# Administrative Measures for the Import of Drugs (2012 Amendment)[1]

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Administrative Measures for the Importation of Drugs (Promulgated by Order No. 4 of the State Food and Drug Administration and the General Administration of Customs on August 18, 2003, and amended pursuant to the Decision of the Ministry of Health and the General Administration of Customs on Amending the Administrative Measures for the Importation of Drugs (Order No. 86 of the Ministry of Health and the General Administration of Customs) on August 24, 2012)

## Chapter I: General Provisions

Article 1

These Measures are hereby promulgated in accordance with the *Pharmaceutical Administration Law of the People's Republic of China*, the *Customs Law*, the *Regulations for the Implementation of the Pharmaceutical Administration Law of the People's Republic of China*, and other applicable laws and regulations, with a view to regulating the record-keeping, customs declaration, and port inspection procedures relating to the importation of drugs, and ensuring the quality and safety of imported pharmaceuticals.

Article 2

The provisions of these Measures shall apply to all activities pertaining to the record-keeping, customs declaration, and port inspection of imported drugs.

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

Article 3

Drugs shall be imported exclusively through ports approved by the State Council for the entry of imported pharmaceuticals.

Article 4

For purposes of these Measures, the term "import record-keeping" refers to the procedure whereby importers submit applications to the relevant administrative authorities in the locality where the port is situated for the issuance of a *Customs Clearance Permit for Imported Drugs*. In the case of narcotic and psychotropic drugs, import record-keeping shall refer to the procedure by which importers apply to the relevant drug administration authorities at the port for an *Imported Drugs Port Inspection Notice*.

The term "port inspection" refers to the examination conducted by drug inspection institutions designated by the State Food and Drug Administration (hereinafter referred to as *port drug inspection institutions*) of imported drugs that have arrived at the port, in accordance with applicable law.

Article 5

No entity shall undertake the procedures for import record-keeping or port inspection of imported drugs unless it has obtained a valid *Drug Import Registration Certificate* or *Pharmaceutical Products Registration Certificate*.

Furthermore, importers of narcotic and psychotropic drugs must have obtained an *Import Permit* for such drugs prior to initiating any record-keeping or port inspection procedures.

Article 6

An import entity shall submit a declaration to the customs authorities based on a valid *Customs Clearance Permit for Imported Drugs*, and the customs authorities shall process the relevant procedures for customs declaration and clearance of such imported drugs.

In the case of narcotic and psychotropic drugs, customs authorities shall carry out the procedures for customs declaration and clearance based on the *Import Permit* issued by the State Food and Drug Administration.

Article 7

The catalogue of drugs eligible for importation shall be formulated, amended, and promulgated by the State Food and Drug Administration in conjunction with the General Administration of Customs.

**Chapter II: Import Record-Keeping**

Article 8

The port-level drug administrations shall be responsible for conducting import record-keeping of drugs, under the guidance and supervision of the State Food and Drug Administration. Their responsibilities shall include:

1-Accepting applications for import record-keeping and examining the relevant documentation;

2-Handling all matters related to the import record-keeping process;

3-Liaising with the customs authorities to facilitate matters pertaining to import record-keeping;

4-Notifying port drug inspection offices to conduct port inspections of imported drugs;

5-Supervising and addressing any issues identified in the course of import record-keeping and port inspection;

6-Performing other duties as prescribed by the State Food and Drug Administration.

Article 9

Only entities constituting independent legal persons and holding a valid *Drug Business License* may apply for drug inspection.

When a pharmaceutical production enterprise imports crude drugs or intermediate preparations (including those repackaged within China) for its own operational use, such enterprise shall hold a valid *Pharmaceutical Production License*.

Article 10

Under any of the following circumstances, the procedures for import record-keeping shall not be completed until the imported drugs have been inspected by the port drug inspection offices and confirmed to comply with the prescribed standards.

For imported drugs failing to meet the prescribed standards, the port-level drug administrations shall not proceed with import record-keeping.

The circumstances include:

1-Biological products as prescribed by the State Food and Drug Administration;

2-Drugs being marketed within China for the first time;

3-Other categories of drugs as prescribed by the State Council.

Article 11

When an import entity signs a purchase contract, it shall select a port from those permitting the entry of imported drugs as the destination of cargo. Drugs falling under the categories specified in Article 10 shall be imported exclusively through ports granted special approval by the State to permit the entry of such pharmaceuticals.

Article 12

Applications for import record-keeping shall be submitted to the drug administration authority at the destination port. The imported drugs shall be inspected by the port drug inspection office responsible for conducting drug inspections at that port.

Article 13

When applying for import record-keeping, the applicant shall complete and submit an *Imported Drugs Inspection Application Form* together with two copies of the relevant documentation concerning the imported drugs to the competent port drug administration. The application shall be made on the basis of the original *Drug Import Registration Certificate* (or *Pharmaceutical*

*Product Registration Certificate*, original or duplicate), and, where applicable, the original *Import Permit* for narcotic and psychotropic drugs.

The following materials shall be submitted:

1-Copy of the *Drug Import Registration Certificate* (or *Pharmaceutical Product Registration Certificate*, original or duplicate), and, where applicable, the *Import Permit* for narcotic and psychotropic drugs;

2-Copy of the applicant's *Drug Business License* or *Enterprise Legal Person Business License*;

3-Copy of the *Certificate of Origin*;

4-Copy of the *Purchase Contract*;

5-Copies of the *Packing List*, *Bill of Lading*, and *Freight Invoice*;

6-Copy of the *Factory Inspection Report*;

7-Copies of the *Drug Directions*, *Packaging*, and *Label Designs* (excluding crude drugs and intermediate preparations);

8-For biological products within the scope of examination, approval, and licensing as specified by the State Food and Drug Administration, a summary of the *Production Inspection Records* and the original *Approval Document* issued by the competent drug authority of the country or region of origin shall be submitted;

9-For the drugs specified under Article 10, a copy of the most recent *Report on the Inspection of Imported Drugs* and the *Customs Clearance Form for Imported Drugs* shall be submitted.

Where a pharmaceutical manufacturing enterprise applies for import record-keeping of crude drugs or intermediate preparations required for its own production, it shall, instead of the materials listed under Item (2) of this Article, submit copies of its *Pharmaceutical Production License* and *Enterprise Legal Person Business License*.

For imported drugs transiting through other countries or regions, the complete set of documentation including: the *Purchase Contract*, *Packing List*, *Bills of Lading*, and *Freight Invoices* covering transportation from the place of origin through all transit locations, shall be submitted concurrently.

All copies of the aforementioned materials shall bear the official seal of the import entity.

Article 14

Upon receipt of the *Imported Drugs Inspection Application Form* and all accompanying materials, the port drug administration shall conduct an examination thereof in accordance with the following requirements:

1-The materials shall be reviewed item by item to verify their completeness and authenticity;

2-The authenticity of the original *Drug Import Registration Certificate* (or *Pharmaceutical Product Registration Certificate*, original or duplicate), or the original *Import Permit* for narcotic and psychotropic drugs, shall be verified;

3-Where, upon examination, no discrepancies are found, the original *Drug Import Registration Certificate* (or *Pharmaceutical Product Registration Certificate*, original or duplicate), or the original *Import Permit* for narcotic and psychotropic drugs shall be promptly returned to the applicant, and the procedures for import record-keeping shall be completed on the same day.

Article 15

For drugs falling within the scope of Article 10 of these Measures, upon confirming that the submitted materials are complete and free of discrepancies, the port drug administration shall issue an *Imported Drugs Port Inspection Notice*, attaching a set of the materials specified in Article 13 of these Measures, to the competent port drug inspection office. At the same time, an *Imported Drugs Sampling Notice* shall be transmitted to the relevant customs office.

The specific administrative provisions governing the sampling activities of port drug inspection offices within customs-supervised areas shall be jointly formulated by the State Food and Drug Administration and the General Administration of Customs.

The port drug inspection office shall collect inspection samples at the sampling location specified in the *Imported Drugs Port Inspection Notice*, perform quality inspection in accordance with the relevant standards, and submit the inspection results to the local port drug administration.

Where the inspection results confirm that the imported drugs conform to the prescribed standards, the port drug administration shall approve the import record-keeping and issue a *Customs Clearance Form for Imported Drugs*. Where the inspection results indicate non-conformity with the prescribed standards, the port drug administration shall deny approval for import record-keeping and shall issue a *Notice of Disapproval of Drug Import Record-Keeping*.

Article 16

For drugs other than those specified in Article 10 of these Measures, upon confirming through examination that the submitted materials are complete and free from discrepancies, the port drug administration shall approve the import record-keeping and issue a *Notice of Customs Clearance for Imported Drugs*. At the same time, it shall issue an *Imported Drugs Port Inspection Notice* to the competent port drug inspection office, attaching a complete set of the materials required under Article 13 of these Measures.

For narcotic and psychotropic drugs, upon verifying that the submitted materials are complete and accurate, the port drug administration shall issue an *Imported Drugs Port Inspection Notice* to the designated port drug inspection office, accompanied by a full set of materials as required under Article 13 of these Measures. In such cases, a *Notice of Customs Clearance for Imported Drugs* need not be issued.

The port drug inspection office shall collect inspection samples from the location specified in the *Imported Drugs Port Inspection Notice*, conduct quality inspection in accordance with the prescribed standards, and submit the inspection results to the local port drug administration. Imported drugs determined, upon inspection, not to conform to the prescribed standards shall be handled by the port drug administration in accordance with the *Pharmaceutical Administration Law of the People's Republic of China* and other relevant laws and regulations.

Article 17

Under any of the following circumstances, the imported drugs shall be denied import record-keeping, and the port drug administration shall issue a *Notice of Disapproval of Import Record-Keeping for Imported Drugs*.

In the case of narcotic and psychotropic drugs, the port drug administration shall not issue an *Imported Drugs Port Inspection Notice*:

1-The applicant fails to submit the original *Drug Import Registration Certificate* (or *Pharmaceutical Product Registration Certificate*, original or duplicate) or the *Import Permit* for narcotic and psychotropic drugs;

2-At the time of applying for import record-keeping, the *Drug Import Registration Certificate* (or *Pharmaceutical Product Registration Certificate*) or *Import Permit* for narcotic and psychotropic drugs has expired;

3-At the time of applying for import record-keeping, the remaining shelf life of the drug is less than twelve months; for drugs whose total shelf life is less than twelve months, the remaining shelf life at the time of application shall not be less than six months;

4-The actual place of manufacture stated in the *Certificate of Origin* is inconsistent with that indicated in the *Drug Import Registration Certificate* (or *Pharmaceutical Product Registration*

*Certificate*), or the *Certificate of Origin* issued by a regional or international institution fails to clearly specify the manufacturing location as stated in the registration certificate;

5-The import entity has not obtained a valid *Drug Business License*; in the case of a manufacturing enterprise, it has not obtained a *Pharmaceutical Production License* and an *Enterprise Legal Person Business License*;

6-The packaging or labeling of the imported drugs as received at the port is inconsistent with the requirements of the State Food and Drug Administration;

7-The drug preparations lack Chinese-language instructions, or the Chinese instructions provided are inconsistent with the approved versions;

8-The applicant fails to import through a port authorized by the State Council for the entry of imported drugs, or the destination of the cargo lies outside the jurisdiction of the relevant port administration;

9-The applicant fails to provide documentary evidence for biological products falling within the scope of examination, approval, and licensing by the competent drug authority of the country or region of manufacture;

10-The applicant has forged or altered relevant documents or certificates;

11-The *Drug Import Registration Certificate* (or *Pharmaceutical Product Registration Certificate*) has been revoked or cancelled;

12-The drugs fall within the categories specified under Article 10 of these Measures and are not subject to sampling by the port drug inspection office pursuant to Article 25 of these Measures;

13-The drugs fall within the categories specified under Article 10 of these Measures and have been confirmed as non-compliant with the prescribed standards upon port inspection;

14-The competent drug regulatory authorities possess other evidence demonstrating that the imported drugs may pose a threat to human health.

Article 18

Imported drugs that are denied import record-keeping shall be returned by the import entity to the consignor. Where return to the consignor is not feasible, such drugs shall be surrendered to and disposed of by the port drug administration in accordance with relevant laws and regulations.

Article 19

The importation of clinical drugs urgently needed for medical use, donated drugs, as well as samples or reference drugs required for new drug research or drug registration, shall be subject to the approval of the State Food and Drug Administration. Import record-keeping procedures shall be carried out on the basis of the *Drug Import Approval Document* issued by the State Food and Drug Administration in accordance with Article 16 of these Measures.

**Chapter III: Port Inspection**

Article 20

Port drug inspection offices shall be established by the State Food and Drug Administration in accordance with the needs of inspection work related to imported drugs. Each port drug inspection office shall perform the following duties:

1-Conduct on-site inspection of consignments of imported drugs arriving at the port;

2-Examine factory inspection reports and *Certificates of Origin*;

3-Collect samples in accordance with the relevant requirements;

4-Carry out port inspections on imported drugs;

5-Conduct re-inspections in cases of disputed inspection results;

6-Perform other duties as prescribed by the State Food and Drug Administration.

Article 21

The *National Institute for the Control of Pharmaceutical and Biological Products* shall be responsible for providing technical guidance and coordination for the port inspection of imported drugs. Standards and reference substances required by the port drug inspection offices shall be verified and certified by the *National Institute for the Control of Pharmaceutical and Biological Products*.

Article 22

Port drug inspection offices shall conduct inspections of imported drugs in accordance with the quality standards specified in the *Drug Import Registration Certificate* (or *Pharmaceutical Product Registration Certificate*).

Article 23

A port drug inspection office shall contact the import entity within two days from the date of receipt of the *Imported Drugs Port Inspection Notice* and shall collect samples from the designated storage location of the consignment.

Prior to sampling, the import entity shall provide the *Factory Inspection Report* and the original *Certificate of Origin*.

Where it is necessary for the port drug inspection office to collect samples within the customs supervision area, it shall, at the same time, coordinate with the customs authorities regarding matters related to sampling and obtain their consent. During such sampling, personnel from both the import entity and the customs authority shall be present on site.

Article 24

When collecting samples on site, the port drug inspection office shall verify the actual condition of the imported drugs, accurately record all relevant information, and complete an *Imported Drugs Sampling Record Form*.

For drugs other than those specified under Article 10 of these Measures, upon completion of sampling, the port drug inspection office shall mark "Sampled" on the original *Customs Clearance Permit for Imported Drugs* and affix its official seal thereto.

For narcotic and psychotropic drugs, upon completion of sampling, the port drug inspection office shall mark "Sampled" on the original *Import Permit* and affix its official seal accordingly.

Article 25

A port drug inspection office shall not collect samples from imported drugs under any of the following circumstances:

1-The original *Factory Inspection Report* or *Certificate of Origin* has not been provided, or the originals are inconsistent with the copies submitted with the import record-keeping application;

2-The shipping marks are inconsistent with those indicated in the accompanying documentation;

3-The batch number or quantity of the imported drugs is inconsistent with the corresponding information in the documentation;

4-The packaging or labeling of the imported drugs is inconsistent with the information provided in the documentation;

5-The drug regulatory authorities possess other evidence demonstrating that the imported drugs may pose a risk to human health.

For drugs exempted from sampling, the port drug inspection office shall, within two days, submit an *Imported Drugs Sampling Record-Keeping Form* to the drug supervision and administration department of the port at which it is located.

Article 26

The port drug inspection office shall conduct inspections on the collected samples in a timely manner and complete such inspections within twenty days from the date of sampling. Upon completion, it shall issue an *Imported Drug Inspection Report*.

Where, due to the nature of special drugs or under exceptional circumstances, the inspection cannot be completed within the prescribed time limit, the time limit may be reasonably extended. In such cases, the port drug inspection office shall promptly notify the import entity and the relevant port drug administration.

The *Imported Drug Inspection Report* shall clearly specify the inspection conclusion as either "Meeting the Prescribed Standards" or "Not Meeting the Prescribed Standards."

For biological products falling within the scope of examination, approval, and issuance as determined by the State Food and Drug Administration, a certificate shall be issued simultaneously for those that both meet the prescribed standards upon port inspection and satisfy the relevant examination requirements.

Article 27

For imported drugs that, upon inspection, are confirmed to meet the prescribed standards, the port drug inspection office shall submit the *Imported Drug Inspection Report* to both the local port drug administration and the import entity.

For imported drugs that fail to meet the prescribed standards, the port drug inspection office shall promptly transmit the *Imported Drug Inspection Report* to the local port drug administration and other relevant port drug inspection offices, and shall simultaneously report the matter to the State Food and Drug Administration and the National Institute for the Control of Pharmaceutical and Biological Products.

Article 28

Samples collected from imported drugs shall be preserved until the expiration of their validity period.

Where preservation is difficult due to the nature of the samples, the preservation period shall be determined in accordance with the actual circumstances.

In cases involving claims, disputes, or rejections of goods, the samples shall be preserved until the relevant matter has been resolved.

Samples that have exceeded the prescribed preservation period shall be disposed of by the port drug inspection office in accordance with the relevant provisions, and such disposal shall be duly recorded for the record.

Article 29

Where an import entity raises an objection to the inspection result, it may, within seven days from the date of receipt of the inspection result, submit an application for re-inspection either to the original port drug inspection office or directly to the *National Institute for the Control of Pharmaceutical and Biological Products*.

For the re-inspection of biological products, the applicant may apply directly to the *National Institute for the Control of Pharmaceutical and Biological Products*.

Upon accepting a re-inspection application, the port drug inspection office shall promptly notify the relevant port drug administration and complete the re-inspection within ten days from the date of acceptance. The re-inspection conclusion shall be communicated to the port drug administration and other port drug inspection offices, and reported simultaneously to the *State Food and Drug Administration* and the *National Institute for the Control of Pharmaceutical and Biological Products*.

**Chapter IV: Supervision**

Article 30

Where the port drug inspection office decides, in accordance with Article 25 of these Measures, not to conduct sampling but the customs clearance procedures for such drugs have already been completed, the port drug administration shall adopt mandatory administrative measures to seal up and detain all relevant batches of the imported drugs.

Article 31

For drugs other than those specified in Article 10 of these Measures that are found, upon inspection by the port drug inspection office, not to meet the prescribed standards, the import entity shall promptly report to the local port drug administration the detailed information regarding the circulation and use of all such imported drugs.

Upon receipt of the *Imported Drug Inspection Report*, the local port drug administration shall immediately implement mandatory administrative measures to seal up and detain the drugs, and shall render a decision on administrative disposition within seven days.

Where an application for re-inspection has been filed, the administrative disposition decision shall be made within fifteen days from the date the re-inspection report is issued.

The port drug administration shall promptly report the relevant information to the State Food and Drug Administration, and simultaneously notify the drug administrations of all provinces, autonomous regions, municipalities directly under the Central Government, as well as other port drug administrations.

Article 32

If the import entity fails to submit an application for re-inspection within the prescribed period, or if the imported drugs are confirmed not to meet the prescribed standards upon re-inspection, the port drug administration shall impose administrative sanctions in accordance with the *Pharmaceutical Administration Law of the People's Republic of China* and other relevant provisions.

The port drug administration shall promptly report the relevant information to the State Food and Drug Administration, and notify the drug administrations of all provinces, autonomous regions, municipalities directly under the Central Government, and other port drug administrations.

Where the imported drugs are confirmed to meet the prescribed standards upon re-inspection, the port drug administration shall lift the mandatory administrative measures of sealing and detention, promptly report the relevant information to the State Food and Drug Administration, and notify the relevant administrative departments as described above.

Article 33

Any other issues identified in the course of drug import record-keeping shall be addressed by the port drug administration in accordance with the *Pharmaceutical Administration Law of the People's Republic of China* and other applicable regulations.

Article 34

When a domestic pharmaceutical manufacturing enterprise, trading enterprise, or medical institution purchases imported drugs, the supplier shall, at the time of sale, provide the following supporting documentation:

1-A photocopy of the Drug Import Registration Certificate (or a copy of the Pharmaceutical Product Registration Certificate) and a photocopy of the Drug Import Approval;

2-A photocopy of the Imported Drug Inspection Report, or a photocopy of the Imported Drug Customs Clearance Form clearly marked "Sampled" and affixed with the official seal; for

biological products falling within the scope of examination, approval, and issuance as determined by the State Food and Drug Administration, the examination, approval, and issuance certificate issued by the port drug inspection office shall also be provided. For suppliers of narcotic and psychotropic drugs, the following shall be provided simultaneously: a photocopy of the Drug Import Certificate (or the copy of the Pharmaceutical Product Registration Certificate), a photocopy of the Import Permit, and a photocopy of the Imported Drug Inspection Report.

All of the above-mentioned copies shall bear the official seal of the supplier.

Article 35

Port drug administrations and port drug inspection offices shall establish and maintain a strict management system for materials related to import record-keeping and port inspections.

All materials submitted by import entities shall be kept confidential, and the port drug administrations and inspection offices shall ensure that such information is not disclosed, reproduced, or misused except as required by law or authorized by the State Food and Drug Administration.

Article 36

Where any port drug administration or port drug inspection office violates the relevant provisions governing import record-keeping or port inspection, the State Food and Drug Administration may impose disciplinary measures, including official criticism or public notice of criticism.

Where the circumstances are serious, the entity concerned shall be disqualified from performing duties related to import record-keeping and port inspection.

Article 37

Entities or individuals that violate relevant customs laws or regulations shall be subject to investigation and penalties imposed by the customs authorities in accordance with the *Customs Law of the People's Republic of China* and the *Detailed Rules for the Implementation of Administrative Penalties under the Customs Law of the People's Republic of China*.

**Chapter V: Supplementary Provisions**

Article 38

For the purposes of these Measures, the term "import entity" refers to any of the following: a commercial operating entity, a recipient entity, or an inspection application entity.

A commercial operating entity refers to an enterprise or organization that signs and executes import or export contracts.

A recipient entity refers to the consignee or consignor designated in the purchase contract and shipping invoice.

An inspection application entity refers to the actual consignor or domestic distributor of a batch of imported drugs, responsible for handling the import record-keeping and port inspection formalities.

The recipient entity and the inspection application entity may be the same unit.

Article 39

Drugs entering bonded warehouses, bonded zones, or export processing zones from abroad shall be exempt from the procedures for import record-keeping and port inspection, and shall remain under customs supervision in accordance with the relevant regulations.

Drugs subsequently entering China from bonded warehouses, export supervision warehouses, bonded zones, or export processing zones shall be subject to import record-keeping and port inspection procedures in accordance with these Measures.

Crude drugs and medicinal materials imported under processing trade arrangements shall likewise be exempt from import record-keeping and port inspection procedures, provided that neither the crude materials nor the finished products shall be sold on the domestic market. Where export is not possible for special reasons, such drugs shall be delivered to the local drug administration for verification and written-off by the customs authorities in accordance with the relevant regulations.

Individuals carrying small quantities of drugs upon entry or exit shall be limited to reasonable quantities for personal use, and such drugs shall be subject to customs supervision.

Article 40

Crude drugs that are not included in the catalogue of imported drugs shall nonetheless comply with the provisions of these Measures and shall be subject to import record-keeping procedures in accordance with the law.

Article 41

Detailed regulations governing the import record-keeping and port inspection procedures shall be formulated separately by the State Food and Drug Administration.

Article 42

Importers of narcotic and psychotropic drugs shall obtain an Import Permit on the basis of the Imported Drug Registration Certificate (or the Pharmaceutical Product Registration Certificate) in accordance with the relevant State Council regulations on the administration and control of narcotic and psychotropic substances.

Article 43

For the purposes of these Measures, the term "narcotic and psychotropic drugs" refers to those used for clinical purposes. The import of such drugs for scientific research, teaching, or veterinary use shall be governed by the relevant provisions of the State Council concerning the administration of narcotic and psychotropic drugs.

Article 44

The authority to interpret these Measures shall reside with the State Food and Drug Administration and the General Administration of Customs.

Article 45

These Measures shall take effect on January 1, 2004. Simultaneously, the previous Administrative Measures for the Import of Drugs shall be repealed.

## Provisions on the Sampling of Imported Drugs

1-These Provisions are formulated to strengthen the management of sampling for imported drugs, to ensure that port inspection sampling is conducted in a representative, scientific, and standardized manner, and that the inspection results are accurate and reliable.

2-Sampling of imported drugs shall be conducted by the port drug inspection office responsible for the relevant inspection work.

The applicant shall be responsible for preparing the necessary sampling tools and designated sampling area, as well as for organizing related operations such as handling, stacking, opening, and repackaging.

3-Imported drugs bearing the same name, country of origin, manufacturer, packaging, batch number, dosage form, specification, trademark, and contract number shall be considered one batch for the purposes of sampling.

Where drugs covered under a single contract are delivered in multiple consignments, each consignment shall be sampled separately.

4-For imported bulk drugs and repackaged preparations, the import entity shall provide the Drug Import Registration Certificate for the bulk drug and the approval document for repackaging.

Sampling shall be conducted based on the repackaged specifications and quantities, with reference to the relevant drug preparations.

5-Sampling Quantity

Except where otherwise stipulated by special regulations or technical requirements, the standard sampling quantity shall be three times the quantity required for inspection.

After inspection, any remaining samples, other than those required for preservation or re-examination, shall be returned to the inspection application entity.

6-Sampling Method

(1) Crude Drugs

(a) Drugs exceeding 10 kilograms per package

For ≤10 packages: 1 sample shall be collected.

For 11–50 packages: 1 sample for every additional 10 packages; packages fewer than 10 shall be treated as 10 packages.

For 51–100 packages: 1 sample for every additional 20 packages; packages fewer than 50 shall be treated as 50 packages.

For >1000 packages: 1 sample for every additional 100 packages; packages fewer than 100 shall be treated as 100 packages.

(b) Drugs of 5–10 kilograms per package (inclusive of 5 kg)

1 sample per 100 kilograms of drugs; quantities fewer than 100 kilograms shall be treated as 100 kilograms.

(c) Drugs of 1–5 kilograms per package (inclusive of 1 kg)

1 sample per 50 kilograms of drugs; quantities ≤50 kilograms shall be treated as 50 kilograms.

(d) Drugs ≤1 kilogram per package

1 sample per 20 kilograms of drugs; quantities ≤20 kilograms shall be treated as 20 kilograms.

Samples shall be collected from the original packages.

(2) Injections

(a) Small-capacity injections

≤20,000 bottles: 1 sample;

≤50,000 bottles: 2 samples;

≤100,000 bottles: 3 samples;

100,000 bottles: 1 sample for every additional 10,000 bottles; quantities <10,000 bottles shall be treated as 10,000 bottles.

(b) Large-capacity injections

For 100–1,000 ml per bottle (inclusive of 1,000 ml): 1 sample per 10,000 bottles; quantities ≤10,000 bottles shall be treated as 10,000 bottles.

For ≥1,000 ml per bottle/bag (including dialysate): 1 sample per 5,000 bottles/bags; quantities ≤5,000 bottles/bags shall be treated as 5,000 bottles/bags.

(3) All other types of preparations

1 sample per 20,000 boxes or bottles; quantities fewer than 20,000 boxes or bottles shall be treated as 20,000 boxes or bottles.

7-Sampling Requirements

Before opening the external package for sample collection, the external packaging, shipping mark or contract number, product name, and quantity shall be verified against the inspection application documents. After the external package is opened, the internal packaging shall be checked for the drug or preparation name, manufacturer, and batch number. Inspectors shall also examine the integrity and cleanliness of the packaging and check for water damage, mildew, rot, or other contamination. If any portion of the packaged drug is spoiled or degraded, the sampling and inspection process shall be repeated.
For crude drugs, samples shall be collected from different portions of the batch to ensure that the total quantity meets the prescribed sampling amount. The collected samples shall be transferred directly into the sample container and thoroughly mixed to achieve uniformity. Once sampling is completed, the opened packages shall be resealed and clearly labeled with the sampled quantity and the date of sampling.

8-Points of Attention for Sampling

The sampling environment must be clean, and all sampling tools must be clean, dry, and appropriate for the type of drug being sampled. Measures shall be taken to prevent contamination, moisture absorption, or deterioration of the drug, and samples must be placed in airtight containers, such as plastic bags, cans, or ground glass bottles, immediately after collection. For liquid drugs, the liquid shall be thoroughly mixed before sampling. If crystals are present, they shall be dissolved prior to sampling without affecting the quality.
For toxic, corrosive, or explosive drugs, appropriate protective measures shall be implemented. Such drugs must be handled carefully to prevent vibrations, and containers shall be clearly labeled as "Dangerous Articles." Metal tools shall not be used when sampling corrosive drugs. Drugs that are sensitive to light shall be sampled under dark conditions, and the samples shall be placed in colored containers. If necessary, the colored containers may be wrapped in black paper.
When sampling is required for aseptic, pyrogen, or microbial limit testing, or for vacuum- or nitrogen-filled crude drugs, the procedure shall comply with aseptic techniques or other specific requirements. Sampling shall be conducted by two or more trained professionals, and relevant personnel from the sampled entity shall be present throughout the process. If it is necessary to adjust the sampling method or quantity due to the quality of the batch or abnormal conditions in the packaging, the port drug inspection office, in consultation with the inspection application entity, shall determine the method to ensure representative sampling. Any



modifications to the sampling procedure shall be documented in the Imported Drugs Sampling Record-Keeping Form.