoction pieces.

Traditional Chinese medicine decoction pieces shall be processed in accordance with the national drug standards; where the national drug standards have no provisions, they shall be processed in accordance with the processing specifications formulated by the drug regulatory department of the provincial people's government.

Traditional Chinese medicine decoction pieces processed in accordance with the processing specifications formulated by the drug regulatory department of the provincial people's government may be sold and used across provincial-level administrative regions. Among them, where traditional Chinese medicine decoction pieces whose processing methods and medication characteristics have regional differences and are likely to cause confusion in clinical medication are sold across provincial-level administrative regions, the manufacturer of traditional Chinese medicine decoction pieces shall indicate the clinical medication reminder information on the labels of the traditional Chinese medicine decoction pieces and file the matter with the drug regulatory department of the provincial people's government at the place of purchase and use; medical institutions shall strengthen procurement management and rational medication monitoring to prevent confusion in clinical medication. The specific measures shall be formulated by the drug regulatory department of the State Council.

The labels of traditional Chinese medicine decoction pieces shall specify the product attributes, product name, specifications, origin of the Chinese medicinal materials, manufacturer, product batch number, date of manufacture, filling quantity, shelf life, applicable standards, storage conditions and other information; for traditional Chinese medicine decoction pieces subject to approval management, the drug approval number shall also be specified.

Article 40 — A manufacturer of traditional Chinese medicine formula granules shall file the varieties of traditional Chinese medicine formula granules it manufactures with the drug regulatory department of the provincial people's government at the place where it is located.

A manufacturer of traditional Chinese medicine formula granules shall process by itself the traditional Chinese medicine decoction pieces used in the manufacturing of traditional Chinese medicine formula granules and manufacture traditional Chinese medicine formula granules by itself; it shall not use purchased traditional Chinese medicine decoction pieces to manufacture traditional Chinese medicine formula granules, and shall not entrust the manufacturing of traditional Chinese medicine formula granules.

Traditional Chinese medicine formula granules shall be manufactured in accordance with the national drug standards; where the national drug standards have no provisions, they shall be manufactured in accordance with the standards for traditional Chinese medicine formula granules formulated by the drug regulatory department of the provincial people's government.

Traditional Chinese medicine formula granules manufactured in accordance with the standards for traditional Chinese medicine formula granules formulated by the drug regulatory department of the provincial people's government may be sold and used across provincial-level administrative regions; where traditional Chinese medicine formula granules are sold across provincial-level administrative regions, the manufacturer of traditional Chinese medicine formula granules shall file the matter with the drug regulatory department of the provincial people's government at the place of purchase and use.

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The labels of traditional Chinese medicine formula granules shall specify the product name, specifications, manufacturer, product batch number, date of manufacture, shelf life, applicable standards, storage conditions, filing number and other information.

Drug distributors shall not distribute traditional Chinese medicine formula granules.

Article 41 — Manufacturing activities involving excipients and packaging materials and containers that come into direct contact with drugs shall comply with the relevant provisions of good manufacturing practice for drugs, and a manufacturing quality management system shall be established and improved to ensure that the entire manufacturing process continuously complies with the statutory requirements.

The use of excipients and packaging materials and containers that come into direct contact with drugs and that have been eliminated by the State shall be prohibited in drug manufacturing.

Chapter V — Drug Distribution

Article 42 — To engage in drug distribution activities, an application shall be submitted to the drug regulatory department of the local people's government at or above the county level at the place where the applicant is located, together with materials proving compliance with the conditions prescribed in Article 52 of the Drug Administration Law. The drug regulatory department of the local people's government at or above the county level shall organize and conduct the review and make a decision within 20 working days from the date of acceptance of the application. Where the prescribed conditions are met, the license shall be granted and a drug distribution license shall be issued; where the prescribed conditions are not met, the license shall not be granted and the reasons shall be explained in writing.

To change the licensed items of a drug distribution license, a drug distributor shall submit an application to the original license-issuing department. The original license-issuing department shall review the application and make a decision within 15 working days from the date of acceptance of the application.

A drug distribution license shall be valid for five years. Upon expiration of the validity period, where it is necessary to continue distributing drugs, an application shall be made for the re-issuance of the drug distribution license.

Article 43 — A drug distributor shall be staffed with pharmacists or other pharmaceutical technical personnel who have been qualified through certification in accordance with the law and who are commensurate with its business scope and scale; provided, however, that a drug retail enterprise distributing only Class B over-the-counter drugs may be staffed with pharmaceutical technical personnel in accordance with the provisions of the drug regulatory department of the State Council.

A drug retail enterprise shall sell prescription drugs only on presentation of a prescription.

Article 44 — In storing and transporting drugs, a marketing authorization holder, a drug manufacturer and a drug distributor shall take effective measures based on the packaging, quality characteristics, temperature control requirements and other aspects of the drugs, so as to ensure the quality of drugs during storage and transportation. Where a marketing authorization holder, a drug manufacturer or a drug distributor entrusts the storage or transportation of drugs, it shall select an entrusted party with the corresponding capability and supervise the entrusted party. The entrusted party shall strengthen the management of the drug storage and transportation process and take effective measures to ensure drug quality.

Drugs delivered by a drug retail enterprise to patients shall have independent packaging and conspicuous labeling.

Article 45 — A provider of a third-party platform for online drug transactions shall establish and improve a quality management system for online drug sales, set up corresponding management departments and staff them with pharmaceutical technical personnel and other relevant professionals, and formulate and implement systems for drug quality management, delivery management and other matters. A provider of a

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third-party platform for online drug transactions shall review the qualifications of the marketing authorization holders and drug distributors applying to operate on the platform, inspect the drug information displayed on the platform, and manage the drug distribution activities occurring on the platform. A provider of a third-party platform for online drug transactions shall, in accordance with the provisions, keep the review and inspection records and the drug information displayed on the platform.

Where a provider of a third-party platform for online drug transactions, a marketing authorization holder or a drug distributor provides services such as information display and link redirection for online drug sales by other providers of third-party platforms for online drug transactions, marketing authorization holders or drug distributors, it shall comply with the provisions of the drug regulatory department of the State Council.

Article 46 — Drugs under special State administration, such as vaccines, blood products, narcotic drugs, psychotropic substances, medical toxic drugs, radioactive drugs and precursor chemicals of the drug category, shall not be sold online; other drugs with higher medication risks shall not be retailed online. The specific catalogue shall be formulated by the drug regulatory department of the State Council.

Article 47 — With respect to an application filed by a medical institution for the import of a small quantity of drugs urgently needed for clinical use, the drug regulatory department of the State Council shall seek the opinions of the competent health department of the State Council, and promptly conduct review and make a decision. Where the State Council authorizes the provincial people's government to carry out the approval, the authorized provincial people's government shall formulate specific approval measures in light of local realities.

Article 48 — The entry of a small quantity of drugs carried or mailed by an individual shall be limited to a reasonable quantity for personal use, and shall comply with the State provisions on the entry administration of personal articles.

Chapter VI — Pharmaceutical Administration in Medical Institutions

Article 49 — A medical institution shall formulate and implement management systems for the purchase inspection and acceptance, custody and use of drugs, and set up a corresponding management department or designate personnel to be responsible for drug quality management.

Article 50 — A medical institution shall strengthen the management of prescription writing, review and dispensing, and improve the level of rational medication by physicians.

Article 51 — A physician shall not, in online diagnosis and treatment activities, prescribe the drugs specified in Article 46 of these Regulations.

Article 52 — A medical institution shall provide patients with prescriptions that comply with the provisions of the competent health department of the State Council, and patients may choose to purchase drugs from a drug retail enterprise by presenting the prescription.

The circulation of prescriptions between medical institutions and drug retail enterprises through informatization means shall be encouraged.

Article 53 — For a drug undergoing clinical trials that is used to treat a disease that is seriously life-threatening and for which there is no effective treatment, where medical observation indicates that the patient may benefit and ethical principles are met, the drug may, after review and approval by the ethics committee and the signing of the informed consent form by the patient or the patient's guardian, be used within the institution conducting the clinical trial for other patients with the same condition who are unable to participate in the clinical trial.

Article 54 — To prepare hospital preparations, a medical institution shall submit an application to the drug regulatory department of the provincial people's government at the place where it is located, together with materials proving compliance with the conditions prescribed in paragraph 1 of Article 75 of the Drug

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Administration Law. The drug regulatory department of the provincial people's government shall organize and conduct the review and make a decision within 30 working days from the date of acceptance of the application. Where the prescribed conditions are met, the license shall be granted and a license for hospital preparations shall be issued; where the prescribed conditions are not met, the license shall not be granted and the reasons shall be explained in writing.

To change the licensed items of a license for hospital preparations, a medical institution shall submit an application to the original license-issuing department. The original license-issuing department shall review the application and make a decision within 15 working days from the date of acceptance of the application.

A license for hospital preparations shall be valid for five years. Upon expiration of the validity period, where it is necessary to continue preparing hospital preparations, an application shall be made for the re-issuance of the license for hospital preparations.

Article 55 — A medical institution shall submit the data, materials and samples of the preparations it intends to prepare to the drug regulatory department of the provincial people's government at the place where it is located, and may prepare them only after obtaining the hospital preparation registration certificate through review and approval; provided, however, that for traditional Chinese medicine preparations prepared solely by traditional techniques, a medical institution may prepare them after filing with the drug regulatory department of the provincial people's government at the place where it is located.

When approving an application for the registration of hospital preparations, the drug regulatory department of the provincial people's government shall approve the quality standard, preparation technique, labels and instructions of the preparations at the same time.

A hospital preparation registration certificate shall be valid for three years. Upon expiration of the validity period, where it is necessary to continue preparing the preparations, an application for renewal of registration shall be made.

Article 56 — For drugs for pediatric use that are genuinely needed in clinical practice, where there is no supply on the market or no dosage forms or specifications for pediatric use, the competent health department of the State Council shall, jointly with the drug regulatory department of the State Council, include them in the list of commonly used hospital preparations for children, and support medical institutions in preparing and using them to meet the clinical medication needs of pediatric patients.

Article 57 — The following drugs shall not be used as hospital preparations:

(1) chemical drugs containing active ingredients that have not yet been used in registered drugs;

(2) chemical drugs whose active ingredients of registered drugs are used for new indications;

(3) compound preparations composed of traditional Chinese medicine and chemical drugs;

(4) traditional Chinese medicine injections;

(5) medical toxic drugs;

(6) biological products other than allergens; and

(7) other drugs prescribed by the drug regulatory department of the State Council.

Article 58 — In preparing hospital preparations, a medical institution shall comply with the good preparation practice for hospital preparations, establish and improve a quality management system for preparation manufacturing, and ensure that the entire preparation process continuously complies with the statutory requirements. The good preparation practice for hospital preparations shall be formulated by the drug regulatory department of the State Council.

The legal representative and the principal person in charge of a medical institution shall bear overall responsibility for the preparation activities of the medical institution.

Article 59 — Hospital preparations may be used only within the medical institution itself on prescription by a physician, and shall not be sold or sold in disguised form on the market, and no advertisement for hospital preparations shall be published.

In the event of a disaster, epidemic or other emergency, or where there is an urgent clinical need and no supply on the market, hospital preparations may, upon approval by the drug regulatory department of the provincial people's government and within the prescribed period, be transferred for use among designated medical institutions; provided, however, that the transferred use of special hospital preparations prescribed by the drug regulatory department of the State Council, and the transferred use of hospital preparations across provincial-level administrative regions, shall be subject to the approval of the drug regulatory department of the State Council. The drug regulatory department of the people's government at or above the provincial level shall review the application and make a decision within five working days from the date of acceptance of the application.

Article 60 — Where a medical institution discovers a suspected adverse drug reaction, it shall promptly report it to the drug regulatory department and the competent health department in accordance with the provisions.

Where a medical institution discovers a suspected cluster event of adverse drug reactions, it shall promptly provide treatment to patients, take measures to control the risk, and promptly report it to the drug regulatory department and the competent health department in accordance with the provisions. The drug regulatory department and the competent health department shall promptly investigate and handle the matter upon receiving the report.

Article 61 — Where a medical institution discovers that the drugs it has purchased or is using have quality problems, it shall immediately take measures to control the risk, promptly notify the supplier and the marketing authorization holder, and report to the drug regulatory department of the county-level people's government at the place where it is located.

The marketing authorization holder and the supplier shall provide or publish their email addresses, telephone numbers, fax numbers and other information, so as to facilitate notification of relevant information by medical institutions.

Article 62 — The drug regulatory department and the competent health department shall, in accordance with their respective duties, supervise and administer the drug quality and drug use conduct in the drug use process respectively.

Chapter VII — Supervision and Administration

Article 63 — In conducting supervision and inspection, the drug regulatory department may take the following measures:

(1) entering the places of drug research, development, manufacturing, distribution and use activities, as well as places providing related products or services for drug research, development, manufacturing, distribution and use, to conduct on-site inspection and take samples;

(2) consulting and copying relevant documents, records, notes, vouchers, electronic data and other materials, and sealing or seizing materials that may be transferred, concealed or destroyed;

(3) sealing or seizing drugs and their related raw materials, excipients and packaging materials and containers that come into direct contact with drugs and that are evidenced to be potentially harmful to human health; and

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(4) sealing or seizing tools, facilities, equipment and places that are evidenced to be potentially used for illegal activities.

When the drug regulatory department conducts supervision and inspection, there shall be no fewer than two law enforcement officers, who shall produce their law enforcement credentials. The relevant entities and individuals shall cooperate with the supervision and inspection and shall not refuse or obstruct it.

Article 64 — The drug regulatory department of the State Council shall formulate unified drug traceability standards and specifications. Marketing authorization holders and drug manufacturers shall affix traceability marks on drug packaging in accordance with the provisions. Marketing authorization holders, drug manufacturers, drug distributors and medical institutions shall provide traceability information in accordance with the provisions, so as to ensure the traceability of drugs.

Article 65 — The drug regulatory department of the State Council shall establish national drug professional and technical institutions in accordance with procedures. The drug regulatory department of the provincial people's government may establish local drug professional and technical institutions in accordance with procedures and in light of the development of the local drug industry and the needs of supervision and administration work. National drug professional and technical institutions shall strengthen technical guidance to local drug professional and technical institutions.

The drug regulatory department of the people's government at or above the provincial level may, based on the needs of drug supervision and administration work, designate institutions that meet the conditions to undertake relevant professional and technical work.

Article 66 — Drug quality sampling inspection shall follow the principles of being scientific, standardized and impartial.

The drug regulatory department shall formulate and implement drug quality sampling inspection plans based on the needs of drug supervision and administration work.

In drug quality sampling inspection, drug sampling shall be carried out by no fewer than two sampling personnel in accordance with the provisions of the drug regulatory department of the State Council. The entity being sampled shall cooperate with the sampling personnel in sampling. Where the entity being sampled refuses to cooperate without justifiable reasons, the drug regulatory department may order the entity being sampled to suspend the sale and use of the sampled drugs.

Based on the needs of drug supervision and administration work, the drug regulatory department may conduct sampling inspection of the quality of excipients and packaging materials and containers that come into direct contact with drugs.

Article 67 — Where a party has objections to the testing results of a drug testing institution, it may apply for re-testing within seven days from the date of receipt of the drug testing results.

An applicant for re-testing shall pay the re-testing fee in advance to the re-testing institution in accordance with the provisions. Where the re-testing conclusion is inconsistent with the original testing conclusion, the re-testing fee shall be borne by the original drug testing institution.

Where a testing item is subject to the national drug standards that provide that re-testing shall not be conducted, or where there are other circumstances in which the drug regulatory department of the State Council provides that re-testing shall not be conducted, re-testing shall not be conducted.

Article 68 — The results of drug quality sampling inspection announced by the drug regulatory department of the people's government at or above the provincial level shall include the product name of the sampled drug, the source of the sample, the labeled marketing authorization holder and manufacturer or the labeled medical institution, the product batch number, specifications, testing institution, testing basis, testing conclusion, non-conforming items and other contents. Where the announcement of drug quality sampling

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inspection results is inappropriate, the issuing department shall make corrections within five working days from the date of confirming the inappropriateness, within the scope of the original announcement.

Article 69 — For drugs that may be adulterated or mixed with other substances, where testing cannot be conducted according to the testing items and testing methods prescribed by the national drug standards and drug registration standards, the drug testing institution may use the supplementary testing items and testing methods approved by the drug regulatory department of the State Council for testing. The testing results obtained using the supplementary testing items and testing methods may be used as the basis for determining drug quality.

Article 70 — Where the drug regulatory department takes risk control measures such as suspension of manufacturing, sale, use and import in accordance with paragraph 3 of Article 99 of the Drug Administration Law, the marketing authorization holder, drug manufacturer, drug distributor and medical institution shall make rectifications and eliminate safety hazards. Where the drug regulatory department, after evaluation, considers that the relevant requirements are met, it shall lift the risk control measures taken.

During the period when the drug regulatory department of the people's government at or above the provincial level takes the risk control measures specified in the preceding paragraph, no advertisement for the relevant drugs shall be published; where an advertisement has already been published, it shall be stopped immediately.

Article 71 — The following circumstances constitute counterfeit drugs as defined in item (2) of paragraph 2 of Article 98 of the Drug Administration Law:

(1) substances that do not have the function of disease prevention, treatment or diagnosis, or substances of unknown composition, that claim on their labels or instructions to have the function of disease prevention, treatment or diagnosis and pass themselves off as drugs;

(2) use of the name or approval number of another drug, with indications or functions and indications that are not actually possessed being marked on the labels or instructions;

(3) drugs whose ingredients are inconsistent with the ingredients marked on their labels or instructions;

(4) drugs marked with false drug approval numbers or false marketing authorization holders; and

(5) other circumstances in which non-drugs pass themselves off as drugs or one kind of drug passes itself off as another kind of drug.

Article 72 — Drug testing shall not be required for determining counterfeit drugs in accordance with item (4) of paragraph 2 of Article 98 of the Drug Administration Law, or for determining substandard drugs in accordance with items (3) through (5) of paragraph 3 of Article 98 of the Drug Administration Law. For determining counterfeit drugs or substandard drugs in accordance with the other provisions of paragraphs 2 and 3 of Article 98 of the Drug Administration Law, drug testing shall be conducted; provided, however, that where evidence such as the purchase and use records of raw materials and excipients can fully prove that a drug is a counterfeit drug or substandard drug, drug testing may be dispensed with.

Article 73 — An entity where a drug safety incident occurs shall immediately take measures to prevent the expansion of the harm and immediately report it to the drug regulatory department of the county-level people's government at the place where the incident occurred.

Where a medical institution discovers that a drug safety incident has occurred, it shall immediately report it to the drug regulatory department of the county-level people's government at the place where the incident occurred and the competent health department.

Upon receiving the report, the drug regulatory department shall immediately report it to the people's government at the same level and the drug regulatory department of the people's government at the next higher level in accordance with the provisions.

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The people's government at or above the county level shall organize and carry out response work in accordance with the emergency response plan for drug safety incidents.

Article 74 — The State shall strengthen drug reserve and implement central and local two-tier reserve. The specific measures shall be formulated by the competent industry and information technology department of the State Council jointly with the relevant departments of the State Council.

Article 75 — The competent health department of the State Council shall, jointly with the relevant departments of the State Council, formulate the national drug policy and the national essential drug system, and improve the management mechanism for the national essential drug list.

Article 76 — The market regulatory department shall strengthen the supervision and administration of anti-monopoly and anti-unfair competition in drug manufacturing and distribution, investigate and handle monopolistic and unfair competition violations in accordance with the law, and maintain the order of fair competition.

Article 77 — Where the drug regulatory department and other departments discover, in the course of supervision and administration, clues that a public official is suspected of duty-related violations or duty-related crimes, they shall promptly transfer such clues to the supervisory authority.

Article 78 — Fees may be charged for drug registration, drug registration testing and mandatory testing. The specific fee items and fee standards shall be formulated by the finance department of the State Council and the development and reform department of the State Council respectively in accordance with the relevant State provisions.

Chapter VIII — Legal Liability

Article 79 — Under any of the following circumstances, the drug regulatory department of the local people's government at or above the county level shall order correction within a prescribed time limit, confiscate the illegally manufactured or sold drugs and the illegal gains, and impose a fine of no less than 10 times and no more than 20 times the value of the illegally manufactured or sold drugs; where the value of the illegally manufactured or wholesale drugs is less than 100,000 yuan, it shall be calculated as 100,000 yuan, and where the value of the illegally retailed drugs is less than 10,000 yuan, it shall be calculated as 10,000 yuan. Where the circumstances are serious, it shall also order suspension of manufacturing or distribution for rectification, up to revocation of the drug manufacturing license or drug distribution license by the original license-issuing department:

(1) where a marketing authorization holder sells commercial-scale batches manufactured before obtaining the drug approval document in violation of Article 36 of these Regulations;

(2) where a manufacturer of traditional Chinese medicine decoction pieces entrusts the processing of traditional Chinese medicine decoction pieces, or a manufacturer of traditional Chinese medicine formula granules entrusts the manufacturing of traditional Chinese medicine formula granules;

(3) where a drug distributor distributes traditional Chinese medicine formula granules or hospital preparations; or

(4) where drugs are sold online in violation of Article 46 of these Regulations.

Article 80 — Under any of the following circumstances, the drug regulatory department of the provincial people's government shall order correction within a prescribed time limit and give a warning; where correction is not made within the prescribed time limit, a fine of no less than 100,000 yuan and no more than 500,000 yuan shall be imposed:

(1) where a manufacturer of traditional Chinese medicine decoction pieces or a manufacturer of traditional Chinese medicine formula granules sells traditional Chinese medicine decoction pieces or traditional

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Chinese medicine formula granules across provincial-level administrative regions without filing in accordance with paragraph 3 of Article 39 or paragraph 4 of Article 40 of these Regulations; or

(2) where a manufacturer of traditional Chinese medicine formula granules manufactures traditional Chinese medicine formula granules without filing in accordance with paragraph 1 of Article 40 of these Regulations.

Article 81 — Where a medical institution uses preparations prepared by another medical institution without approval, it shall be punished in accordance with Articles 129 and 139 of the Drug Administration Law.

Where a medical institution has any of the following circumstances, the drug regulatory department of the local people's government at or above the county level shall order correction within a prescribed time limit; where correction is not made within the prescribed time limit, a fine of no less than 10,000 yuan and no more than 100,000 yuan shall be imposed:

(1) failing to formulate and implement management systems for the purchase inspection and acceptance, custody and use of drugs in accordance with the provisions; or

(2) discovering that the purchased or used drugs have quality problems but failing to take measures or make a report in accordance with the provisions.

Article 82 — Where, in applying for the qualification certification of a non-clinical safety evaluation institution, a drug clinical trial license, a drug manufacturing license, a drug distribution license, a license for hospital preparations, drug registration, or other licenses, an applicant provides false certificates, data, materials or samples or adopts other fraudulent means, the drug regulatory department of the people's government at or above the county level shall not accept the application or shall not grant the license, shall not accept the corresponding application within 10 years, and shall impose a fine of no less than 500,000 yuan and no more than 5,000,000 yuan. Where the circumstances are serious, it shall also impose a fine of no less than 20,000 yuan and no more than 200,000 yuan on the legal representative, the principal person in charge, the directly responsible person in charge and other responsible persons, and prohibit them from engaging in drug manufacturing and distribution activities within 10 years.

Where the false certificates, data, materials or samples submitted by an applicant are forged or fabricated by a non-clinical safety evaluation institution, a drug clinical trial institution or another institution entrusted to carry out drug research and development-related activities, the drug regulatory department of the people's government at or above the provincial level shall, in accordance with Article 126 of the Drug Administration Law, impose penalties on the non-clinical safety evaluation institution, the drug clinical trial institution or the other institution entrusted to carry out drug research and development-related activities.

Article 83 — Where a drug clinical trial institution that has undergone filing no longer meets the filing conditions, the drug regulatory department of the people's government at or above the provincial level shall order correction within a prescribed time limit; where the institution still fails to meet the filing conditions within the prescribed time limit, the filing for the relevant drug clinical trial specialty or the filing of the drug clinical trial institution shall be cancelled, and the institution shall be prohibited from carrying out clinical trials of the relevant specialty or prohibited from carrying out drug clinical trials within one year.

Where false certificates are provided when undergoing filing of a drug clinical trial institution, the drug regulatory department of the people's government at or above the provincial level shall cancel the filing for the relevant drug clinical trial specialty or the filing of the drug clinical trial institution, prohibit the institution from carrying out clinical trials of the relevant specialty or prohibit it from carrying out drug clinical trials within three years, confiscate the illegal gains, impose a fine of no less than 100,000 yuan and no more than 500,000 yuan, and the relevant clinical trial data shall not be used in applying for drug registration.

Article 84 — Where a provider of a third-party platform for online drug transactions fails to establish and improve a quality management system for online drug sales in accordance with the provisions, the drug regulatory department of the provincial people's government shall order correction within a prescribed time

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limit and give a warning; where correction is not made within the prescribed time limit, a fine of no less than 100,000 yuan and no more than 500,000 yuan shall be imposed; where the circumstances are serious, a fine of no less than 500,000 yuan and no more than 2,000,000 yuan shall be imposed.

Where a provider of a third-party platform for online drug transactions, a marketing authorization holder or a drug distributor provides services such as information display and link redirection for online drug sales by other providers of third-party platforms for online drug transactions, marketing authorization holders or drug distributors, and violates the provisions of the drug regulatory department of the State Council, the drug regulatory department of the provincial people's government shall order correction within a prescribed time limit and give a warning; where correction is not made within the prescribed time limit, the illegal gains shall be confiscated and a fine of no less than 100,000 yuan and no more than 500,000 yuan shall be imposed; where the circumstances are serious, the illegal gains shall be confiscated and a fine of no less than 500,000 yuan and no more than 2,000,000 yuan shall be imposed.

Article 85 — Where an entity refuses to implement the risk control measures lawfully taken by the drug regulatory department, such as suspension of manufacturing, sale, use and import, the drug regulatory department of the people's government at or above the county level shall impose a fine of no less than five times and no more than 10 times the value of the drugs illegally manufactured, sold, used or imported; where the value is less than 10,000 yuan, it shall be calculated as 10,000 yuan. Where the circumstances are serious, it shall also order suspension of manufacturing or distribution for rectification, up to revocation of the drug approval document, drug manufacturing license, drug distribution license and license for hospital preparations by the original license-issuing department, and impose a fine of no less than 20,000 yuan and no more than 200,000 yuan on the legal representative, the principal person in charge, the directly responsible person in charge and other responsible persons.

Where an entity refuses or obstructs supervision and inspection in violation of the Drug Administration Law, the Vaccine Administration Law or these Regulations, the drug regulatory department of the people's government at or above the county level shall order correction within a prescribed time limit and impose a fine of no more than 50,000 yuan; where the circumstances are serious, it shall order suspension of manufacturing or distribution for rectification.

Article 86 — Where a drug distributor or a medical institution has performed its obligations such as purchase inspection and acceptance as prescribed by the Drug Administration Law, the Vaccine Administration Law and these Regulations, and there is sufficient evidence to prove that it did not know that the drugs it sold or used were counterfeit drugs or substandard drugs, it shall be exempted from punishment, but the counterfeit drugs or substandard drugs it sold or used shall be confiscated; where personal injury, property damage or other damage is caused, it shall bear compensation liability in accordance with the law.

Article 87 — Where the drug regulatory department or its staff members, in violation of these Regulations, disclose undisclosed test data or other data of a marketing authorization holder, causing losses to the marketing authorization holder, the drug regulatory department shall bear compensation liability in accordance with the law; after the drug regulatory department has paid compensation, it shall order the staff members who acted intentionally or with gross negligence to bear part or all of the compensation costs, and impose sanctions in accordance with the law on the responsible leading personnel and directly responsible personnel.

Chapter IX — Supplementary Provisions

Article 88 — The time required for drug registration review and approval, as well as the time required for technical review involved in the review of applications for the qualification of non-clinical safety evaluation institutions, drug manufacturing licenses, drug distribution licenses and licenses for hospital preparations, shall not be included in the time limit for the drug regulatory department to carry out administrative licensing.

Article 89 — These Regulations shall come into force on May 15, 2026.

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