Regulations for the Implementation of the Drug Administration Law of the People's Republic of China (2024 Revision)[1]

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Chapter I: General Provisions

Article 1

Pursuant to the *Drug Administration Law of the People's Republic of China* (hereinafter the "Drug Administration Law"), these Regulations are hereby formulated.

Article 2

The drug supervision and administration department of the State Council shall establish the National Drug Inspection Institution.

The drug supervision and administration departments of the people's governments of provinces, autonomous regions, and municipalities directly under the Central Government may establish drug inspection institutions within their respective administrative regions. The establishment of such local drug inspection institutions shall be planned by the provincial-level drug supervision authority and submitted to the provincial, autonomous region, or municipal government for approval.

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

The drug supervision and administration departments of the State Council and of provincial-level governments may, as necessary, designate qualified inspection institutions to undertake drug testing tasks.

Chapter II: Administration of Drug Manufacturing Enterprises

Article 3

In order to establish a drug manufacturing enterprise, the applicant shall submit an application to the drug supervision and administration department of the provincial-level government at the locality of the proposed enterprise. The provincial-level department shall, within 30 working days of receipt, organize an inspection in accordance with the establishment requirements set forth in Article 8 of the Drug Administration Law; where the inspection is passed, a "Drug Manufacturing License" shall be issued.

Article 4

If a drug manufacturing enterprise seeks to amend any item of its Drug Manufacturing License, it must apply to the original issuing authority for a license amendment at least 30 days before the change becomes effective. No change may be made without approval. The issuing authority shall render its decision within 15 working days of receipt of the application.

Article 5

Drug supervision and administration departments at or above the provincial level shall organize certification of drug manufacturing enterprises in accordance with the *Good Manufacturing Practice* (GMP) and the implementation methods and procedures prescribed by the State Council's drug regulatory department. Enterprises that meet GMP standards shall be issued certification. Certification of manufacturers producing injectable preparations, radioactive drugs, and those producing biologics as stipulated by the State Council's drug regulatory department shall be handled by the State Council itself.

The format of the GMP certification certificate shall be uniformly provided by the State Council's drug regulatory department.

Article 6

Any newly established drug manufacturing enterprises, enterprises constructing new production workshops, or enterprises adding new dosage forms must, within 30 days of receiving drug production approval documents or formal authorization to produce, apply to the drug supervision and administration department for GMP certification. The department shall, within six months of receiving the application, organize a certification inspection; enterprises that pass shall receive the certificate.

Article 7

The State Council's drug regulatory department shall establish a registry of GMP certification inspectors. Inspectors must meet the qualifications prescribed by the State Council. A GMP inspection shall be conducted by a team of inspectors randomly selected from the database of GMP inspectors according to the provisions of the drug regulatory department under the State Council.

Article 8

The Drug Manufacturing License is valid for five years. Enterprises wishing to continue manufacturing drugs after its expiration must apply to renew the license six months prior to expiration in accordance with State Council rules.

Where a drug manufacturing enterprise terminates production or closes, the original issuing authority shall cancel the Drug Manufacturing License.

Article 9

Active pharmaceutical ingredients used by drug manufacturing enterprises must carry a drug approval number issued by the State Council's drug regulatory department or hold an import drug registration certificate or pharmaceutical product registration certificate. Traditional Chinese medicine materials and decoction pieces not subject to approval-number administration are exempt.

Article 10

In accordance with the provisions in Article 13 of the Drug Administration Law , any drug manufacturer being entrusted with contract production of the drug shall have a GMP certificate corresponding to the contracted drug.

Vaccines, blood products, and other drugs specified by the State Council's drug regulatory department may not be subcontracted for production.

Chapter III: Administration of Drug Distribution Enterprises

Article 11

To establish a drug wholesale or retail enterprise, one must submit an application for a drug distribution permit in accordance with the Drug Administration Law, accompanied by documentation proving compliance with statutory requirements.

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Article 12

A decision on the permit application shall be made within 20 working days from acceptance. Where requirements are met, a permit shall be granted and a Drug Distribution License issued; where not met, a written refusal with reasons shall be issued.

Article 13

The drug administrative departments of the people's governments of provinces, autonomous regions, or municipalities directly under the Central Government and the drug administrative agencies at the level of a districted city shall be responsible for organizing the certification of pharmaceutical trading enterprises. A pharmaceutical trading enterprise shall, according to the implementation measures and the implementation steps prescribed by the drug administrative department of the State Council, pass the certification of compliance with the Good Distribution Practices for Pharmaceutical Products ("GDP") organized by the drug administrative department of the people's government of the province, autonomous region, or municipality directly under the Central Government or the drug administrative agency at the level of a districted city, and obtain a GDP certificate. The format of a GDP certificate shall be uniformly prescribed by the drug administrative department of the State Council.

A newly-formed pharmaceutical wholesaler or retailer shall, within 30 days of obtaining the Pharmaceutical Distribution Permit, apply for the GDP certification to the drug administrative department or agency which issued the Pharmaceutical Distribution Permit to it. The drug administrative department or agency accepting the application shall, within three months of receipt of the application, organize the certification of GDP compliance of the pharmaceutical wholesaler or retailer applying for certification in accordance with the provisions issued by the drug administrative department of the State Council, and issue a GDP certificate to the pharmaceutical wholesaler or retailer if it passes the certification.

Article 14

The drug regulatory departments of the people's governments of provinces, autonomous regions, and municipalities directly under the Central Government shall establish a registry of inspectors for the certification of the *Good Supply Practice for Pharmaceutical Products* (GSP). GSP certification inspectors must meet the qualifications prescribed by the drug regulatory authority under the State Council. When conducting GSP certification, inspectors must be randomly selected from the GSP inspector registry, in accordance with the provisions set by the drug regulatory authority under the State Council, to form a certification inspection team and carry out the certification inspection.

Article 15

The State adopts a classification system for prescription drugs and non-prescription drugs. The State subdivides non-prescription drugs into Class A drugs and Class B drugs according to the level of safety.

Any drug retailer distributing prescription drugs or Class A non-prescription drugs shall have licensed pharmacists or other pharmaceutical technicians whose qualifications are legally recognized. Any retailer distributing Class B non-prescription drugs shall have pharmacy staff members who have passed the examination organized by the local drug regulatory institution of the municipality divided into districts or by the local drug regulatory institution at the county level which is directly set up by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government.

Article 16

Where a pharmaceutical distribution enterprise intends to amend any item listed in its Drug Distribution License, it shall submit an application for modification registration to the original licensing authority no less than 30 days prior to the proposed change. No modification may be implemented without prior approval. The licensing authority shall render a decision on the application within 15 working days of the date of submission.

Article 17

A Drug Distribution License is valid for five years. Where continuation of drug distribution is desired post-expiry, the license holder must apply for renewal six months in advance, in accordance with State Council rules.

Where a drug distribution enterprise ceases operation or closes, its license shall be revoked by the original issuing authority.

Article 18

In remote and poorly accessible rural and urban fair-trade markets where no pharmaceutical retail enterprises are present, local pharmaceutical retail enterprises may, upon approval by the county (or municipal) drug regulatory authority at their place of registration and after completing registration with the administrative department for industry and commerce, establish sales outlets within such markets. These outlets may sell over-the-counter (OTC) drugs within the approved scope of business.

Article 19

Drug transactions conducted online by manufacturing or distribution enterprises, medical institutions, or involving drugs themselves, must comply with the Drug Administration Law and these Regulations. Regulations governing online drug trading services shall be formulated by the State Council's drug regulatory department together with relevant State Council ministries.

Chapter IV: Control over Drugs in Medical Institutions

Article 20

To establish a pharmaceutical preparation unit in a medical institution, an application shall be submitted to the local health administrative department of the people's government of the province, autonomous region or municipality directly under the Central Government, and, after being consented upon examination, be presented to the drug regulatory department of the people's government at the same level for review and approval. Approval shall be given to the medical institution if it passes the review by the said drug regulatory department and a Pharmaceutical Preparation License for Medical Institution shall be issued to it.

The health administrative department and the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government shall, within 30 working days from the dates they receive the application respectively, make their own decisions whether or not to consent or approve the application accordingly.

Article 21

If a medical institution needs to change the licensed items of its *Medical Institution Preparation License*, it shall apply for modification of the license to the original reviewing and approving authorities 30 days before the changes take place, in accordance with Article 20 of these Regulations. No changes shall be made without approval. The original reviewing and approving authorities shall make a decision within 15 working days from the date of receipt.

Any medical institution which intends to add new dosage forms or change dispensing sites shall, after passing the acceptance inspection by the local drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government, go through the registration of alteration of the Pharmaceutical Preparation Certificate for Medical Institution according to the provisions in the preceding paragraph.

Article 22

The Preparation License for Medical Institutions shall be valid for a period of five years. Where continued preparation is necessary upon expiration of the license, the medical institution shall, six months prior to the expiry date, apply for renewal of the license in accordance with the provisions of the drug regulatory department under the State Council. Where a medical institution terminates the preparation of formulation or ceases operations, the original issuing authority shall cancel the Preparation License for Medical Institutions.

Article 23

A medical institution, when preparing formulations, must submit relevant documentation and samples in accordance with the provisions of the drug regulatory authority under the State Council. Only upon approval by the drug regulatory authority of the province, autonomous

region, or municipality directly under the Central Government, and the issuance of a preparation approval number, may the preparation proceed.

Article 24

Preparations made by medical institutions shall not be sold on the market or disguised as market sales, nor may advertisements be issued for such preparations.

In the event of disasters, epidemics, emergencies, or clinical urgency where the required drug is not available on the market, and upon approval by the drug regulatory authority under the State Council or the relevant authority at the provincial, autonomous region, or municipal level, such preparations may be shared and used among designated medical institutions within a specified period.

Special preparations designated by the drug regulatory authority under the State Council and inter-provincial transfers of institutional preparations must be approved by the drug regulatory authority under the State Council.

Article 25

Personnel responsible for reviewing and dispensing prescriptions within medical institutions shall be pharmacy professionals who have lawfully obtained relevant qualifications.

Article 26

Medical institutions shall maintain true and complete drug procurement records. These records shall include the generic name, dosage form, specification, batch number, expiration date, manufacturer, supplier, quantity purchased, purchase price, purchase date, and any other information required by the drug regulatory authority under the State Council.

Article 27

The drugs provided by medical institutions to patients shall correspond to the scope of diagnosis and treatment and must be dispensed based on prescriptions issued by licensed doctors or licensed assistant doctors.

Family planning service institutions shall procure and dispense drugs in accordance with their approved scope of services, based on prescriptions issued by licensed doctors or licensed assistant doctors.

Privately established outpatient departments and clinics may only be equipped with commonly used drugs and emergency medicines. The specific categories and types of such medicines shall be determined by the health administrative department of the people's government at the

provincial, autonomous region, or municipal level, in conjunction with the corresponding drug regulatory authority.

Chapter V: Drug Administration

Article 28

Drug non-clinical safety evaluation institutions must comply with the Good Laboratory Practice for Non-clinical Studies of Drugs. Drug clinical trial institutions must comply with the Good Clinical Practice for Drug Clinical Trials. These two sets of regulations are formulated by the State Council's drug regulatory authority in consultation with the State Council's scientific and technological administrative department and the health administrative department, respectively.

Article 29

Drug clinical trials, drug production, and drug imports shall comply with the provisions of the Drug Administration Law and relevant regulations and require review and approval by the drug regulatory authority under the State Council. The State Council's drug regulatory authority may entrust the drug regulatory departments of provincial, autonomous region, and municipal governments to review the development status and conditions of the drugs under application, conduct a formal review of the application materials, and inspect samples of trial products. Specific measures shall be formulated by the drug regulatory authority under the State Council.

Article 30

For the development of new drugs requiring clinical trials, approval must be obtained from the drug regulatory authority under the State Council in accordance with Article 29 of the Drug Administration Law.

After approval of the clinical trial application by the drug regulatory authority under the State Council, the applicant shall select a qualified clinical trial institution, legally recognized to conduct drug clinical trials, to carry out the trial. This clinical trial institution must be reported to and filed with both the drug regulatory authority and the health administrative department under the State Council.

Clinical trial institutions must inform subjects or their guardians of the true situation before conducting clinical trials and obtain their written consent.

Article 31

For the production of drugs with existing national standards, an application shall be submitted, in accordance with the regulations of the drug regulatory authority under the State Council, to the drug regulatory department of the people's government of the province, autonomous region, or municipality directly under the Central Government, or directly to the drug regulatory authority under the State Council. Relevant technical documents and supporting certificates must be provided.

The drug regulatory department of the people's government of the province, autonomous region, or municipality directly under the Central Government shall review the application within 30 working days from the date of acceptance, submit its opinions to the drug regulatory authority under the State Council for further review, and simultaneously notify the applicant of the review results.

If the drug regulatory authority under the State Council confirms compliance after review, it shall issue the drug approval number.

Article 32

To make changes to the approved certification documents or their annexes for the development of new drugs, the production of drugs, or the import of drugs, a supplementary application shall be submitted to the drug regulatory authority under the State Council. If the changes are found to be compliant upon review, the authority shall grant approval. Where the changes do not affect the intrinsic quality of the drug, the supplementary application shall be submitted to the drug regulatory department of the people's government of the province, autonomous region, or municipality directly under the Central Government. If, upon review, the changes are found to comply with relevant provisions, approval shall be granted and the matter reported to the drug regulatory authority under the State Council for the record. The specific items subject to supplementary application that do not involve changes to the intrinsic quality of the drug shall be determined by the drug regulatory authority under the State Council.

Article 33

In order to protect public health, the drug regulatory authority under the State Council may impose a monitoring period of no more than five years for new drug varieties produced by drug manufacturers. During the monitoring period, no approval shall be granted for the production or import of the same drug variety by other enterprises.

Article 34

The State shall protect undisclosed test data and other data that is independently obtained and submitted by producers or sellers who have obtained a license to produce or sell drugs containing new chemical entities. No one may make improper commercial use of such undisclosed test data and other data.

For a period of six years from the date on which the producer or seller obtains the license for the production or sale of a drug containing a new chemical entity, the drug regulatory authority shall not grant a license to any other applicant who applies to produce or sell the same drug by relying on the aforementioned data without the consent of the original license holder. However, this does not apply if the other applicant submits independently obtained data.

Except under the following circumstances, the drug regulatory authority shall not disclose the data referred to in the first paragraph of this Article:

1-When required for the public interest;

2-When measures have been taken to ensure the data will not be improperly used for commercial purposes.

Article 35

Drugs applying for import must have already been granted market approval in their country or region of manufacture. If a drug has not been approved for marketing in its country or region of manufacture, the drug may still be approved for import in accordance with the Drug Administration Law and these Regulations, provided that the drug regulatory authority under the State Council confirms that the drug is safe, effective, and clinically necessary.

Imported drugs must be registered in accordance with the provisions of the drug regulatory authority under the State Council. Drugs produced by foreign enterprises may be imported only after obtaining a Registration Certificate for Imported Drugs. Drugs produced by enterprises in Hong Kong, Macao, or Taiwan may be imported only after obtaining a Medical Product Registration Certificate.

Article 36

Medical institutions that urgently need to import a small quantity of drugs for clinical use shall apply to the drug regulatory authority under the State Council with their Medical Institution Practice License. Importation may only proceed after approval. The imported drugs shall be used within the designated medical institution for specific medical purposes.

Article 37

After imported drugs arrive at the port of entry, the importing entity shall submit the Registration Certificate for Imported Drugs or Medical Product Registration Certificate, along with the original certificate of origin, a copy of the purchase contract, packing list, bill of lading, freight invoice, factory inspection report, instructions, and other relevant documents, to the drug regulatory department at the port of entry for record filing.

Upon review, if the submitted materials meet the requirements, the drug regulatory department at the port of entry shall issue an Imported Drug Customs Clearance Certificate. The importing entity shall use this certificate to complete customs declaration and inspection procedures.

The drug regulatory department at the port of entry shall notify the drug inspection agency to conduct batch-by-batch sampling inspections of the imported drugs, except in circumstances stipulated in Article 41 of the Drug Administration Law.

Article 38

Vaccine products, blood products, in vitro diagnostic reagents used for blood source screening, and other biological products as stipulated by the drug regulatory authority under the State Council shall undergo inspection or approval according to the regulations of the drug regulatory authority before sale or import. Products that fail inspection or are not approved shall not be sold or imported.

Article 39

The State encourages the cultivation and development of traditional Chinese medicinal materials. For varieties of Chinese medicinal materials that are cultivated in centralized, large-scale operations with controllable quality and that meet the conditions prescribed by the drug regulatory authority under the State Council, approval number management shall be implemented.

Article 40

The drug regulatory authority under the State Council shall conduct re-evaluations of drugs that have been approved for production and sale. Based on the results of such re-evaluations, measures may be taken to order revisions to the drug instructions, or to suspend production, sale, and use. For drugs with serious adverse reactions or other reasons that endanger human health, the approval certificate for the drug shall be revoked.

Article 41

The validity period of the drug approval number issued by the State Council drug regulatory department, the "Imported Drug Registration Certificate," and the "Medical Product Registration Certificate" is five years. Upon expiration of the validity period, if continued production or importation is required, re-registration shall be applied for six months prior to the expiration of the validity period. At the time of drug re-registration, relevant documentation shall be submitted in accordance with the provisions of the State Council drug regulatory department. Upon expiration of the validity period, if re-registration has not been applied for, or if the re-registration is reviewed and found to not comply with the provisions of the State Council drug regulatory department, the drug approval number, "Imported Drug Registration Certificate," or "Medical Product Registration Certificate" shall be revoked.

Re-registration of the drug approval number shall be approved by the drug regulatory departments of the people's governments of provinces, autonomous regions, and municipalities directly under the Central Government, and shall be filed with the State Council drug regulatory department for the record; re-registration of the "Imported Drug Registration Certificate" and the "Medical Product Registration Certificate" shall be approved by the State Council drug regulatory department.

Article 42

Non-drugs shall not include any content involving the prevention, treatment, or diagnosis of human diseases in their packaging, labels, instructions, or related promotional materials; except as otherwise provided by laws and administrative regulations.

Chapter VI: Management of Drug Packaging

Article 43

Packaging materials and containers that directly contact drugs and are used by drug manufacturing enterprises must comply with pharmaceutical requirements and standards that ensure human health and safety.

The administrative measures, product catalogs, and pharmaceutical requirements and standards for packaging materials and containers that directly contact drugs shall be formulated and published by the State Council drug regulatory department.

Article 44

In the production of Chinese herbal medicine decoction pieces, packaging materials and containers compatible with the properties of the medicine shall be selected; Chinese herbal medicine decoction pieces with packaging not in compliance with regulations shall not be sold. The packaging of Chinese herbal medicine decoction pieces must bear or be affixed with a label.

The label of Chinese herbal medicine decoction pieces must indicate the name of the product, specification, place of origin, manufacturer, product batch number, production date, and, for those under approval number management, the drug approval number.

Article 45

Drug packaging, labels, and instructions must be printed in accordance with Article 54 of the Drug Administration Law and the provisions of the State Council drug regulatory department.

The trade name of the drug shall comply with the regulations of the State Council drug regulatory department.

Article 46

Packaging materials and containers that directly contact drugs and are used in the preparation of formulations by medical institutions, as well as the labels and instructions of the formulations, shall comply with Chapter VI of the Drug Administration Law and the relevant provisions of these Regulations, and be approved by the drug regulatory departments of the people's governments of provinces, autonomous regions, and municipalities directly under the Central Government.

Chapter VII: Management of Drug Prices and Advertisements

Article 47

When the government price authority implements drug price monitoring in accordance with Article 28 of the Price Law, in order to grasp and analyze drug price fluctuations and trends, it may designate certain drug manufacturing enterprises, drug business enterprises, and medical institutions as price monitoring designated units; designated units shall cooperate and support the effort and truthfully provide relevant information and materials.

Article 48

To publish drug advertisements, relevant materials must be submitted to the drug regulatory department of the people's government of the province, autonomous region, or municipality directly under the Central Government where the drug manufacturing enterprise is located. The drug regulatory department shall, within 10 working days from the date of receipt of the materials, decide whether to issue the drug advertisement approval number; if the drug advertisement approval number is issued, it shall also be filed with the State Council drug regulatory department. The specific measures shall be formulated by the State Council drug regulatory department.

To publish advertisements for imported drugs, application for the drug advertisement approval number shall be made to the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government where the agency for imported drugs is located, in accordance with the preceding provisions.

To publish drug advertisements outside the province, autonomous region, or municipality directly under the Central Government where the drug manufacturing enterprise or the agency for imported drugs is located, the enterprise publishing the advertisement shall file with the drug regulatory department of the local people's government before publication. If the drug regulatory department receiving the filing discovers that the drug advertisement approval content does not comply with the regulations for drug advertisement management, it shall refer to the original issuing department for handling.

Article 49

If the production, sale, or use of a drug is ordered to be suspended by decision of the drug regulatory authority under the State Council or by the drug regulatory authority of the provincial, autonomous regional, or municipal government directly under the Central Government, no advertisements for that drug may be released during the suspension period; if any such advertisement has already been issued, it must be promptly withdrawn.

Article 50

Drug advertisements that have not been approved by the drug regulatory authorities of the people's governments of provinces, autonomous regions, or municipalities directly under the Central Government; or that utilize forged, misappropriated, or expired drug advertisement approval numbers; or whose approval numbers have been revoked due to other violations of advertising regulations, shall be immediately ceased by the advertising enterprises, advertising operators, and advertisement publishers.

Where drug advertisements are published in violation of the law and the circumstances are deemed serious, the drug regulatory authorities of the people's governments of provinces, autonomous regions, or municipalities directly under the Central Government may issue a public notice thereof.

Chapter VIII: Drug Supervision

Article 51

Drug regulatory departments (including drug regulatory institutions legally established by provincial-level people's governments, hereinafter the same) shall supervise and inspect drug research, production, distribution, and usage in accordance with the law.

Article 52

Drug sampling must be carried out by two or more drug regulatory inspection personnel and conducted in accordance with the provisions of the State Council drug regulatory department. The entity subject to sampling shall provide the sample and shall not refuse.

If the drug sampling unit refuses inspection without legitimate reasons, the State Council drug regulatory department and the drug regulatory department of the people's government of the province, autonomous region, or municipality directly under the Central Government where the unit is located may order the suspension of the listing, sale, and use of the drug in question.

Article 53

For drugs suspected of adulteration or counterfeiting, if the national drug standards do not contain applicable testing methods or items, drug testing institutions may supplement testing methods and items for drug inspection; upon approval by the State Council drug regulatory department, test results obtained through the supplementary testing methods and items may serve as the basis for the drug regulatory department to determine drug quality.

Article 54

The State Council and the drug regulatory departments of the people's governments of provinces, autonomous regions, or municipalities directly under the Central Government shall regularly issue drug quality bulletins based on the results of drug quality sampling inspections. Drug quality bulletins shall include the name of the sampled drug, source of the sample, manufacturer, batch number, drug specifications, testing institution, testing basis, testing results, and non-conforming items. If a drug quality bulletin is found to be improper, the issuing department shall correct it within five days from the date of confirmation, within the original scope of the bulletin.

Where the party has any objection to the results of testing conducted by the drug testing institution and applies for re-testing, it shall submit a written application and the original testing report to the drug testing institution responsible for re-testing. The sample for re-testing shall be taken from the retaining sample kept by the original testing institution.

Article 55

Where there is evidence indicating that a drug may endanger human health, the drug regulatory departments may, in accordance with the law, take administrative enforcement measures such as sealing or seizing the drug and relevant evidence. A decision on whether to initiate a case shall be made within 7 days from the date of taking such enforcement measures. If an inspection is required, the decision shall be made within 15 days from the date the inspection report is issued. If the conditions for filing a case are not met, the enforcement measures shall be lifted. Where it is necessary to suspend the sale and use of the drug, a decision shall be made by the drug regulatory department of the State Council or that of the people's government of the relevant province, autonomous region, or municipality directly under the Central Government.

Article 56

No fees shall be charged for drug sampling and testing.

Where a party has objections to the drug testing results and applies for re-testing, they shall prepay the testing fees to the re-testing institution in accordance with the regulations of the relevant departments under the State Council or the relevant departments of the people's government of the province, autonomous region, or municipality directly under the Central

Government. If the re-test results are inconsistent with the original test results, the original drug testing institution shall bear the re-testing fees.

Article 57

Fees may be charged for the issuance of certificates, drug registration, drug certification, and for drug approval testing and compulsory inspection in accordance with the provisions of the *Drug Administration Law* and this Regulation. The specific charging standards shall be formulated by the financial department and the pricing department under the State Council.

Chapter IX: Legal Liability

Article 58

Where a pharmaceutical manufacturing or trading enterprise commits any of the following acts, the drug regulatory department shall impose penalties in accordance with Article 79 of the *Drug Administration Law*:

1-The establishment of a pharmaceutical manufacturing enterprise, the construction of a new manufacturing workshop, or the addition of new dosage forms without having passed the certification of *Good Manufacturing Practice (GMP)* within the timeframe specified by the drug regulatory department under the State Council, yet continuing production activities;

2-The establishment of a pharmaceutical trading enterprise without having passed the certification of *Good Supply Practice (GSP)* within the timeframe specified by the drug regulatory department under the State Council, yet continuing trading activities.

Article 59

Where drug production is entrusted or accepted without authorization, in violation of Article 13 of the *Drug Administration Law*, both the entrusting and entrusted parties shall be penalized in accordance with Article 74 of the *Drug Administration Law*.

Article 60

Any unauthorized setting up of stalls to sell drugs at rural or urban marketplaces, or the sale of drugs beyond the approved scope of operation in such markets, shall be penalized in accordance with Article 73 of the *Drug Administration Law*.

Article 61

Any unauthorized use by medical institutions of preparations formulated by other medical institutions without approval shall be penalized in accordance with Article 80 of the *Drug Administration Law*.

Article 62

Where outpatient departments or clinics established by individuals provide drugs to patients that exceed the prescribed scope and types, penalties shall be imposed in accordance with Article 73 of the *Drug Administration Law*.

Article 63

Where medical institutions use counterfeit or substandard drugs, penalties shall be imposed in accordance with Articles 74 and 75 of the *Drug Administration Law*.

Article 64

Any unauthorized conduct of clinical trials in violation of Article 29 of the *Drug Administration Law* shall be penalized in accordance with Article 79 of the *Drug Administration Law*, and the penalty shall apply to the institution undertaking the trial.

Article 65

Where a drug applicant submits false information or samples concerning the development method, quality standards, pharmacological or toxicological tests during clinical trial application, the State Council drug regulatory department shall disapprove the clinical trial and issue a warning. If the circumstances are serious, applications for clinical trials of the same variety from the applicant shall not be accepted for 3 years.

Article 66

Where traditional Chinese medicine (TCM) decoction pieces are produced without national drug standards and do not conform to the processing standards formulated by the drug regulatory

department of the province, autonomous region, or municipality directly under the Central Government, or where medical institutions fail to prepare preparations in accordance with the approved standards, penalties shall be imposed in accordance with Article 75 of the *Drug Administration Law*.

Article 67

Where drug regulatory departments or their personnel, in violation of regulations, disclose undisclosed experimental data or other information submitted by manufacturers or sellers in the process of applying for production or marketing of drugs containing new chemical ingredients, and such disclosure causes losses to the applicant, the drug regulatory department shall be held liable for compensation according to law. After providing compensation, the department shall order the staff member responsible due to intent or gross negligence to bear part or all of the compensation and shall impose administrative sanctions on the directly responsible persons.

Article 68

Where the packaging, labels, or instructions of drugs produced or traded by pharmaceutical enterprises or prepared by medical institutions violate the provisions of the *Drug Administration Law* or this Regulation, penalties shall be imposed in accordance with Article 86 of the *Drug Administration Law*.

Article 69

Where a pharmaceutical manufacturing or trading enterprise or medical institution changes matters related to drug production or operation permits without handling the required modification registration, the original issuing department shall issue a warning and order rectification within a time limit. If the modification is not handled within the time limit, their *Drug Manufacturing License*, *Drug Trading License*, and *Medical Institution Preparation License* shall be declared invalid. If they continue production or trading activities, penalties shall be imposed in accordance with Article 73 of the *Drug Administration Law*.

Article 70

Where the content of an approved drug advertisement is altered without authorization, the drug regulatory department shall order the advertiser to immediately stop the publication of the advertisement, and the original approving drug regulatory department shall impose penalties in accordance with Article 92 of the *Drug Administration Law*.

After revoking the drug advertisement approval number, the drug regulatory department shall notify the advertisement regulatory authority within 5 working days from the date of the administrative decision. The advertisement regulatory authority shall, within 15 working days of receiving such notice, make an administrative decision in accordance with the *Advertising Law of the People's Republic of China*.

Article 71

Where a drug advertisement is published outside the province, autonomous region, or municipality directly under the Central Government where the pharmaceutical enterprise or the agent for imported drugs is located and fails to be filed with the local drug regulatory department as required, the drug regulatory authority of the publication location shall order correction within a specified period. If correction is not made within the time limit, publication of advertisements for that drug in the said location shall be suspended.

Article 72

Where a drug advertisement is published without the approval of the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government, the drug regulatory department shall notify the advertisement regulatory authority to investigate and punish the case according to law.

Article 73

Where violations of the *Drug Administration Law* and this Regulation involve any of the following acts, the drug regulatory departments shall impose heavier penalties within the statutory range:

1-Impersonating other drugs with narcotic, psychotropic, toxic, or radioactive drugs, or vice versa;

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

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

4-Causing personal injury through the production, sale, or use of counterfeit or substandard drugs;

5-Recidivism in the production, sale, or use of counterfeit or substandard drugs after having been penalized;

6-Refusing or evading supervision and inspection, forging, destroying, or concealing evidence, or arbitrarily disposing of sealed or seized items.

Article 74

Agencies established by drug regulatory departments are authorized to impose administrative penalties as stipulated in the *Drug Administration Law* and this Regulation, including warnings, fines, and confiscation of illegally produced or sold drugs and illegal income.

Article 75

Where drug trading enterprises or medical institutions do not violate the *Drug Administration Law* or this Regulation and can provide sufficient evidence to prove that they were unaware that the drugs sold or used were counterfeit or substandard, the counterfeit or substandard drugs and the illegal income shall be confiscated, but other administrative penalties may be exempted.

Article 76

Items confiscated in accordance with the provisions of the *Drug Administration Law* and this Regulation shall be disposed of under the supervision of the drug regulatory department in accordance with prescribed procedures.

Chapter X: Supplementary Provisions

Article 77

For the purposes of this Regulation, the following terms shall have the meanings as defined below:

-Drug qualification certificate and other identifiers: This refers to the drug production approval documents, drug testing reports, and the drug's packaging, labels, and instructions.

-New drug: Refers to a drug that has not been marketed or sold within the territory of China.

-Prescription drug: Refers to drugs that may only be purchased, dispensed, and used with a prescription issued by a licensed physician or licensed assistant physician.

-Over-the-counter (OTC) drug: Refers to drugs published by the drug regulatory department under the State Council that may be judged, purchased, and used by consumers without a prescription from a licensed physician or assistant physician.

-Medical institution preparation: Refers to preparations compounded and used exclusively by medical institutions, based on the clinical needs of the institution and with appropriate approvals.

-Drug certification: Refers to the process by which the drug regulatory department inspects, evaluates, and decides whether to issue the corresponding certification to institutions engaged in drug research, production, trading, and use, in accordance with relevant quality management standards.

-Drug trading mode: Refers to wholesale and retail modes of drug distribution.

-Scope of drug operation: Refers to the categories and varieties of drugs approved for business operation by the drug regulatory department.

-Drug wholesale enterprise: Refers to a drug trading enterprise that sells purchased drugs to drug manufacturers, drug trading enterprises, or medical institutions.

-Drug retail enterprise: Refers to a drug trading enterprise that sells purchased drugs directly to consumers.

Article 78

The term “drugs sold for the first time in China” in Article 41 of the *Drug Administration Law* refers to drugs sold in China for the first time by either domestic or foreign drug manufacturing enterprises and includes the same variety of drugs produced by different manufacturers.

Article 79

The phrase “prohibition on drug manufacturers, trading enterprises, or their agents from providing monetary or other benefits under any pretext to persons in charge of medical institutions, pharmaceutical procurement personnel, or physicians involved in the use of their drugs” in Paragraph 2 of Article 59 of the *Drug Administration Law* shall mean: any improper benefit provided by drug manufacturers, trading enterprises, or their agents to the aforementioned persons for the purpose of influencing drug procurement or prescription behaviors.

Article 80

[Omitted]