Measures for the Drug Administration Registration[1]

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Chapter I: General Provisions

Article 1

These Measures are formulated to regulate the conduct of drug registration activities and to ensure the safety, efficacy, and quality control of pharmaceuticals. They are enacted in accordance with the *Drug Administration Law of the People's Republic of China* (hereinafter "Drug Administration Law"), the *Law of the People's Republic of China on Traditional Chinese Medicine*, the *Vaccine Administration Law of the People's Republic of China*, the *Administrative Licensing Law of the People's Republic of China*, the *Regulations for the Implementation of the Medicinal Product Administration Law*, and other relevant statutory and regulatory provisions.

Article 2

These Measures apply to activities related to drug development, registration, supervision, and management conducted within the territory of the People's Republic of China for the purpose of drug marketing authorization.

Article 3

"Drug registration" refers to the procedural activities whereby an applicant formally submits applications and supplementary materials for clinical trials, marketing approval, re-registration, and related approvals in accordance with statutory requirements. The competent medical products regulatory authority evaluates these submissions based on established laws, regulations, and current scientific standards to determine whether to grant approval. Upon issuance of a drug registration certificate, the applicant becomes the official marketing authorization holder (hereinafter "holder").

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

Article 4

Drug registration is subject to classification administration encompassing traditional Chinese medicines, chemical drugs, and biological products. The classification of traditional Chinese medicines includes, but is not limited to, innovative traditional Chinese drugs, modified new traditional Chinese drugs, compound preparations of ancient classic prescriptions, and drugs sharing identical names and prescriptions. Chemical drugs are classified into innovative chemical drugs, modified new chemical drugs, and generics. Biological products are classified into innovative biological drugs, modified new biological drugs, and marketed biological products (including biosimilars). The National Medical Products Administration (hereinafter "NMPA") shall promulgate detailed classification criteria and corresponding application requirements, taking into account product characteristics, innovation levels, and evaluation needs, which shall be publicly announced. Applications for drugs produced abroad shall adhere to the applicable classification and documentation requirements.

Article 5

The NMPA holds national authority over drug registration management, including establishment of regulatory frameworks, standard-setting, evaluation, approval, supervision, and administration of drug registration. The Center for Drug Evaluation under NMPA is tasked with the technical evaluation of applications for clinical trials, marketing authorizations, supplementary applications, and re-registrations of foreign-manufactured drugs. Supporting professional institutions such as the National Institutes for Food and Drug Control (NIFDC), Chinese Pharmacopoeia Commission (CHP), Center for Food and Drug Inspection, Center for Drug Reevaluation, and others execute examination, inspection, monitoring, reevaluation, certification, and information management duties in accordance with legal mandates.

Article 6

The medical products administrative department of a province, autonomous region, or municipality directly under the Central Government shall be responsible for the administration concerning the following drug registration within its respective administrative region:

(1) accepting, reviewing, and approving re-registration applications for domestically produced drugs;

(2) administering records of post-marketing changes and related reports;

(3) supervising institutions engaged in non-clinical drug safety reevaluation and clinical drug trials;

(4) cooperating in inspections and evaluations organized by the NMPA;

(5) handling entrusted matters from the NMPA.

Their designated technical institutions undertake evaluation, inspection, monitoring, and reevaluation to support supervision.

Article 7

Drug registration administration shall be conducted in accordance with principles of openness, fairness, and impartiality, guided by clinical value. It shall promote innovation in drug research and development while encouraging generic drug development. The NMPA is committed to continuous reform of the evaluation and approval system to enhance procedural efficiency and establish an integrated management system incorporating evaluation, inspection, examination, monitoring, and re-evaluation.

Chapter II: Basic System and Requirements

Article 8

Drug development and registration activities must comply with applicable laws, regulations, technical rules, standards, and specifications. When adopting new re-evaluation methodologies or technologies, applicants must demonstrate their scientific validity and applicability. Throughout the process, information must be authentic, accurate, complete, and traceable.

Drugs shall conform to national pharmacopoeial standards and NMPA-approved quality standards, which serve as the benchmarks for registration. These standards shall meet or exceed the general technical requirements of the *Pharmacopoeia of the People's Republic of China*. Should the pharmacopoeia not provide for certain tests or indicators applicable to the drug under registration, sufficient supporting data must be submitted.

The Center for Drug Evaluation and relevant institutions shall develop and publicly announce technical guidance and procedures reflecting scientific progress and regulatory needs.

Article 9

Applicants must be legally constituted enterprises or drug development institutions capable of assuming legal responsibility. Foreign applicants are required to designate a legal entity within China to handle drug registration matters.

Article 10

Before applying for the marketing registration of a drug, the applicant shall complete relevant research work, including pharmaceutical, pharmacological and toxicological studies, and clinical drug trials.

Non-clinical safety evaluation studies of drugs shall be conducted at institutions that have been certified in accordance with the Good Laboratory Practice (GLP) for non-clinical studies and shall comply with the relevant GLP requirements.

Clinical drug trials shall be subject to prior approval, with bioequivalence studies subject to record-filing; such trials shall be conducted at qualified clinical trial institutions in accordance with applicable regulations and shall comply with Good Clinical Practice (GCP) standards.

When applying for drug registration, the applicant shall submit authentic, sufficient, and reliable data, documentation, and samples to demonstrate the safety, efficacy, and quality controllability of the drug. Where overseas research data and materials are used to support drug registration, the origin, research institutions or laboratory conditions, quality system requirements, and other relevant management aspects shall comply with the prevailing principles of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and meet the relevant regulatory requirements of China for drug registration management.

Article 11

Any modification to the parameters or content specified in the original drug registration approval and its annexes requires the applicant to conduct thorough studies and verification. The impact of such changes on safety, efficacy, and quality control must be fully assessed. Appropriate supplementary applications, recordation, or reporting shall be conducted in accordance with technical guidance.

Article 12

Drug registration certificates are valid for a period of five years. Holders must ensure ongoing compliance with safety, efficacy, and quality requirements during the validity term and shall apply for re-registration six months prior to certificate expiration.

Article 13

The NMPA shall implement an accelerated registration system to promote clinically valuable drug innovation. Qualified applications may seek designation as breakthrough therapies, conditional approvals, preferential evaluations, or special approval procedures. During drug development and registration, regulatory authorities shall provide technical guidance, facilitate communication, prioritize resource allocation, shorten evaluation timelines, and extend other policy and technical support.

Article 14

The NMPA shall establish an integrated evaluation and approval system for chemical active pharmaceutical ingredients (APIs), excipients, and packaging materials in direct contact with drugs. Approval of drug preparations shall incorporate joint evaluation of these components. The Center for Drug Evaluation shall maintain a public information platform for registration data concerning APIs, excipients, and packaging materials, enabling informed selection by applicants and holders.

Article 15

Prescription drugs and over the counter (OTC) drugs shall be subject to differentiated registration and conversion management. The Center for Drug Evaluation shall develop and publish technical guidance for OTC drug registration, while the Center for Drug Re-evaluation shall establish criteria for the conversion between prescription and OTC drugs post-marketing.

Article 16

At key stages such as prior to submitting a clinical trial application, during the clinical trial process, and before applying for marketing authorization, applicants may engage in communication and exchange with the Center for Drug Evaluation and other relevant professional technical institutions regarding major issues. During the drug registration process, the Center for Drug Evaluation and other professional technical institutions may also, based on work requirements, organize communication and exchange with applicants.

The procedures, requirements, and timeframes for such communication and exchange shall be separately formulated by the Center for Drug Evaluation and other professional technical institutions in accordance with their respective functions and shall be made publicly available.

Article 17

The Center for Drug Evaluation and associated technical institutions shall maintain expert consultation mechanisms, including the formation of expert committees. Expert opinions shall be solicited on critical evaluation, inspection, examination, and naming issues to enhance technical support.

Article 18

The NMPA shall compile and maintain catalogs of newly approved chemical drugs and those passing quality and efficacy consistency re-evaluation. These catalogs shall include drug name, active ingredients, dosage form, specifications, reference status, holder, and other pertinent information, and shall be updated and publicly disseminated. Cataloging procedures shall be developed by the Center for Drug Evaluation.

Article 19

The NMPA shall support the preservation and innovation of traditional Chinese medicine by establishing a registration management and technical reevaluation system tailored to its characteristics. The administration shall encourage integration of modern scientific

methodologies with traditional practices, strengthen quality control, and enhance clinical trial standards. Applicants for traditional Chinese medicine registration must emphasize clinical value and resource sustainability.

Chapter III: Marketing Registration of Drugs

Section 1: Clinical Drug Trials

Article 20

Clinical drug trials, as defined herein, are human research studies undertaken to evaluate the safety and efficacy of drugs in support of marketing registration.

Article 21

Clinical trials shall be categorized as Phase I, II, III, IV, and bioequivalence studies. According to the characteristics of a drug and the research purpose, the research contents shall include clinical pharmacological research, exploratory clinical trial, confirmatory clinical trial and post-marketing research.

Article 22

Clinical trials must be conducted at institutions possessing requisite qualifications and recordation. Vaccine clinical trials are restricted to Grade 3 medical institutions or provincial-level disease prevention and control centers that meet NMPA and National Health Commission requirements.

Article 23

After completing the pharmaceutical, pharmacological, toxicological, and other relevant studies supporting the clinical trial of a drug, the applicant shall submit an application for a clinical trial in accordance with the requirements for the application materials, and provide the relevant research data. Upon formal examination, applications with materials that meet the requirements shall be accepted.

The Center for Drug Evaluation shall organize pharmaceutical, medical, and other technical experts to review the accepted clinical trial applications. A decision on whether to approve the clinical trial shall be made within 60 days from the date of acceptance, and the applicant shall be notified of the outcome via the website of the Center for Drug Evaluation. If no notification is given within the prescribed time limit, the application shall be deemed approved, and the applicant may carry out the clinical trial according to the submitted protocol.

An applicant approved to conduct a clinical trial shall be designated as the clinical trial sponsor (hereinafter referred to as the “sponsor”).

Article 24

Applicants undertaking bioequivalence tests must complete recordation procedures with the Center for Drug Evaluation and conduct tests in accordance with the approved protocol.

Article 25

Clinical trials require approval by an ethics committee. Management of investigational drugs shall comply with Good Clinical Practice requirements.

Article 26

An approved sponsor intending to conduct a subsequent phase of a clinical drug trial shall formulate an appropriate clinical trial protocol. The trial may proceed only upon review and approval by the ethics committee and shall be submitted—together with supporting documentation—via the designated platform of the Center for Drug Evaluation (CDE).

Article 27

Where a sponsor seeks to add indications (or therapeutic functions) to an already approved investigational drug or intends to include a combination therapy with other pharmaceutical products, a new application for clinical drug trial must be submitted and shall be subject to approval prior to initiation.

Likewise, when clinical trials are required for additional indications (or functions) of a drug that has already been approved for marketing, a separate clinical trial application must be submitted in accordance with applicable requirements.

Article 28

The sponsor shall regularly submit Development Safety Update Reports (DSURs) to the Center for Drug Evaluation (CDE) via its website. The DSUR shall be submitted once a year, within two months after each anniversary of the drug clinical trial approval date. The CDE may require the sponsor to adjust the reporting frequency based on the review situation.

For any suspected and unexpected serious adverse reactions, as well as other potential serious safety risk information arising during the clinical trial, the sponsor shall report to the CDE in a timely manner in accordance with relevant requirements. Depending on the severity of the safety risk, the sponsor may be required to take measures to strengthen risk control, such as revising the clinical trial protocol, informed consent form, or investigator's brochure. If necessary, the sponsor may be required to suspend or terminate the clinical trial.

The specific requirements for the DSUR shall be formulated and published by the CDE.

Article 29

During the course of a clinical drug trial, if there are any changes to the clinical trial protocol, non-clinical or pharmaceutical data, or any new findings, the sponsor shall, in accordance with relevant regulations and with applicable technical guidelines, conduct a comprehensive assessment of the impact on subject safety.

If the sponsor concludes that the changes do not affect subject safety, such changes may be implemented directly and reported in the Development Safety Update Report (DSUR). However, if the changes may increase the risk to subject safety, a supplemental application must be submitted. A decision on the supplemental application shall be made within 60 days from the date of acceptance, and the result shall be published on the website of the Center for Drug Evaluation. If no notice is given within the prescribed period, the application shall be deemed approved.

In the event of a change in the sponsor, the new sponsor shall assume all related responsibilities and obligations for the clinical drug trial.

Article 30

If safety concerns or other risks are identified during a clinical drug trial, the sponsor shall promptly revise the clinical trial protocol, suspend, or terminate the clinical trial, and report the situation to the Center for Drug Evaluation.

Under any of the following circumstances, the sponsor may be required to revise the clinical trial protocol, suspend, or terminate the clinical drug trial:

1-The ethics committee fails to fulfill its duties;

2-Subject safety cannot be effectively ensured;

3- The sponsor fails to submit the Development Safety Update Report as required;

4-The sponsor fails to timely handle and report suspected unexpected serious adverse reactions;

5-There is evidence proving that the investigational drug is ineffective;

6-There are quality issues with the clinical trial drug;

7-Falsification occurs during the clinical trial process;

8-Other violations of Good Clinical Practice (GCP).

In the event of widespread and unexpected serious adverse reactions, or where there is evidence indicating serious quality issues with the investigational drug, the sponsor and the clinical trial institution shall immediately discontinue the clinical drug trial. The drug regulatory

authority may, in accordance with its responsibilities, order adjustments to the clinical trial protocol, or suspend or terminate the clinical trial.

Article 31

If a clinical drug trial is ordered to be suspended, the sponsor must submit a supplemental application for resumption after completing the necessary rectification. The clinical trial may only resume upon approval of the application. If the trial remains suspended for 3 years without an approved application for resumption, the clinical trial authorization shall automatically become invalid. If a clinical drug trial has been terminated and the sponsor intends to resume it, a new clinical trial application must be submitted.

Article 32

A clinical drug trial shall be initiated within 3 years after approval. If no subject has signed an informed consent form within 3 from the date of trial approval, the clinical trial authorization shall automatically become invalid. If the sponsor still intends to conduct the clinical trial, a new application must be submitted.

Article 33

Prior to initiating a clinical drug trial, the sponsor shall register the clinical trial protocol and other relevant information on the Clinical Trial Registration and Information Disclosure Platform.

During the clinical trial, the sponsor shall continuously update the registration information and register the results of the clinical trial upon its completion. The registered information shall be disclosed on the platform, and the sponsor shall be responsible for the authenticity of the clinical trial registration information. The specific requirements for registration and information disclosure of clinical trials shall be formulated and published by the Center for Drug Evaluation.

Section 2: Drug Marketing Authorization

Article 34

After completing the pharmaceutical, pharmacological and toxicological, and clinical studies supporting drug marketing registration, establishing quality standards, completing validation of commercial-scale manufacturing processes, and preparing for regulatory inspection and testing for drug registration, the applicant shall submit a drug marketing authorization application and provide relevant research materials in accordance with the requirements for application dossiers. Upon formal review of the submitted materials, if they meet the requirements, the application shall be accepted.

Article 35

For generic drugs, in vitro diagnostic reagents regulated as drugs, and other applicable circumstances, where the applicant has assessed that it is unnecessary or infeasible to conduct clinical trials and the conditions for exemption from clinical trials are met, the applicant may directly submit a drug marketing authorization application. The technical guidelines and specific requirements for exemption from clinical trials shall be formulated and published by the Center for Drug Evaluation. Generic drugs shall be consistent with the reference preparation in terms of quality and efficacy. Applicants shall select appropriate reference preparations in accordance with relevant technical guidelines.

Article 36

The following categories of drugs may directly apply for over-the-counter (OTC) drug marketing authorization:

1-Drugs already marketed domestically as OTC with the same active ingredients, indications (or functions and purposes), dosage forms, and specifications;

2-OTC drugs identified by the National Medical Products Administration (NMPA) that have undergone changes in dosage form or specifications, provided that the indications (or functions and purposes), dosage, and route of administration remain unchanged;

3-New compound preparations composed of active ingredients included in OTC drugs designated by the NMPA;

4-Other circumstances qualifying for direct OTC drug marketing authorization application.

Article 37

If the generic name of the drug proposed in the application is not included in the national drug standards or drug registration standards, the applicant shall simultaneously submit an application for the approval of the generic name when submitting the marketing authorization application.

Once the marketing authorization application is accepted, the supporting materials for generic name approval shall be transferred to the Pharmacopoeia Commission, which will approve the name and provide feedback to the Center for Drug Evaluation. If the generic name proposed is already included in the national drug standards or registration standards, and the Center for Drug Evaluation determines during the review process that approval of the generic name is still necessary, it shall notify the Pharmacopoeia Commission to approve the generic name and provide the relevant materials. The Pharmacopoeia Commission shall provide the approval result to the Center for Drug Evaluation.

The Pharmacopoeia Commission shall communicate with the applicant during the approval process and inform the applicant of the outcome.

Article 38

The Center for Drug Evaluation shall organize pharmaceutical, medical, and other technical personnel to review accepted drug marketing authorization applications as required.

Based on a risk-based approach, regulatory inspections and testing for drug registration may be initiated during the review process. Relevant technical institutions shall complete such inspections and testing within the prescribed time limits.

The Center for Drug Evaluation shall conduct a comprehensive review of the drug's safety, efficacy, and quality controllability based on the application materials, inspection results, and test results. For OTC drugs, a suitability assessment shall also be conducted by the Drug Evaluation Center.

Article 39

Where the comprehensive evaluation conclusion is approved, the drug shall be authorized for marketing, and a drug registration certificate shall be issued. Where the comprehensive evaluation conclusion is not approved, a decision of disapproval shall be made. The drug registration certificate shall indicate information such as the drug approval number, the holder, and the manufacturing enterprise. For over-the-counter (OTC) drugs, the drug registration certificate shall also specify the OTC category.

The approved drug manufacturing process, quality standards, instructions, and labeling shall be issued as attachments to the drug registration certificate to the applicant. When necessary, post-marketing research requirements shall also be attached. The above information shall be incorporated into the drug variety file and updated promptly according to any post-marketing changes.

After the drug is approved for marketing, the holder shall produce the drug in accordance with the manufacturing process and quality standards approved by the National Medical Products Administration (NMPA) and shall refine and implement production according to Good Manufacturing Practice (GMP) requirements.

Article 40

During the review period of a drug marketing authorization application, if there occur significant changes that may affect the drug's safety, efficacy, or quality controllability, the applicant shall withdraw the original registration application and resubmit it after supplemental research.

Changes such as the applicant's name or registered address that do not involve technical review content shall be promptly notified in writing to the Drug Evaluation Center, along with the relevant supporting documents.

Section 3: Related Review and Approval

Article 41

When reviewing drug formulation registration applications, the Drug Evaluation Center shall conduct related reviews on the chemical active pharmaceutical ingredients (APIs), excipients, and packaging materials and containers that directly contact the drug formulation.

Manufacturers of chemical APIs, excipients, and packaging materials and containers that directly contact drugs shall register their product information and research data on the platform designated for related review and approval in accordance with the related review and approval system. The Drug Evaluation Center shall publicly disclose basic information such as registration number, product name, enterprise name, and production address to facilitate selection by drug formulation applicants.

Article 42

Applicants for drug formulations may directly select registered chemical APIs, excipients, and packaging materials and containers when submitting registration applications. If unregistered chemical APIs, excipients, or packaging materials and containers are selected, the relevant research data shall be submitted together with the drug formulation registration application.

Article 43

During the review of drug formulation registration applications, the Drug Evaluation Center shall conduct related reviews on the selected chemical APIs, excipients, and packaging materials and containers. If supplementary data are required, the drug formulation applicant or the enterprise registering the chemical API, excipient, or packaging material and container shall provide the supplementary data according to the prescribed procedures. Based on risk, an extended inspection of the enterprises producing chemical APIs, excipients, or packaging materials and containers may be requested.

For chemical APIs used in generic drugs that are already marketed domestically, a separate review and approval may be applied for.

Article 44

For chemical active pharmaceutical ingredients (APIs), excipients, and packaging materials and containers that directly contact drugs, upon passing the related review and approval or passing separate review and approval, the Drug Evaluation Center shall update the registration status indicators on the registration platform for chemical APIs, excipients, and packaging materials and containers, and publicly disclose relevant information to society. For chemical APIs, an approval notice as well as the approved manufacturing process, quality standards, and labeling shall be issued. The approval notice for the chemical API shall include the registration number.

If approval is denied, a notice of disapproval shall be issued for the chemical API. If the related review and approval is not passed, the registration status of the chemical APIs, excipients, and

packaging materials and containers shall remain unchanged, and related drug formulation applications shall not be approved.

Section 4: Drug Registration Inspection

Article 45

Drug registration inspection refers to the activities conducted to verify the authenticity and consistency of submitted application materials, as well as to check the compliance of drug development and the reliability of data, and to confirm the conditions for commercial-scale drug production. These activities include inspections of drug development sites and production sites, and, when necessary, extended inspections of manufacturers, suppliers, or other entrusted institutions involved with the chemical APIs, excipients, and packaging materials and containers related to the drug registration application. The principles, procedures, time limits, and requirements for initiating drug registration inspections shall be formulated and published by the Drug Evaluation Center. The principles, procedures, time limits, and requirements for implementing drug registration inspections shall be formulated and published by the Drug Inspection Center.

Article 46

Based on factors such as the degree of drug innovation and the prior inspection history of the drug research institution, the Drug Evaluation Center shall decide whether to conduct on-site inspection of the drug development site based on risk assessment. If the Drug Evaluation Center decides to initiate on-site inspection of the drug development site, it shall notify the Drug Inspection Center to organize the inspection during the review period and inform the applicant. The Drug Inspection Center shall complete the on-site inspection within the prescribed time limit and submit inspection findings and conclusions to the Drug Evaluation Center for comprehensive evaluation.

Article 47

Based on the registered drug variety, manufacturing process, facilities, prior inspection history, and other factors, the Drug Evaluation Center shall decide whether to initiate on-site inspection of the drug production site based on risk assessment. Innovative drugs, improved new drugs, and biological products shall undergo drug production site inspection and Good Manufacturing Practice (GMP) inspection before marketing. For generic drugs, the decision to conduct drug production site inspection and pre-marketing GMP inspection shall be risk-based, considering whether the applicant has obtained the corresponding drug production license for the scope of production and whether the same dosage forms have been marketed.

Article 48

After acceptance of the drug registration application, the Drug Evaluation Center shall conduct a preliminary review within 40 days. If a drug production site inspection is required, the Drug Evaluation Center shall notify the Drug Inspection Center to organize the inspection, provide the necessary materials, and inform the applicant and the drug regulatory authorities of the applicant's or manufacturer's province, autonomous region, or municipality.

The Drug Inspection Center shall, in principle, complete the inspection within 40 days before the review deadline and submit inspection reports and results to the Drug Evaluation Center.

If a pre-marketing GMP inspection is required, the Drug Inspection Center shall coordinate relevant provincial, autonomous region, or municipal drug regulatory authorities to conduct the inspection simultaneously with the drug production site inspection. The management requirements for pre-marketing GMP inspections shall comply with relevant provisions of the Drug Production Supervision and Administration Measures. Applicants shall accept inspections within the prescribed time limit.

Article 49

If, during the review process, the Drug Evaluation Center finds doubts about the authenticity of the submitted materials or receives clear whistleblower reports or other leads, it shall initiate cause-based inspections and, if necessary, conduct sampling tests.

Article 50

When applying for drug marketing authorization, the applicant and manufacturer shall have obtained the corresponding drug production license.

Section 5: Drug Registration Examination

Article 51

Drug registration examination includes standard verification and sample testing. Standard verification refers to the laboratory evaluation of the scientific validity of the drug standards declared by the applicant, the feasibility of the testing methods, and the rationality of quality control indicators.

Sample testing refers to laboratory testing of samples according to the drug quality standards declared by the applicant or determined by the Drug Evaluation Center. The principles, procedures, time limits, and requirements for initiating drug registration examination are formulated and published by the Drug Evaluation Center. The specific working procedures and technical requirements for drug registration examination, when requested before acceptance of the registration application, are formulated and published by the National Institute for Food and Drug Control (NIFDC).

Article 52

If the testing items and methods used for drugs of the same variety recorded in the national drug standards are consistent, only sample testing is required, and standard verification may be exempted. In other cases, both standard verification and sample testing shall be conducted.

Article 53

Drug registration examination shall be undertaken by the NIFDC or drug testing institutions designated by the National Medical Products Administration (NMPA) for the following drugs:

(1) innovative drugs;

(2) improved new drugs (excluding traditional Chinese medicines);

(3) biological products, radioactive drugs, and in vitro diagnostic reagents regulated as drugs;

(4) other drugs stipulated by the NMPA.

Drug registration examination for drugs produced abroad shall be conducted by the NIFDC through port drug inspection agencies. Registration examination for other drugs shall be undertaken by the provincial-level drug testing institutions in the applicant's or manufacturer's location.

Article 54

After completing the pharmaceutical research supporting drug marketing, determining quality standards, and completing commercial scale production process validation, the applicant may apply for drug registration examination at the NIFDC or provincial/municipal drug regulatory authorities before acceptance of the drug registration application. If the applicant does not apply for registration examination before acceptance of the application, the Drug Evaluation Center shall initiate drug registration examination within 40 days after acceptance. In principle, the applicant may only apply once for drug registration examination before acceptance and shall not submit applications simultaneously to multiple testing institutions.

The submitted inspection materials must be consistent with the corresponding contents of the drug registration application materials, and no changes to the inspection institution, samples, or materials are allowed during the examination process.

Article 55

For registration applications of domestically produced drugs, if the applicant requests drug registration examination prior to acceptance of the registration application, the applicant shall apply to the drug regulatory authorities of the relevant province, autonomous region, or

municipality directly under the central government for sample collection. The provincial, autonomous region, or municipal drug regulatory authorities shall organize the sampling and sealing, and the applicant shall submit the sampling form, samples, required testing materials, and reference standards to the corresponding drug examination institution.

For registration applications of drugs produced overseas, if the applicant requests drug registration examination prior to acceptance of the registration application, the applicant shall extract samples in accordance with the prescribed requirements and submit the samples, required testing materials, and reference standards to the National Institute for Food and Drug Control (NIFDC).

Article 56

For registration applications of domestically produced drugs, if drug registration examination is required after acceptance of the registration application, the Drug Evaluation Center shall issue a drug registration examination notice to the drug inspection institution and the applicant within 40 days after acceptance. The applicant shall apply to the relevant provincial, autonomous region, or municipal drug regulatory authorities for sample collection, which shall organize the sampling and sealing. The applicant shall submit the sampling form, samples, required testing materials, and reference standards to the corresponding drug examination institution within the prescribed time limit.

For registration applications of drugs produced overseas, if drug registration examination is required after acceptance of the registration application, the applicant shall extract samples in accordance with prescribed requirements and submit the samples, required testing materials, and reference standards to the NIFDC.

Article 57

The drug examination institution shall review the submitted samples and materials within five days and decide whether to accept them and notify the Drug Evaluation Center accordingly. If corrections are needed, the applicant shall be informed once in full. In principle, the drug examination institution shall provide the standard verification opinions and inspection reports to the Drug Evaluation Center before the expiry of the review period.

Article 58

During the drug evaluation and examination process, if there are doubts regarding the authenticity of the submitted materials, clear whistleblower reports, or if deemed necessary to conduct sample testing, samples may be taken for examination. During the evaluation process, the Drug Evaluation Center may request targeted re-verification of specific quality standard items based on risk assessment.

Chapter IV: Accelerated Drug Marketing Authorization Procedures

Section 1: Breakthrough Therapy Drug Procedure

Article 59

During the course of clinical trials, for innovative drugs or improved new drugs intended to prevent or treat diseases that are life-threatening or seriously impair quality of life, and for which no effective treatment currently exists or there is sufficient evidence showing a significant clinical advantage compared to existing treatments, the applicant may apply for the breakthrough therapy drug procedure.

Article 60

Applicants seeking to apply for the breakthrough therapy drug procedure shall apply to the Drug Evaluation Center. If the conditions are met, the Drug Evaluation Center will publicly announce the inclusion of the drug in the breakthrough therapy drug procedure according to the prescribed process.

Article 61

For clinical trials of drugs included in the breakthrough therapy drug procedure, the following policy supports shall be provided:

1-The applicant may request communication with the Drug Evaluation Center at key stages of the clinical trials. The Drug Evaluation Center will arrange for reviewers to engage in communication and exchange.

2-The applicant may submit interim research data to the Drug Evaluation Center. Based on the existing research data, the Center will provide opinions or suggestions on the next research plan and feedback to the applicant.

Article 62

If the applicant discovers that the drug no longer meets the inclusion criteria for the breakthrough drug therapy procedure, the applicant shall promptly apply to the Drug Evaluation Center to terminate the procedure. If the Drug Evaluation Center finds that the drug no longer meets the inclusion criteria, it shall promptly terminate the breakthrough therapy drug procedure for that drug and notify the applicant.

Section 2: Conditional Approval Procedure

Article 63

During the period of drug clinical trials, drugs meeting any of the following conditions may apply for conditional approval:

1-Drugs intended for the treatment of serious, life-threatening diseases for which there is no effective treatment available, and for which clinical trial data have confirmed efficacy and can predict clinical value;

2-Drugs urgently needed for public health purposes, for which clinical trial data have demonstrated efficacy and can predict clinical value;

3-Vaccines urgently needed to respond to major public health emergencies or other vaccines deemed urgently needed by the National Health Commission, for which a benefit-risk assessment concludes that benefits outweigh risks.

Article 64

Applicants seeking conditional approval shall communicate with the Drug Evaluation Center regarding the conditions for conditional marketing approval and the post-marketing research obligations. Upon confirmation of these communications, the applicant may submit a marketing authorization application.

Upon review, if the application meets the requirements for conditional approval, the drug registration certificate shall specify the validity period of the conditional approval, the post-marketing research to be completed, deadlines for completion, and other relevant matters.

Article 65

If during the review process it is found that the drug registration application under the conditional approval procedure no longer satisfies the conditions for conditional approval, the Drug Evaluation Center shall terminate the conditional approval process for the drug and notify the applicant to proceed with research and application according to the standard procedures.

Article 66

For drugs granted conditional approval, the marketing authorization holder shall implement corresponding risk management measures after marketing and complete the required clinical

trials and other related studies within the prescribed timeframe, submitting supplementary applications as required.

For vaccines approved with further research requirements, the vaccine holder shall complete such studies within the stipulated deadlines.

Article 67

If the marketing authorization holder of a conditionally approved drug fails to complete the required studies within the specified timeframe or cannot demonstrate that the benefits outweigh the risks, the National Medical Products Administration shall take legal measures, including the cancellation of the drug registration certificate.

Section 3: Priority Review and Approval Procedure

Article 68

When applying for drug marketing authorization, drugs with the following significant clinical value may apply for priority review and approval:

1-Shortage drugs urgently needed clinically, innovative drugs and improved new drugs for the prevention and treatment of major infectious diseases and rare diseases;

2-New varieties, dosage forms, and specifications of pediatric drugs that meet the physiological characteristics of children;

3-Vaccines and innovative vaccines urgently needed for disease prevention and control;

4-Drugs included in the breakthrough therapy designation program;

5-Drugs eligible for conditional approval;

6-Other circumstances prescribed by the National Medical Products Administration (NMPA) for priority review and approval.

Article 69

Before submitting a drug marketing authorization application, the applicant shall communicate with the Drug Evaluation Center. Upon confirmation of such communication, the applicant may submit the priority review and approval request simultaneously with the marketing authorization application. Drugs meeting the conditions will be publicly announced in accordance with procedures and included in the priority review and approval process.

Article 70

For drug marketing authorization applications included in the priority review and approval process, the following policy supports shall be provided:

1-The review period for drug marketing authorization applications shall be 130 days;

2-For clinically urgent, rare disease drugs already marketed abroad but not yet marketed domestically, the review period shall be 70 days;

3-Priority shall be given to the verification, inspection, and approval of drug generic names as required;

4-Additional technical materials may be submitted upon confirmation through communication.

Article 71

If during the review process it is found that the drug registration application included in the priority review and approval process no longer meets the conditions for priority review, the Drug Evaluation Center shall terminate the priority review procedure and review the application according to the standard procedure, notifying the applicant accordingly.

Section 4: Special Approval Procedure

Article 72

When threatened by or after the occurrence of a public health emergency, the National Medical Products Administration may decide to implement special approval for drugs needed urgently to prevent and treat the emergency.

Article 73

For drug registration applications under special approval, the National Medical Products Administration shall organize accelerated and simultaneous drug registration acceptance, review, verification, and inspection, adhering to principles of unified command, early intervention, rapid and efficient processing, and scientific evaluation. The circumstances, procedures, time limits, and requirements for special approval shall be implemented in accordance with regulations on special approval procedures for drugs.

Article 74

For drugs included in the special approval procedure, their use may be restricted to certain periods and scopes based on specific needs for disease prevention and control.

Article 75

If drugs included in the special approval procedure are found no longer to meet the inclusion criteria, the special approval procedure for such drugs shall be terminated, and the applicant shall be notified.

Chapter V: Post-Marketing Changes and Re-registration of Drugs

Section 1: Post-Marketing Studies and Changes

Article 76

The marketing authorization holder shall proactively conduct post-marketing studies to further confirm the safety, efficacy, and quality controllability of the drug, and strengthen the continuous management of marketed drugs.

If the drug registration certificate or its attachments require the holder to conduct related post-marketing studies, the holder shall complete them within the prescribed timeframe and submit supplementary applications, filings, or reports as required.

After drug approval for marketing, the holder shall continue safety and efficacy studies and, based on relevant data, timely file reports or submit supplementary applications to revise the drug label, continuously updating and improving the instructions and packaging. The drug regulatory authorities, in accordance with their duties, may require holders to revise the instructions and labeling based on adverse drug reaction monitoring and post-marketing evaluation results.

Article 77

Post-marketing changes to drugs shall be classified according to their potential risk and impact on drug safety, efficacy, and quality controllability, into approval-required changes, filing-required changes, and report-required changes.

The holder shall comprehensively assess and verify the impact of the proposed changes on drug safety, efficacy, and quality controllability following relevant regulations and technical guidelines, and conduct corresponding research work.

Technical guidelines for post-marketing change studies shall be formulated by the Drug Evaluation Center and made publicly available.

Article 78

The following changes shall be submitted as supplementary applications and may only be implemented after approval:

1-Major changes in the drug production process;

2-Changes to the drug label involving efficacy or other content that increases safety risks;

3-Transfer of the drug marketing authorization holder;

4-Other changes requiring approval as prescribed by the National Medical Products Administration (NMPA).

Article 79

The following changes shall be filed with the provincial, autonomous region, or municipality drug regulatory authority before implementation:

1-Moderate changes in the drug production process;

2-Changes to drug packaging and labeling content;

3-Drug repackaging;

4-Other changes requiring filing as prescribed by the NMPA.

For changes occurring in drugs manufactured abroad, the holder shall file with the Drug Evaluation Center before implementing the change. The procedures and requirements for drug repackaging filing shall be formulated and published by the Drug Evaluation Center.

Article 80

The following changes shall be reported in the annual report:

1-Minor changes in the drug production process;

2-Other changes requiring reporting as prescribed by the NMPA.

Article 81

For supplementary applications submitted post-marketing that require verification and inspection, the procedures for drug registration verification and inspection as provided in these Measures shall apply.

Section 2: Drug Re-registration

Article 82

The marketing authorization holder shall apply for re-registration six months prior to the expiration of the drug registration certificate. Applications for domestically produced drugs shall be submitted to the provincial, autonomous region, or municipality drug regulatory authority where the holder is located. Applications for drugs produced abroad shall be submitted to the Drug Evaluation Center.

Article 83

Upon acceptance of the re-registration application, the provincial, autonomous region, municipality drug regulatory authority or Drug Evaluation Center shall review the holder's post-marketing evaluation and adverse reaction monitoring, compliance with drug approval documents and regulatory requirements, and any changes in information specified in the approval documents. If the application meets requirements, re-registration shall be granted and a re-registration approval notice issued. If not, re-registration shall be denied and the case reported to the NMPA for cancellation of the drug registration certificate.

Article 84

Re-registration shall be denied under any of the following circumstances:

1-Failure to submit a re-registration application before the expiration of the validity period;

2-The holder fails to fulfill responsibilities for continuous monitoring of drug quality, efficacy, and adverse reactions during the validity period;

3-Failure to complete required studies as per the approval documents and regulatory requirements within the prescribed timeframe without reasonable cause;

4-Post-marketing evaluation indicates uncertain efficacy, significant adverse reactions, or other reasons that threaten human health;

5-Other circumstances prescribed by laws and administrative regulations for denial of re-registration.

Drugs not granted re-registration shall have their registration certificates cancelled upon expiration.

Chapter VI: Acceptance, Withdrawal of Applications, Approval Decisions, and Dispute Resolution

Article 85

Upon receipt of a drug registration application, the drug regulatory authority shall conduct a formal review and make an immediate decision regarding acceptance based on the following:

1-If the subject matter does not require administrative licensing under law, the authority shall promptly issue a decision of non-acceptance with reasons.

2-If the matter is outside the authority's jurisdiction, the authority shall promptly issue a non-acceptance decision and advise the applicant to apply to the relevant administrative agency.

3-If the submitted documentation contains correctable errors, the authority shall allow immediate correction; if after corrections the materials are complete and in legally required form, the application shall be accepted.

4-If the documentation is incomplete or fails to meet formal requirements, the authority shall notify the applicant of all deficiencies either on the spot or within five days. If statutes require it, materials should be returned with the notice. The applicant must complete corrections within 30 days. Failure to correct without justified reason shall be deemed withdrawal of the application, and no formal non-acceptance decision is required. If no correction request is issued within the timeframe, the application shall be deemed accepted from the date of receipt.

5-If the matter falls within the authority's jurisdiction and the documentation is complete or corrected as required, the drug registration application shall be accepted. After acceptance, if fees are required, the applicant must pay by the prescribed deadline. Failure to pay shall result in termination of the review and approval process.

Article 86

Once accepted, the applicant must promptly report any newly identified safety concerns and submit supplementary information.

Article 87

Following the acceptance of a drug registration application, if additional technical data are required based on the originally submitted materials, the Center for Drug Evaluation (CDE) shall, in principle, issue a single request for supplementary materials. The request shall clearly list all issues and notify the applicant in writing to submit the supplementary documents within 80 days. The applicant must submit all requested materials in one complete package. The time spent preparing and submitting these supplementary materials shall not be counted within the statutory review period. Upon receipt of the full set of supplementary materials, the CDE shall restart the review, and the original review period shall be extended by one-third. If the application is subject to the priority review and approval process, the review period shall be extended by one-fourth.

If only clarifications or explanations of the originally submitted materials are needed and no new technical data are required, the CDE shall notify the applicant to submit the requested clarifications within 5 days.

If the CDE determines that the application contains material deficiencies that cannot be remedied, it shall not request supplementary materials and shall instead make a decision of non-approval based on the existing application dossier.

Article 88

During the review of an application for drug clinical trials or for a supplementary application during ongoing clinical trials, the applicant shall not submit any new technical materials. If further research is required, the applicant may withdraw the current application and resubmit it following completion of the additional research.

Article 89

After a drug registration application has been accepted, the applicant may submit a request for withdrawal. If the withdrawal request is approved, the CDE or the relevant provincial-level drug regulatory authority shall terminate the registration process and notify all technical institutions involved in inspection, verification, or testing. However, if any suspected intentional concealment of facts or submission of false information is discovered during the review, inspection, or testing process, the matter shall be handled according to law, and the applicant shall not be permitted to withdraw the application.

Article 90

During the drug registration process, if the review concludes with a decision of non-approval, the CDE shall notify the applicant of the reasons for the decision. The applicant may, within 15 days, submit an objection to the CDE. The CDE shall then conduct a comprehensive reassessment in light of the applicant's objections and provide feedback.

If the applicant still disagrees with the reassessment outcome, the CDE shall, in accordance with relevant regulations, convene with an expert advisory committee within 50 days to conduct a technical review. The CDE shall make a final review conclusion based on the results of the expert consultation.

The time consumed for the objection process and expert consultation shall not be counted toward the statutory review period.

Article 91

During the registration process, if an applicant believes that staff involved in acceptance, review, inspection, testing, or approval have acted in violation of regulations or engaged in irregular conduct, they may file a complaint with the relevant authority or its superior administrative body.

Article 92

If a drug registration application meets statutory requirements, it shall be approved. However, approval shall be denied under any of the following circumstances:

1-The submitted data for a clinical trial application are insufficient to support the trial or fail to ensure subject safety;

2-The application materials reveal major deficiencies in drug safety, efficacy, or quality control;

3-The submitted data fail to demonstrate safety, efficacy, or quality control, or an assessment concludes that risks outweigh benefits;

4-The applicant fails to submit supplementary materials within the prescribed time limit;

5-The applicant refuses or, without justified reason, fails to undergo the required inspection or testing within the stipulated timeframe;

6-There is evidence that the application materials are not authentic, and the applicant cannot provide proof of authenticity;

7-On-site inspections or sample testing results do not meet regulatory standards;

8-Other circumstances as provided by laws and regulations under which approval shall not be granted.

If a registration certificate reaches its expiration without approval, it shall be revoked.

Article 93

After the conclusion of the registration review, if the applicant disagrees with the administrative licensing decision, they may seek administrative reconsideration or initiate administrative litigation in accordance with the law.

Chapter VII: Time Limits for Work Procedures

Article 94

The time limits prescribed in this regulation represent the maximum durations for the acceptance, review, inspection, testing, and approval processes of drug registration. Time limits related to the priority review and approval procedures shall be implemented in accordance with relevant priority review regulations.

The Drug Evaluation Center and other professional technical institutions shall establish clear internal work procedures and timelines and disclose these publicly.

Article 95

After receiving a drug registration application, the drug regulatory authority shall conduct a formal examination and make a decision on acceptance, correction, or non-acceptance within five days.

Article 96

The time limits for drug registration review are as follows:

1-The review and approval period for drug clinical trial applications and supplementary applications during clinical trials is 60 days;

2-The review period for drug marketing authorization applications is 200 days, with 130 days for priority review and approval procedures, and 70 days for priority review and approval of clinically urgent rare disease drugs already marketed abroad;

3-The review period for independent applications for generic domestic chemically synthesized active pharmaceutical ingredients is 200 days;

4-The review period for supplementary applications involving approval-type changes is 60 days; for supplementary applications combined with other matters, it is 80 days; if clinical trial data review or drug registration inspection and testing are involved, the review period is 200 days;

5-The approval time for drug generic names is 30 days;

6-The suitability review period for over-the-counter (OTC) drugs is 30 days.

The review time for related evaluations shall be consistent with that of the related drug formulation.

Article 97

The time limits for drug registration inspection are as follows:

1-The Drug Evaluation Center shall notify the Drug Inspection Center to initiate inspection within 40 days after the acceptance of the drug registration application, and simultaneously notify the applicant;

2-The Drug Inspection Center shall, in principle, complete the on-site production inspection 40 days before the review deadline and submit relevant materials including inspection situation and results to the Drug Evaluation Center.

Article 98

The time limits for drug registration testing are as follows:

1-Sample testing shall be completed within 60 days; if testing and standard re-verification are conducted simultaneously, the period is 90 days;

2-The time limit for submitting supplementary data during drug registration testing is 30 days;

3-The drug testing institution shall, in principle, complete testing work 40 days before the review deadline, and provide the standard re-verification opinions and test reports to the Drug Evaluation Center.

Article 99

The review and approval period for drug re-registration is 120 days.

Article 100

Administrative approval decisions shall be made within 20 days.

Article 101

The drug regulatory authority shall issue and deliver the relevant administrative license documents within 10 days from the date of the drug registration approval decision.

Article 102

If, due to the characteristics of the drug or special circumstances encountered during review, inspection, or testing, an extension of the time limit is necessary, the extension shall not exceed one-half of the original time limit. Such extension requires approval by the heads of the related technical institutions for evaluation, inspection, and testing, and the technical institution granting the extension shall notify the applicant in writing and inform other related technical institutions.

Article 103

The following time periods shall not be included within the relevant work time limits:

1-The time taken by the applicant to supplement data, make corrections after inspection, or verify production processes, quality standards, and instructions as required;

2-Delays in inspection, testing, or convening expert consultation meetings caused by the applicant;

3-Time periods during which the review and approval process is suspended according to laws and regulations;

4-Time consumed for initiating overseas inspections.

Chapter VIII: Supervision and Administration

Article 104

The National Medical Products Administration (NMPA) shall be responsible for supervising, assessing, evaluating, and guiding the work related to drug registration management carried out by technical institutions such as the Center for Drug Evaluation, as well as the drug regulatory authorities of provinces, autonomous regions, and municipalities directly under the Central Government.

Article 105

Drug regulatory authorities shall, in accordance with laws and regulations, conduct supervision and inspection of drug research and development activities. When necessary, they may extend such inspections to entities and individuals that provide products or services for drug research and development. Relevant entities and individuals shall cooperate and must not refuse or conceal information.

Article 106

The Information Center shall be responsible for establishing drug product archives and implementing coding management. It shall collect and continuously update information related to drug registration applications, safety reports during clinical trials, evaluations, verifications, inspections, approvals, and post-marketing changes, including approvals, filings, and reports. The systems related to drug product archives and coding management shall be formulated and published by the Information Center.

Article 107

Drug regulatory authorities at the provincial, autonomous region, and municipal levels shall organize routine supervision and inspection of non-clinical safety evaluation institutions and clinical trial institutions within their jurisdictions, to ensure compliance with Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) requirements. The NMPA may, as needed, conduct supervision and inspection of these research institutions.

Article 108

The NMPA shall establish a drug safety credit management system. The Center for Drug Inspection shall be responsible for establishing credit records for non-clinical safety evaluation institutions and clinical trial institutions. These records shall include information such as license issuance, results of routine supervision and inspections, and administrative penalties for violations. Such information shall be made public and updated in a timely manner. Drug

regulatory authorities shall increase the frequency of inspections for entities with negative credit records and may implement joint disciplinary measures in accordance with national regulations. The specific system for managing drug safety credit records shall be formulated and published by the Center for Drug Inspection.

Article 109

The NMPA shall publish the list of drug registration approval items, their legal basis, approval requirements, and processing time limits. It shall disclose the progress of drug registration applications to applicants and publish the evaluation conclusions and bases for approved marketed drugs, as well as any violations identified during supervision and inspection, thereby accepting public supervision.

The package inserts of approved marketed drugs shall be made public and updated in a timely manner. In the case of vaccines, label information shall also be disclosed and updated accordingly.

Without the consent of the applicant, drug regulatory authorities, professional technical institutions, their staff, and participating expert reviewers shall not disclose any trade secrets, undisclosed information, or confidential business information submitted by the applicant, unless otherwise provided by law or necessary for national security or significant public interest.

Article 110

The NMPA shall revoke the drug registration certificate and make a public announcement in any of the following circumstances:

1-The Marketing Authorization Holder (MAH) voluntarily applies for the cancellation of the drug registration certificate;

2-Re-registration is denied in accordance with this Regulation;

3-The MAH's drug registration certificate, drug manufacturing license, or other administrative licenses are lawfully revoked or annulled;

4-In accordance with Article 83 of the Drug Administration Law, where the drug is ineffective, has serious adverse reactions, or poses other health risks;

5-In accordance with Article 61 of the Vaccine Administration Law, where post-marketing evaluation reveals serious adverse reactions or other health risks associated with vaccination;

6-In accordance with Article 62 of the Vaccine Administration Law, where post-marketing evaluation shows that the product design, manufacturing process, safety, efficacy, or quality controllability of the vaccine is significantly inferior to that of other vaccines for the same disease;

7-Where the MAH, without justified reasons, fails to complete required research within the specified time as per the drug marketing authorization or regulatory authority's requirements, in violation of laws or administrative regulations;

8-Any other circumstances under which the drug registration certificate should be lawfully revoked.

Chapter IX: Legal Liability

Article 111

During the drug registration process, if false certificates, data, materials, samples are provided or other means are used to fraudulently obtain clinical trial approval or drug registration approval, it shall be handled in accordance with Article 123 of the Drug Administration Law.

Article 112

For applicants who provide false data, materials, samples, or engage in other deceptive behaviors in vaccine clinical trial or registration applications, they shall be handled in accordance with Article 81 of the Vaccine Administration Law.

Article 113

During the drug registration process, if the drug non-clinical safety evaluation research institutions, drug clinical trial institutions, etc., fail to comply with the Drug Non-clinical Research Quality Management Standards, Drug Clinical Trial Quality Management Standards, or other regulations, it shall be handled in accordance with Article 126 of the Drug Administration Law.

Article 114

Conducting drug clinical trials without approval shall be handled according to Article 125 of the Drug Administration Law; conducting bioequivalence trials without filing shall be handled according to Article 127 of the Drug Administration Law.

Article 115

During drug clinical trials, if safety issues or other risks are discovered, and the clinical trial sponsor fails to timely adjust the clinical trial plan, suspend or terminate the clinical trial, or fails to report to the National Medical Products Administration, it shall be handled in accordance with Article 127 of the Drug Administration Law.

Article 116

Violating the provisions of Articles 28 and 33 of these Measures, if the sponsor has any of the following circumstances, a correction shall be ordered within a time limit; if overdue without correction, a fine of no less than 10,000 yuan and no more than 30,000 yuan shall be imposed:

1-Failure to register on the drug clinical trial registration and information disclosure platform before conducting drug clinical trials as required;

2-Failure to submit safety update reports during R&D as required;

3- Failure to register clinical trial results and other information after the completion of drug clinical trials.

Article 117

If a drug testing institution issues false testing reports when undertaking testing work required for drug registration, it shall be handled according to Article 138 of the Drug Administration Law.

Article 118

Approving drug clinical trials that do not meet conditions or issuing drug registration certificates for drugs that do not meet conditions shall be handled according to Article 147 of the Drug Administration Law.

Article 119

If the drug regulatory authorities and their staff violate laws and regulations during drug registration management, they shall be handled according to relevant laws and regulations.

Chapter X: Supplementary Provisions

Article 120

Registration applications for drugs subject to special management such as narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs, and precursor chemicals for drugs shall, besides handling according to these Measures, also comply with other relevant national regulations.

Article 121

The standards for exported vaccines shall conform to the standards of the importing country (region) or contract requirements.

Article 122

For drug-device combination products intended for registration, if there is an existing similar product already defined as a drug by attribute, it shall be declared as a drug; if not yet defined by attribute, the applicant shall apply to the National Medical Products Administration for product attribute definition before registration. If the attribute is defined mainly as a drug, registration shall follow the procedures stipulated by these Measures. Research data for the medical device part shall be reviewed by the Medical Device Technical Review Center of the National Medical Products Administration and then transferred to the Drug Review Center for comprehensive review.

Article 123

The format of the approval document number for domestically produced drugs is: NMPA Approval Number H (Z, S) + four-digit year number + four-digit sequence number. The format of the approval document number for drugs produced in Hong Kong, Macao, and Taiwan Region is: NMPA Approval Number H (Z, S) C + four-digit year number + four-digit sequence number.

The format of the approval document number for drugs produced overseas is: NMPA Approval Number H (Z, S) J + four-digit year number + four-digit sequence number.

H stands for chemical drugs, Z stands for traditional Chinese medicine, and S stands for biological products.

The approval document number for drugs shall not be changed due to changes in the registration items after marketing.

Where there are other provisions on traditional Chinese medicine, such provisions shall apply.

Article 124

The electronic files of drug registration approval certificates and active pharmaceutical ingredient approval files made by the drug regulatory departments have the same legal effect as paper documents.

Article 125

The time limits specified in these Measures are calculated in working days.

Article 126

These Measures shall come into effect on July 1, 2020. The previous Drug Registration Management Measures promulgated by the former State Food and Drug Administration Order No. 28 on July 10, 2007, shall be repealed simultaneously.