Measures for the Supervision of Drug Quality Sampling and Testing (Draft for Public Comment)[1]

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Chapter I: General Provisions

Article 1

These Measures are formulated in order to regulate the sampling and testing of drug quality, in accordance with the *Drug Administration Law of the People's Republic of China*, the *Implementing Regulations of the Drug Administration Law of the People's Republic of China*, and other relevant provisions.

Article 2

These Measures shall apply to the organization and implementation of drug quality sampling and testing conducted by drug regulatory authorities within the territory of the People's Republic of China.

Article 3

Drug quality sampling and testing constitutes a technical measure for post-marketing supervision of drugs and shall adhere to the principles of scientific rigor, standardization, legality, and fairness.

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

Article 4

The drug regulatory department of the State Council shall be responsible for organizing and implementing national drug quality sampling and testing, conducting sampling and testing of drug quality across production, distribution, and usage stages nationwide, and providing guidance for local drug quality sampling and testing.

Provincial-level drug regulatory departments shall be responsible for organizing and implementing drug quality sampling and testing within their administrative regions, conducting sampling and testing of drugs at the production stage as well as at wholesale and retail chain headquarters and third-party internet sales platforms. They shall also organize municipal and county-level drug regulatory departments to conduct sampling and testing of drug quality at retail and usage stages within their administrative regions, and undertake drug quality sampling and testing tasks assigned by superior drug regulatory authorities.

Article 5

Drug testing institutions established or designated by drug regulatory authorities shall undertake the testing tasks required for drug quality sampling and testing.

Article 6

Entities and personnel engaged in drug production, distribution, or use shall cooperate with the drug regulatory authorities in the organization and implementation of drug quality sampling and testing. They shall not interfere with, obstruct, or refuse to participate in sampling and testing, nor shall they transfer or conceal drugs, refuse to provide supporting materials, or deliberately provide false information.

Article 7

The drug regulatory department of the State Council shall be responsible for establishing the national drug sampling and testing information system and strengthening the development of information technologies, including coordination of sampling and testing, verification and handling, and data sharing. Provincial-level drug regulatory departments are encouraged to establish provincial drug sampling and testing information systems, which shall be interoperable with the national system, in order to enhance routine management of sampling and testing and the collection, aggregation, and analysis of data.

Article 8

Drug regulatory authorities, as well as entities and personnel participating in drug quality sampling and testing, shall maintain the confidentiality of internal documents, sampling and testing data, trade secrets, personal privacy, and other sensitive information obtained during the course of sampling and testing, and shall not disclose such information without authorization.

Chapter II: Planning

Article 9

The drug regulatory authorities of the State Council and the provincial drug regulatory authorities shall formulate annual drug quality sampling and testing plans, arranging and deploying drug quality sampling and testing work in a systematic manner to ensure that objectives are clear, priorities are emphasized, coordination is maintained, and coverage is effective.

The drug quality sampling and testing plans formulated by provincial drug regulatory authorities shall be aligned with the national drug quality sampling and testing plan, with clearly defined responsibilities and areas of focus, expanding coverage while avoiding duplication in principle. Furthermore, drug quality sampling and testing activities organized by municipal and county-level drug regulatory authorities within the province shall be incorporated into the plan for unified management.

Article 10

Municipal and county-level drug regulatory authorities shall, in accordance with the plans formulated by higher-level drug regulatory authorities and in consideration of the supervisory needs within their administrative regions, develop specific implementation programs for drug quality sampling and testing.

Article 11

Drug regulatory authorities responsible for organizing sampling and testing may, based on supervisory needs, make adjustments to the drug quality sampling and testing plans.

Article 12

When formulating drug quality sampling and testing plans, drug regulatory authorities shall focus on the following categories of drugs:

(1) Drugs produced within the administrative region;

(2) Drugs previously found non-compliant in sampling and testing;

(3) Drugs associated with a concentrated number of adverse reaction reports;

(4) Drugs with large clinical usage or broad scope of application;

(5) Drugs whose quality standards, formulations, or manufacturing processes have undergone significant changes;

(6) Drugs requiring stringent storage conditions or whose active ingredients are prone to variation;

(7) Newly approved or newly manufactured drugs;

(8) Other drugs deemed necessary to include in the sampling and testing plan.

Article 13

The expenses necessary for drug quality sampling and testing shall be borne by the drug regulatory authority organizing the respective tasks and allocated from the fiscal budget, in strict accordance with relevant financial management regulations.

Chapter III: Drug Sampling

Article 14

Drug regulatory authorities shall be responsible for organizing drug sampling and may either conduct the sampling themselves or entrust units with the requisite capabilities to perform the sampling on their behalf.

Article 15

Units undertaking drug sampling (hereinafter referred to as "sampling units") shall, in accordance with the drug quality sampling and testing plans and the *Principles and Procedures for Drug Sampling*, formulate specific implementation programs for sampling and carry out the sampling accordingly. The *Principles and Procedures for Drug Sampling* shall be formulated under the organization of the drug regulatory authorities of the State Council.

Article 16

Sampling units shall strengthen the training and management of sampling personnel to ensure the quality of sampling work. Sampling personnel shall be familiar with laws and regulations related to drug administration and possess the competencies appropriate to their sampling duties.

Article 17

When conducting on-site sampling, there shall be no fewer than two sampling personnel present. They shall present relevant certification or documentation to the unit being sampled. In principle, the same individual shall not concurrently undertake both the sampling and the testing of the same batch.

Article 18

The location for on-site sampling shall be determined by the sampling personnel based on the type of the sampled entity. For sampling in the pharmaceutical manufacturing stage, the site shall generally be the finished product warehouse or the warehouse for pharmaceutical raw materials, excipients, or packaging materials. For sampling in the pharmaceutical distribution stage, the site shall generally be the pharmaceutical warehouse of the business entity or the retail premises of the pharmacy. For sampling at the point of drug use, the site shall generally be the drug storage facility.

Samples to be collected must be drugs that have been released or accepted into inventory and are intended for sale or use. Products that are clearly marked as pending testing, non-compliant, or returned shall not be sampled.

Article 19

On-site sampling operations shall be conducted in a standardized manner and must not compromise the quality of the samples or unpacked drugs. The quantity of samples shall comply with applicable requirements. Sample selection shall generally follow a random principle; however, targeted sampling may be conducted based on regulatory needs or specific concerns.

Sampling personnel shall seal samples on-site using dedicated seals, complete the "Drug Sampling Record and Certificate" as required, and obtain signatures from both the sampling personnel and relevant personnel of the sampled entity, with the official seals of both the sampling and sampled entities affixed. Where necessary for inspection purposes, sampling personnel may request copies of relevant documents or supporting evidence from the sampled entity, which must bear the entity's official seal. If the sampled entity refuses to sign or affix a seal, the sampling personnel shall record this fact in the Drug Sampling Record and Certificate and sign to confirm.

During on-site sampling, sampling personnel shall preserve evidence of the sampling site, storage conditions, and sample information by means of photography, videography, or other appropriate methods.

Article 20

When carrying out on-site sampling tasks, sampling personnel shall conduct necessary on-site inspections of storage conditions, temperature and humidity records, and other relevant matters. Where any issues affecting the quality of drugs or other illegal or non-compliant conduct are discovered during such inspections, the sampling personnel shall secure and preserve the relevant evidence and transfer such evidence or samples to the drug regulatory authority having jurisdiction over the sampled entity for handling in accordance with law.

Article 21

Drugs that are close to the expiration date may be sampled only where the time limits for testing, notification of results, and re-testing can be met, unless otherwise specially required by the drug regulatory authority organizing the sampling and testing.

Article 22

The sampling unit shall, within the prescribed time limits, deliver or mail the samples, together with the Drug Sampling Record and Certificate and other relevant materials, to the drug testing institution undertaking the testing task. Samples collected shall be stored and transported in accordance with their prescribed storage conditions. The storage and transportation of drugs subject to special control shall be carried out in accordance with the relevant provisions of the drug regulatory authority.

Article 23

For varieties manufactured under cross-provincial contract manufacturing arrangements, the provincial drug regulatory authority at the location of the marketing authorization holder shall be responsible for sampling and testing, which shall be incorporated into the annual sampling plan. The sampling tasks may be completed through cross-provincial sampling, online sampling, or other forms. Where sampling and testing involve the production stage, the provincial drug regulatory authority at the location of the marketing authorization holder may notify the provincial drug regulatory authority at the location of the contract manufacturer of the sampling plan. The latter shall organize sampling and/or testing of the commissioned products under production in accordance with the plan, and the purchase cost of samples shall be borne by the provincial drug regulatory authority at the location of the marketing authorization holder. Based on regulatory needs, the provincial drug regulatory authority at the location of the contract manufacturer may also conduct sampling and testing of commissioned products.

Article 24

During the sampling process, sampling personnel shall not engage in any of the following conduct: sampling seals shall not be opened or samples replaced without authorization after sealing; commercial secrets of the sampled entity shall not be disclosed; sampling shall not be carried out on behalf of the sampling personnel by the sampled entity; and no other conduct that may compromise the impartiality of sampling shall be undertaken.

Article 25

For drug quality sampling and testing, samples shall be purchased and the corresponding purchase costs shall be paid. The purchase costs may be paid on site by the sampling personnel, or may be paid off-site by means such as bank transfer after the sampled entity issues an invoice or voucher.

Chapter IV: Drug Testing

Article 26

Drug testing institutions shall be responsible for their testing activities, and shall conduct testing in accordance with the technical requirements for drug testing, following the principles of scientific rigor, independence, objectivity, and fairness, and shall comply with laboratory management requirements.

Article 27

Drug testing institutions shall verify the appearance, condition, sealing, and any other matters of submitted samples that may affect the test results. They shall also verify the contents of the Drug Sampling Record and Certificate, including signatures and seals on the sampling seals. Samples shall be accepted only after verification has been completed and confirmed to be correct. For samples requiring cold-chain preservation or other special storage and transportation conditions, acceptance shall take place only after verifying that temperature and humidity records throughout storage and transportation meet the applicable requirements.

A drug testing institution may refuse to accept samples under any of the following circumstances:

(1) The appearance of the sample is damaged or contaminated;

(2) The sealing or packaging of the sample is incomplete, not sealed at the prescribed sealing position, or may otherwise affect the impartiality of the sample;

(3) The Drug Sampling Record and Certificate contain inaccurate or incomplete information, or the identification on the documents is clearly inconsistent with the physical sample;

(4) The batch number or product variety is confused;

(5) The packaging container does not comply with requirements and may affect the test results;

(6) There is evidence that storage or transportation conditions did not comply with requirements and may affect the quality of the sample;

(7) The quantity of samples clearly does not meet the plan requirements;

(8) The product category is inconsistent with the current sampling and testing plan;

(9) The sampling time limit has been exceeded;

(10) Any other circumstance exists that may affect the quality of the samples or the reliability of the test results.

Where samples are refused, the drug testing institution shall, in accordance with the requirements of the drug regulatory authority organizing the sampling and testing, explain the reasons to the sampling unit, return the samples, and report the matter to the drug regulatory authority organizing the sampling and testing.

Article 28

Drug testing institutions shall register each sample upon receipt and affix an identifying label, and shall allocate the samples either for testing or for retention in accordance with storage requirements.

Unless otherwise provided in the sampling and testing plan, a drug testing institution shall issue a test report within 30 working days from the date of receipt of the samples. Where special circumstances require an extension, approval shall be obtained from the drug regulatory authority that organized the sampling and testing.

Article 29

Drug testing institutions shall properly retain retained samples. For samples that conform to the requirements, the retention period shall be one year from the date of issuance of the test report or until the expiration date of the product, whichever is later.

For samples that do not conform to the requirements, the samples shall be retained until the expiration date of the product, but no longer than two years.

Article 30

Except where the drug regulatory authority organizing the sampling and testing makes special requirements or where full-item testing cannot be carried out due to other objective reasons, drug testing institutions shall conduct full-item testing of the sampled products in accordance with national drug standards, drug registration standards, and other applicable provisions, determine the results, and issue a test report.

Where necessary, other testing methods that have been verified and validated may be used for testing, and corresponding test data shall be issued.

Where a drug testing institution lacks the required qualifications for certain test items or is otherwise unable to complete the testing tasks on time, it may, with the consent of the drug regulatory authority organizing the sampling and testing, entrust another drug testing institution with the appropriate qualifications to complete the testing tasks.

Article 31

According to regulatory needs, for drugs suspected of adulteration or falsification, drug testing institutions shall conduct testing in accordance with the supplementary testing methods for drugs approved by the drug regulatory authority of the State Council and issue a test report.

Drug testing institutions are encouraged to carry out research on supplementary testing methods for drugs. The declaration and approval of supplementary testing methods shall be conducted in accordance with the relevant provisions of the drug regulatory authority of the State Council.

Article 32

Drug testing institutions shall be responsible for the drug test reports they issue. Test reports shall have a standardized format, be true and complete in content, contain accurate data, and present clear conclusions. Electronically issued test reports that comply with legal requirements shall have the same legal effect as paper reports.

The retention period for original test records and test reports shall not be less than five years.

Article 33

Drug testing institutions shall establish a quality management system covering the entire testing process, strengthen the management of quality elements such as testing personnel, instruments and equipment, laboratory materials, and testing environment, and reinforce process control over testing quality.

Drug testing institutions shall properly manage testing data, promptly and accurately record original test data in a complete manner, and ensure that testing results are accurate and fully traceable.

Article 34

During the testing process, drug testing institutions and testing personnel shall not engage in the following conduct:

(1) Substituting samples;

(2) Concealing or falsifying test data, or issuing false test reports;

(3) Disclosing the technical secrets of the parties concerned;

(4) Disclosing test results or releasing sampling and testing information without authorization;

(5) Other conduct that may affect the impartiality of test results.

Article 35

During the testing process, when a drug testing institution discovers any of the following situations, it shall immediately report to the drug regulatory authority organizing the sampling and testing, and shall not delay or omit the report:

(1) Drugs that pose a serious quality or safety risk (such as noncompliance in pyrogen, bacterial endotoxin, sterility, or other items) requiring immediate control measures;

(2) Suspected adulteration or falsification;

(3) Suspected illegal or noncompliant production activities;

(4) Multiple batches of products from the same enterprise failing to meet standards, suggesting possible

Article 36

Drug testing institutions shall submit or transmit test reports within the prescribed time. Unless otherwise provided, upon issuance of a test report, the drug testing institution shall promptly transmit the test report, together with sampling records and supporting documentation, to the sampling unit and complete the reporting of results.

If the test results do not comply with the relevant standards, the drug testing institution shall, within two working days, transmit the test report and the drug sampling records and supporting documentation to the provincial-level drug regulatory authority in the location of the sampled unit, the provincial-level drug regulatory authority in the location of the marketing authorization holder, or the drug regulatory authority having jurisdiction over the relevant units involved.

Article 37

Drug testing institutions may, in strict accordance with the work requirements of the drug regulatory authority organizing the sampling and testing, as well as the principles and procedures for exploratory research on drug sampling and testing, carry out exploratory research. The principles and procedures for exploratory research on drug sampling and testing shall be formulated and organized by the drug regulatory authority of the State Council.

Chapter V: Re-examination

Article 38

If the sampled unit or the marketing authorization holder has objections to a test report issued by a drug testing institution, they may submit an application for re-examination within seven working days from the date of receipt of the test report. Applications submitted after this period shall not be accepted by the drug testing institution.

Where the sampled unit is a business or user entity, the application for re-examination shall be made in consultation with the marketing authorization holder, and either party may submit the application. If a contract manufacturing enterprise has objections to the test report, the application for re-examination shall be submitted by the marketing authorization holder.

The re-examination application shall be submitted to the original drug testing institution or to a drug testing institution established or designated by the superior drug regulatory authority. It may also be submitted directly to the National Institute for Food and Drug Control (NIFDC). No other drug testing institution shall accept a re-examination application.

Article 39

A re-examination may be applied for only once. An application for re-examination shall include the following materials:

(1) A Re-examination Application Form affixed with the official seal;

(2) A copy of the test report issued by the drug testing institution;

(3) The original authorization letter of the legal person;

(4) Identification of the handling personnel;

(5) Proof of the validity period;

(6) Other relevant materials.

Article 40

A drug testing institution shall, within seven working days from the receipt of a re-examination application, review the submitted materials and issue a Re-examination Application Receipt, informing the applicant whether the re-examination will be accepted. The institution shall report to the drug regulatory authority organizing the sampling and testing within two working days.

A re-examination application shall not be accepted under any of the following circumstances:

(1) Test items for which re-examination is prohibited under the national drug standards;

(2) Test items that are unsuitable for re-examination, such as weight differences, fill quantity differences, sterility, pyrogen, bacterial endotoxin, microbial limits, and mycotoxins;

(3) Applications submitted after the prescribed time limit or applications for which re-examination has already been requested;

(4) Samples that do not meet the quantity required for re-examination, have expired, or are insufficient within the validity period to complete the re-examination;

(5) Other circumstances in which, due to special reasons, retained samples cannot fulfil the purpose of re-examination.

Where obvious visible foreign matter is detected, the relevant enterprise or unit may, within seven working days from the date of receipt of the test report, visit the original drug testing institution for on-site confirmation of the item, which shall not constitute a re-examination.

Article 41

The drug testing institution designated to accept the re-examination (hereinafter referred to as the re-examination institution) shall, within three working days from the issuance of the Re-examination Application Receipt, send a sample transfer notice to the original drug testing institution. The original drug testing institution shall respond regarding the availability of retained samples upon receipt of the notice and, within seven working days, provide the retained samples for re-examination after testing.

The samples provided shall meet retention requirements, be sealed by the sampling unit with intact seals, and be stored and transported in accordance with the prescribed storage conditions.

Article 42

After receiving the retained samples for re-examination, the re-examination institution shall verify the quantity of the samples as well as the integrity of their packaging and seals. Where, upon verification, the retained samples are found not to meet the requirements for re-examination, the re-examination institution shall suspend the re-examination procedure and notify the applicant for re-examination, the original drug testing institution, and the drug regulatory authority that organized the sampling and testing within two working days.

Article 43

The re-examination institution shall issue a re-examination conclusion within thirty working days from the date of receipt of the retained samples. Within two working days from the date of issuance of the inspection report, the institution shall transmit the report to the applicant for re-examination, the original drug testing institution, the sampled entity, and the provincial-level drug regulatory authority at the place where the labeled marketing authorization holder is located, or the drug regulatory authority having jurisdiction over the applicant for re-examination.Where an extension is required due to special circumstances, approval shall be obtained from the drug regulatory authority that organized the sampling and testing.

The re-examination conclusion issued by the re-examination institution shall constitute the final inspection conclusion.

Article 44

The applicant for re-examination shall, in accordance with the relevant provisions, prepay the drug testing fees to the re-examination institution. Where the re-examination conclusion is inconsistent with the original inspection conclusion, the re-examination fees shall be borne by the original drug testing institution.

Where the competent departments of the State Council or the relevant departments of a provincial-level people's government have otherwise provided special provisions, such provisions shall prevail.

Chapter VI: Online Sampling and Testing

Article 45

"Online sampling" refers to the purchase of samples from online drug retail enterprises. When purchasing samples, the sampling entity or personnel shall not disclose the purpose of sampling to the online drug retailer. Where prescription drug samples are purchased, the sampling entity may request a medical institution to issue a prescription.

Article 46

Prior to carrying out an online sampling assignment, sampling personnel shall verify the qualifications and sales compliance of the online retail store or third-party platform. Relevant evidence shall be preserved by means such as screenshots, photographs, or video recordings, including information on the sampled online drug retailer, the online sales platform, the product as displayed on the webpage, and the purchase transaction records.

Article 47

Upon receipt of the samples, sampling personnel shall verify the shipping package, the sample packaging, and the drug traceability codes.

Where the authenticity of the samples is in doubt, verification and confirmation shall be conducted in accordance with the requirements of the department organizing the sampling and testing.

Article 48

Where the samples are confirmed to meet the sampling requirements, the samples shall be sealed with special seals, and the "Online-Purchased Drug Sampling Record and Voucher" shall be completed as required, signed by the sampling personnel, and affixed with the official seal of the sampling entity. The signature or seal of the sampled entity shall not be required.

Article 49

Where online sampling and testing samples submitted for testing involve confusion of batch numbers or where the quantity of samples does not meet the planned requirements, the drug testing institution may, in accordance with the requirements of the drug regulatory authority that organized the sampling and testing, conduct partial-item testing on the samples that meet the applicable conditions, or convert them into samples for exploratory research use.

Article 50

Where online sampling and testing samples are found, upon examination, not to comply with the relevant requirements, the drug testing institution shall also transmit the inspection report and the drug sampling records and vouchers, among other materials, to the provincial-level drug regulatory authority at the location of the third-party online drug trading platform.

Chapter VII: Supervision and Administration

Article 51

Drug regulatory authorities at all levels shall, in accordance with their respective responsibilities, investigate and handle non-compliant results and other issues identified during sampling and testing. Where matters involve other provinces, the relevant drug regulatory authorities shall strengthen communication and cooperation, promptly handle requests for assistance in investigations, and, where necessary, conduct joint investigations.

Article 52

Within five working days from the date of receipt of a non-compliance report, the drug regulatory authority shall organize the delivery of the inspection report to the sampled entity and the labelled marketing authorization holder.

Article 53

Upon receipt of a non-compliance inspection report, the sampled entity and the marketing authorization holder (MAH) shall confirm the circumstances of the sampling and testing.

The provincial-level drug regulatory authority at the location of the MAH shall, within ten working days of delivery of the non-compliance inspection report, communicate the MAH's confirmation to the provincial-level drug regulatory authority at the location of the sampled entity, either through the drug sampling and testing information system or by written notice.

Where the MAH denies having produced the product, it shall provide supporting documentation. The provincial-level drug regulatory authority at the MAH's location shall organize an investigation and verification, and the results shall be promptly communicated to the provincial-level drug regulatory authority at the sampled entity's location.

If it is confirmed that the MAH did not produce the product, the MAH and the provincial-level drug regulatory authority at the sampled entity's location shall cooperate to jointly verify the source of the problematic product.

Article 54

Where a drug is produced under cross-provincial contract manufacturing and is found non-compliant, the provincial-level drug regulatory authority at the MAH's location and the provincial-level drug regulatory authority at the contract manufacturer's location shall promptly notify each other of the non-compliant drug information. They shall conduct extended inspections of the contract manufacturer or request assistance from the provincial-level drug regulatory authority at the contract manufacturer's location. Where necessary, a joint investigation may be conducted.

Article 55

Upon receipt of a non-compliance inspection report, the sampled entity and the marketing authorization holder (MAH) shall perform the following obligations:

(1) Recall non-compliant drugs that have been sold;

(2) Conduct internal investigations and deviation analyses, and carry out risk assessments;

(3) Take necessary risk control measures based on the results of the investigations and assessments.

During the period in which a re-examination is requested, the risk control measures taken for the non-compliant drugs shall continue to be implemented.

Article 56

Drug regulatory authorities shall supervise relevant enterprises and entities in handling non-compliant drugs, analyzing causes, and implementing internal corrective actions. Where necessary, on-site inspections may be organized for the sampled entity and the MAH, with follow-up inspections to monitor the progress of corrective actions.

Article 57

Drug regulatory authorities shall investigate and handle relevant enterprises or entities involved with non-compliant drugs in accordance with the law. Where the conditions for filing a case are met, a case shall be filed and investigated in accordance with regulations, and the results of the investigation shall be publicly disclosed as required. Suspected criminal conduct shall be transferred to judicial authorities in accordance with the law.

Article 58

For drugs found non-compliant upon inspection, the provincial-level drug regulatory authority at the location of the MAH shall investigate and assess the enterprise's rectification and corrective actions. Where there is evidence that the quality issues arose during the production process, the provincial-level drug regulatory authority at the location of the sampled entity shall be notified. Based on such notifications, the drug regulatory authority having jurisdiction over the sampled entity may, at its discretion, mitigate or exempt penalties for the business or user entity.

Article 59

For drug quality risks identified in exploratory research reports, the drug regulatory authority that organizes or conducts sampling and testing shall establish a technical evaluation body or mechanism to carry out technical analyses and comprehensive assessments. Based on the results of such analyses and assessments, the authority shall implement corresponding risk control measures and, where necessary, report to the higher-level drug regulatory authority.

Article 60

Drug regulatory authorities shall supervise and provide guidance on the drug quality sampling and testing activities organized by their own departments and by lower-level drug regulatory authorities.

Drug testing institutions designated by the State Council's drug regulatory authority shall provide technical guidance to drug testing institutions undertaking national drug quality sampling and testing. Provincial-level drug testing institutions shall provide technical guidance to lower-level drug testing institutions undertaking drug quality sampling and testing within their administrative regions.

Article 61

Where drug manufacturing, distribution, or use entities, without legitimate reason, refuse to accept sampling and testing, the State Council's drug regulatory authority and provincial-level drug regulatory authorities may suspend the marketing, sale, or use of the drugs subject to the refused sampling and testing.

Chapter VIII: Information Disclosure

Article 62

The State Council drug regulatory authority and provincial-level drug regulatory authorities that organize drug quality sampling and testing shall disclose the results of drug quality sampling and testing in accordance with relevant regulations.

Article 63

The content disclosed for drug quality sampling and testing results shall include, at minimum:

-The name of the sampled drug;

-The marketing authorization holder (MAH) indicated on the label;

-The indicated manufacturer;

-The production batch number;

-The drug specification;

-The sampled entity (for online sampling, the relevant third-party online drug sales platform shall also be included);

-The basis for testing;

-The inspection conclusion;

-Non-compliant items;

-The testing institution.

Where evidence exists indicating the cause of non-compliance, it may be noted appropriately.

Drug quality sampling and testing results shall be disclosed as required after the final inspection conclusion is issued. Where disclosure must be postponed due to objections, ongoing investigations, or other reasons, disclosure shall occur once such reasons are resolved.

Where drug quality sampling and testing results are improperly disclosed, corrections shall be made within five working days from the date the improper disclosure is confirmed, within the original scope of disclosure.

Article 64

For drug quality sampling and testing information that may have significant impact, the drug regulatory authority organizing the sampling and testing shall conduct evaluation and assessment, and implement disclosure in accordance with the *Regulations of the People's Republic of China on Open Government Information* and other relevant provisions.

Chapter IX: Supplementary Provisions

Article 65

Based on the practical needs of drug regulatory work, drug regulatory authorities may, as appropriate, organize special sampling and testing. The relevant work may be carried out with reference to the provisions of these Measures.

Article 66

Where drug quality sampling and testing is conducted for purposes such as supervision and inspection, monitoring and evaluation, regulatory enforcement, emergency response, or risk surveillance, it shall not be limited by the number of samples, location, or sample status. The procedures for drug sampling and testing may be conducted with reference to these Measures.

Article 67

These Measures shall come into effect from the date of issuance. The *Notice of the National Medical Products Administration on Issuing the Measures for the Administration of Drug Quality Sampling and Testing* (Guo Yao Jian Yao Guan [2019] No. 34) shall be repealed from the date of issuance of these Measures.