Order of the State Food and Drug Administration

No. 28 _

The "Decision of the State Food and Drug Administration on Amending the Good Manufacturing Practices for Pharmaceutical Products" was reviewed and adopted at the executive meeting of the State Food and Drug Administration on June 30, 2016. It is hereby announced and will come into effect on the date of issuance. .

Director Bi Jingquan

July 13, 2016

State Food and Drug Administration Decision on Amending the "Good Manufacturing Practices for Pharmaceutical Products"

The State Food and Drug Administration has decided to make the following changes to the "Good Manufacturing Practices for Pharmaceutical Products":

1. Amend Article 2 to read: "This specification is the basic guideline for pharmaceutical business management and quality control.

"Enterprises should take effective quality control measures in drug procurement, storage, sales, transportation and other links to ensure drug quality, and establish a drug traceability system in accordance with relevant national requirements to achieve drug traceability."

2. Amend the second paragraph of Article 22 to read: "Those engaged in vaccine distribution shall also have at least two professional and technical personnel specifically responsible for vaccine quality management and acceptance. The professional and technical personnel shall have expertise in preventive medicine, pharmacy, microbiology Or a bachelor's degree or above in medicine or other majors, an intermediate professional technical title or above,

and more than 3 years of experience in vaccine management or technical work.”

3. Amend Article 36, Article 21 to read: “Provisions on drug traceability;”

4. Amend Article 49 to read: “To store and transport refrigerated and frozen drugs, the following facilities and equipment should be equipped:

“(1) Cold storage that is suitable for its business scale and variety, and those that store vaccines should be equipped with two or more independent cold storages;

“(2) Equipment used for automatic monitoring, display, recording, regulation and alarm of cold storage temperature;

“(3) Standby generator sets or dual-circuit power supply systems for cold storage refrigeration equipment;

“(4) For drugs with special low-temperature requirements, facilities and equipment that meet their storage requirements should be equipped;

″(5) Refrigerated trucks and vehicle-mounted refrigerated boxes or insulated boxes and other equipment.″

5. Amend Article 57 to read: “Enterprises should establish a computer system that can meet the management and quality control requirements of the entire business process to achieve drug traceability.”

6. Amend Article 62 to read: “In the review of a first-run enterprise, the following information stamped with its original official seal shall be inspected and confirmed to be true and valid:

“(1) A copy of the “Pharmaceutical Production License” or “Pharmaceutical Business License”;

“(2) Copies of business license, tax registration, organization code, and the disclosure of the company’s annual report for the previous year;

“(3) A copy of the Good Manufacturing Practice for Pharmaceutical Products certification or the Good Manufacturing Practice for Pharmaceutical Products certification;

“(4) Relevant seals and styles of accompanying receipts (tickets);

″(5) Account opening name, account opening bank and account number.″

7. Delete Article 81.

8. Delete Article 82.

9. Change Article 84 to Article 82, and amend it to read: “If an enterprise conducts direct transfer of drugs in accordance with Article 69 of these specifications, it may entrust the purchasing unit to conduct drug acceptance. The purchasing unit shall strictly Inspect and accept drugs in accordance with the requirements of this specification, and establish special acceptance records for directly transferred drugs. Information related to the acceptance records should be passed on to the directly transferred enterprises on the day of acceptance.”

10. Delete Article 102.

11. Change Article 138 to Article 135, and amend Item 17 to read: “Provisions on drug traceability;”

12. Change Article 149 to Article 146, and amend it to read: “Enterprises should establish computer systems that can meet business and quality management requirements, and meet drug traceability requirements.”

13. Change Article 161 to Article 158 and amend it to read: “Drugs that pass the acceptance inspection shall be put into the warehouse or put on the shelves in a timely manner. Those that fail the inspection shall not be put into the warehouse or put on the shelves, and the quality shall be reported. Management handles it.”

14. Delete Article 176.

15. Add an article as Article 181: “The traceability of narcotic drugs, psychotropic drugs, and pharmaceutical precursor chemicals shall comply with relevant national regulations.”

16. Change Article 186 to Article 183, and amend it to read: “If a drug trading enterprise violates these regulations, the food and drug regulatory department shall comply with Article 7 of the Drug Administration Law of the People’s Republic of China. Punishment shall be imposed in accordance with the provisions of Article 18.”

In addition, the order of the provisions will be adjusted accordingly.

This decision shall come into effect from the date of promulgation.

The "Good Manufacturing Practices for Pharmaceutical Products" will be revised accordingly and re-announced based on this decision.

Good Manufacturing Practices for Pharmaceutical Products

(Original State Food and Drug Administration Order No. 20 on April 30, 2000, 2012

The original Ministry of Health executive meeting on November 6, 2015 revised the national version for the first time on May 18, 2015.
The second revision of the Bureau Executive Meeting of the Food and Drug Administration was based on June 30, 2016
State Food and Drug Administration Bureau Executive Meeting "About Modification of "Pharmaceutical Business Quality" Management Code>Decision>Amendment)

Chapter 1 General Provisions

Article 1 In order to strengthen the quality management of drug distribution, standardize drug operation behavior, and ensure the safety and effectiveness of human drugs, these norms are formulated in accordance with the "Drug Administration Law of the People's Republic of China" and the "Regulations for the Implementation of the Drug Administration Law of the People's Republic of China".

Article 2 This specification is the basic guideline for pharmaceutical business management and quality control.

Enterprises should take effective quality control measures in drug procurement, storage, sales, transportation and other links to ensure drug quality, and establish a drug traceability system in accordance with relevant national requirements to achieve drug traceability.

Article 3 Pharmaceutical trading enterprises shall strictly implement these regulations.

Drug manufacturers selling drugs and other activities involving the storage and transportation of drugs in the drug circulation process should also comply with the relevant requirements of this specification.

Article 4 Pharmaceutical trading enterprises shall adhere to honesty and trustworthiness and operate in accordance with the law. Any false or deceptive behavior is prohibited.

Chapter 2 Quality Management of Pharmaceutical Wholesale

Section 1 Quality Management System

Article 5 Enterprises shall establish a quality management system in accordance with relevant laws, regulations and the requirements of this specification, determine quality policies, formulate quality

management system documents, and carry out quality planning, quality control, quality assurance, quality improvement, quality risk management and other activities.

Article 6: The quality policy document formulated by an enterprise shall clarify the overall quality objectives and requirements of the enterprise, and shall be implemented into the entire process of pharmaceutical business activities.

Article 7 An enterprise's quality management system shall be commensurate with its business scope and scale, including organizational structure, personnel, facilities and equipment, quality management system documents and corresponding computer systems, etc.

Article 8 Enterprises shall organize internal audits regularly and when there are major changes in key elements of the quality management system.

Article 9 Enterprises shall analyze the internal audit situation, formulate corresponding quality management system improvement measures based on the analysis conclusions, continuously improve the quality control level, and ensure the continuous and effective operation of the quality management system.

Article 10 Enterprises shall use a prospective or retrospective approach to assess, control, communicate and review quality risks in the drug circulation process.

Article 11 Enterprises shall evaluate the quality management systems of drug suppliers and purchasing units, confirm their quality assurance capabilities and quality reputation, and conduct on-site inspections when necessary.

Article 12: An enterprise shall involve all employees in quality management. Personnel in each department and position should correctly understand and perform their duties and assume corresponding quality responsibilities.

Section 2 Organizational Structure and Quality Management Responsibilities

Article 13 An enterprise shall establish organizational structures or positions that are compatible with its business activities and quality management, and clearly define its responsibilities, authorities and mutual relationships.

Article 14 The person in charge of the enterprise is the main person responsible for drug quality and is fully responsible for the daily management of the enterprise. He is responsible for providing the necessary conditions to ensure that the quality management department and quality management personnel effectively perform their duties and ensure that the enterprise achieves quality objectives and operates in accordance with the requirements of this specification. drug.

Article 15 The person in charge of quality of an enterprise shall be a senior manager who shall be fully responsible for drug quality management, perform duties independently, and have the power to make decisions on drug quality management within the enterprise.

Article 16 An enterprise shall establish a quality management department to effectively carry out quality management work. The responsibilities of the quality management department shall not be performed by other departments and personnel.

Article 17 The quality management department shall perform the following duties:

(1) Supervise relevant departments and personnel to implement laws and regulations on drug management and these specifications;

(2) Organize the formulation of quality management system documents, and guide and supervise the implementation of the documents;

(3) Responsible for reviewing the legality of the supplying unit and purchasing unit, the legality of purchased drugs, and the legal qualifications of the supplying unit's sales personnel and purchasing unit purchasers, and conduct dynamic management based on changes in the audit content;

(4) Responsible for the collection and management of quality information and establishing drug quality files;

(5) Responsible for the acceptance of drugs, guiding and supervising the quality management of drug procurement, storage, maintenance, sales, returns, transportation and other links;

(6) Responsible for the confirmation of substandard drugs and supervision of the handling process of substandard drugs;

(7) Responsible for the investigation, handling and reporting of drug quality complaints and quality incidents;

(8) Responsible for reporting on counterfeit and substandard drugs;

(9) Responsible for drug quality inquiries;

(10) Responsible for guiding the setting of computer system quality control functions;

(11) Responsible for the review of computer system operation authority and the establishment and update of basic quality management data;

(12) Organize the verification and calibration of relevant facilities and equipment;

(13) Responsible for the management of drug recalls;

(14) Responsible for reporting adverse drug reactions;

(15) Organize internal audits and risk assessments of the quality management system;

(16) Organize inspections and evaluations of the quality management system and service quality of drug suppliers and purchasers;

(17) Organize a review of the transportation conditions and quality assurance capabilities of the carrier entrusted with transportation;

(18) Assist in quality management education and training;

(19) Other duties that should be performed by the quality management department.

Section 3 Personnel and Training

Article 18: Personnel engaged in drug operation and quality management in an enterprise shall meet the qualification requirements stipulated in relevant laws, regulations and these specifications, and shall not be prohibited from practicing by relevant laws and regulations.

Article 19 The person in charge of an enterprise shall have a college degree or above or a professional technical title above the intermediate level, have received basic pharmaceutical professional knowledge training, and be familiar with laws and regulations related to drug management and these specifications.

Article 20: The person in charge of enterprise quality shall have a bachelor's degree or above, a practicing pharmacist qualification and more than three years of experience in drug operation quality management, and have the ability to make correct judgments and ensure implementation in quality management work.

Article 21 The person in charge of the enterprise's quality management department shall have the qualification of a practicing pharmacist and more than three years of experience in drug operation quality management, and be able to independently solve quality problems in the operation process.

Article 22 An enterprise shall be equipped with personnel for quality management, acceptance and maintenance positions who meet the following qualification requirements:

(1) Those engaged in quality management work should have a technical secondary school degree in pharmacy or a college degree or above in medicine, biology, chemistry or other related majors, or a professional technical title above junior level in pharmacy.

(2) Those engaged in acceptance and maintenance work must have a technical secondary school degree or above in pharmacy or medicine, biology, chemistry or other related majors, or have a professional technical title above junior level in pharmacy.

(3) Those who are engaged in the acceptance of Chinese medicinal materials and Chinese herbal pieces must have a technical secondary school degree or above in the major of Chinese materia medica or have an intermediate professional technical title or above in Chinese materia medica; those who are engaged in the maintenance of Chinese herbal materials and Chinese herbal pieces must have a technical secondary school degree or above in the major of Chinese materia medica. degree or have a junior or above professional and technical title in Chinese Materia Medica; when purchasing real estate Chinese medicinal materials directly, the acceptance personnel should have an intermediate or above professional and technical title in Chinese Materia Medica.

Those engaged in vaccine distribution should also have at least two professional and technical personnel responsible for vaccine quality management and acceptance. Professional and technical personnel should have a bachelor's degree or above in preventive medicine, pharmacy, microbiology or medicine, and a professional technical title above intermediate level, and have more than three years of experience in vaccine management or technical work.

Article 23 Personnel engaged in quality management and acceptance work shall be on-the-job and shall not work part-time in other business jobs.

Article 24 Personnel engaged in procurement work shall have a technical secondary school degree or above in pharmacy or medicine, biology, chemistry or other related majors, and persons engaged in sales, storage, etc. shall have a high school education or above.

Article 25: Enterprises shall provide pre-job training and continuing training for personnel in each position related to their

responsibilities and work content to comply with the requirements of this specification.

Article 26 The training content should include relevant laws and regulations, pharmaceutical professional knowledge and skills, quality management systems, responsibilities and job operating procedures, etc.

Article 27 Enterprises shall formulate annual training plans and conduct training in accordance with the training management system so that relevant personnel can correctly understand and perform their duties. Training work should be well recorded and archived.

Article 28 Personnel engaged in the storage and transportation of specially managed drugs and refrigerated and frozen drugs shall receive relevant laws, regulations and professional knowledge training and must pass the assessment before taking up their posts.

Article 29 Enterprises shall formulate employee personal hygiene management systems, and the clothing of personnel in storage, transportation and other positions shall comply with labor protection and product protection requirements.

Article 30: Personnel in positions such as quality management, acceptance, maintenance, storage, etc. who have direct contact with pharmaceuticals shall undergo pre-job and annual health examinations and establish health files. Those suffering from infectious diseases or other diseases that may contaminate medicines are not allowed to engage in work with direct contact with medicines. Those whose physical conditions do not meet the specific requirements of the corresponding positions shall not engage in relevant work.

Section 4 Quality Management System Documents

Article 31: The quality management system documents formulated by an enterprise shall be consistent with the actual situation of the enterprise. Documents include quality management systems, department and job responsibilities, operating procedures, files, reports, records and vouchers, etc.

Article 32: The drafting, revision, review, approval, distribution, storage, modification, cancellation, replacement, destruction, etc. of documents shall be carried out in accordance with the document management operating procedures, and relevant records shall be kept.

Article 33: Documents shall indicate the title, category, purpose, document number and version number. The text should be accurate, clear, and understandable.

Documents should be stored in categories for easy reference.

Article 34: Enterprises shall review and revise documents regularly, and the documents used shall be current and valid documents. Documents that have been abolished or invalid shall not appear at the work site except for keeping files for future reference.

Article 35: Enterprises shall ensure that each position obtains necessary documents corresponding to its work content and carry out work in strict accordance with regulations.

Article 36 The quality management system shall include the following contents:

(1) Provisions for internal audit of the quality management system;

(2) Provisions on quality veto power;

(3) Management of quality management documents;

(4) Management of quality information;

(5) Regulations on qualification review of supplier units, purchasing units, supplier unit sales personnel, and purchasing unit purchasing personnel;

(6) Management of drug procurement, receipt, acceptance, storage, maintenance, sales, shipment, and transportation;

(7) Regulations on drugs under special management;

(8) Management of drug validity period;

(9) Management of substandard drugs and drug destruction;

(10) Management of drug returns;

(11) Management of drug recalls;

(12) Management of quality inquiries;

(13) Management of quality accidents and quality complaints;

(14) Regulations on reporting adverse drug reactions;

(15) Regulations on environmental sanitation and personnel health;

(16) Regulations on quality education, training and assessment;

(17) Management of the storage and maintenance of facilities and equipment;

(18) Management of facility and equipment verification and calibration;

(19) Management of records and vouchers;

(20) Management of computer systems;

(21) Regulations on drug traceability;

(22) Other contents that should be stipulated.

Article 37 Department and position responsibilities should include:

(1) Responsibilities of quality management, procurement, storage, sales, transportation, finance and information management and other departments;

(2) Job responsibilities of the person in charge of the enterprise, the person in charge of quality, and the person in charge of quality management, procurement, storage, sales, transportation, finance and information management departments;

(3) Job responsibilities such as quality management, procurement, receipt, acceptance, storage, maintenance, sales, outbound review, transportation, finance, information management, etc.;

(4) Other job responsibilities related to pharmaceutical operations.

Article 38: Enterprises shall formulate operating procedures for drug procurement, receipt, acceptance, storage, maintenance, sales, warehouse review, transportation and other links as well as computer systems.

Article 39 Enterprises should establish relevant records such as drug procurement, acceptance, maintenance, sales, warehouse review, post-sale returns and purchases and exits, transportation, storage and transportation temperature and humidity monitoring, and disposal of unqualified drugs to be true, complete, and accurate , effective and traceable.

Article 40 When recording data through the computer system, relevant personnel should follow the operating procedures and log in with authorization and password before entering or reviewing the data; changes to the data should be reviewed by the quality management department and carried out under its supervision. The change process Records should be kept.

Article 41 Written records and vouchers must be filled in in a timely manner and must be written clearly and must not be altered or torn at will. If the record is changed, the reason, date and signature should be indicated, and the original information should be kept clear and legible.

Article 42 Records and vouchers shall be kept for at least 5 years. Records and vouchers of vaccines and specially managed drugs are kept in accordance with relevant regulations.

Section 5 Facilities and Equipment

Article 43: An enterprise shall have business premises and warehouses that are commensurate with its pharmaceutical business scope and business scale.

Article 44: The location, design, layout, construction, renovation and maintenance of warehouses shall comply with the requirements for drug storage and prevent contamination, cross-contamination, confusion and errors of drugs.

Article 45: The drug storage operation area and auxiliary operation area should be separated from the office area and living area by a certain distance or have isolation measures.

Article 46 The scale and conditions of the warehouse should meet the reasonable and safe storage of drugs, and meet the following requirements to facilitate storage operations:

(1) The environment inside and outside the warehouse is clean and tidy, with no sources of pollution, and the ground in the warehouse area is hardened or greened;

(2) The interior walls and ceiling of the warehouse are smooth and clean, the floor is flat, and the doors and windows are tightly constructed;

(3) The warehouse has reliable safety protection measures that can control the entry of irrelevant personnel and prevent drugs from being stolen, substituted or mixed with counterfeit drugs;

(4) There are measures to prevent outdoor loading, unloading, handling, receiving, shipping and other operations from being affected by abnormal weather.

Article 47 The warehouse shall be equipped with the following facilities and equipment:

(1) Equipment for effective isolation between medicines and the ground;

(2) Light protection, ventilation, moisture-proof, insect-proof, rodent-proof and other equipment;

(3) Equipment to effectively control temperature, humidity and indoor and outdoor air exchange;

(4) Equipment that automatically monitors and records warehouse temperature and humidity;

(5) Lighting equipment that meets the requirements for storage operations;

(6) Operation areas and equipment used for piece picking, LCL shipping operations and review;

(7) Storage place of packaging materials;

(8) Dedicated places for acceptance, delivery and returns;

(9) Special storage place for unqualified drugs;

(10) Drugs under special management must have storage facilities that comply with national regulations.

Article 48 Those who deal in Chinese herbal medicines and Chinese herbal medicine pieces should have dedicated warehouses and maintenance workplaces, and those who directly purchase real estate Chinese herbal medicines should set up a Chinese medicine sample room (cabinet).

Article 49 When storing and transporting refrigerated or frozen medicines, the following facilities and equipment should be equipped:

(1) Cold storage that is suitable for its business scale and variety. Those that store vaccines should be equipped with two or more independent cold storages;

(2) Equipment used for automatic monitoring, display, recording, regulation and alarm of cold storage temperature;

(3) Standby generator sets or dual-circuit power supply systems for cold storage refrigeration equipment;

(4) For drugs with special low-temperature requirements, facilities and equipment that meet their storage requirements should be equipped;

(5) Refrigerated trucks and vehicle-mounted refrigerated boxes or insulated boxes and other equipment.

Article 50: Closed cargo transport vehicles shall be used to transport medicines.

Article 51 Refrigerated trucks and vehicle-mounted refrigerated boxes and insulated boxes that transport refrigerated and frozen medicines must meet the requirements for temperature control during the transportation of medicines. The refrigerated truck has the functions of automatically regulating temperature, displaying temperature, storing and reading temperature monitoring data; the refrigerated box and the insulated box have the function of external display and collection of temperature data inside the box.

Article 52: Regular inspection, cleaning and maintenance of storage and transportation facilities and equipment shall be carried out by dedicated personnel, and records and files shall be established.

Section 6 Calibration and Verification

Article 53 Enterprises shall, in accordance with relevant national regulations, regularly calibrate or verify measuring instruments, temperature and humidity monitoring equipment, etc.

Enterprises should conduct pre-use verification, periodic verification, and verification if the outage time exceeds the prescribed time limit for cold storage, storage and transportation temperature and humidity monitoring systems, and refrigerated transportation and other facilities and equipment.

Article 54: Enterprises shall formulate verification control documents according to relevant verification management systems, including verification plans, reports, evaluations, deviation handling and preventive measures, etc.

Article 55: Verification shall be implemented in accordance with a predetermined and approved plan, verification reports shall be reviewed and approved, and verification documents shall be archived.

Article 56: Enterprises shall use relevant facilities and equipment correctly and reasonably based on the parameters and conditions determined by verification.

Section 7 Computer Systems

Article 57: Enterprises should establish a computer system that can meet the requirements for full-process management and quality control of operations to achieve drug traceability.

Article 58: Enterprise computer systems shall meet the following requirements:

(1) Have servers and terminals that support the normal operation of the system;

(2) Have a safe and stable network environment, a fixed way to access the Internet, and a safe and reliable information platform;

(3) There is a local area network that enables information transmission and data sharing between departments and positions;

(4) Have the functions of generating, printing and managing pharmaceutical business bills;

(5) Have application software and related databases that meet the requirements of this specification and the actual needs of enterprise

management.

Article 59: The entry, modification, storage and other operations of various types of data shall comply with the requirements of the scope of authorization, operating procedures and management systems to ensure that the data is original, authentic, accurate, safe and traceable.

Article 60: Data related to enterprise operation and management during the operation of computer systems shall be stored in a safe and reliable manner and backed up on a daily basis. Backup data shall be stored in a safe place. The storage period of record data shall comply with Article 42 of this Code. Article requirements.

Section 8 Procurement

Article 61: An enterprise's procurement activities shall meet the following requirements:

(1) Determine the legal qualifications of the supplier;

(2) Determine the legality of the purchased drugs;

(3) Verify the legal qualifications of the supplier's sales personnel;

(4) Sign a quality assurance agreement with the supplier.

For first-run enterprises and first-run varieties involved in procurement, the procurement department shall fill in the relevant application forms, which shall be reviewed and approved by the quality management department and the enterprise's quality director. When necessary, on-site inspections should be organized to evaluate the quality management system of the supplier.

Article 62: In the review of a first-run enterprise, the following information stamped with its original official seal shall be inspected and confirmed to be true and valid:

(1) A copy of the "Drug Production License" or "Drug Business License";

(2) Copies of business license, tax registration, organization code, and the disclosure of the company's annual report for the previous year;

(3) A copy of the "Good Manufacturing Practice for Pharmaceutical Products" certification certificate or the "Good Manufacturing Practice for Pharmaceutical Products" certification certificate;

(4) Relevant seals and styles of accompanying receipts (tickets);

(5) Account name, bank and account number.

Article 63: When purchasing first-market varieties, the legality of drugs must be reviewed, and copies of drug production or import approval documents stamped with the original official seal of the supplier must be obtained and reviewed. Only if the review is correct can the purchase be made.

The above information should be included in the drug quality files.

Article 64: Enterprises shall verify and retain the following information of the supplier's sales personnel:

(1) A copy of the salesperson's ID card stamped with the original official seal of the supplier;

(2) A letter of authorization stamped with the original official seal of the supplier and the seal or signature of the legal representative. The letter of authorization shall state the name of the authorized person, ID number, as well as the variety, region and period of authorized sales;

(3) Information related to supplier units and supply varieties.

Article 65: The quality assurance agreement signed between the enterprise and the supplier shall at least include the following contents:

(1) Clarify the quality responsibilities of both parties;

(2) The supplier shall provide information that meets the regulations and be responsible for its authenticity and validity;

(3) The supplier shall issue invoices in accordance with national regulations;

(4) Drug quality meets drug standards and other relevant requirements;

(5) Drug packaging, labels, and instructions comply with relevant regulations;

(6) Quality assurance and responsibility for drug transportation;

(7) Validity period of the quality assurance agreement.

Article 66: When purchasing drugs, the enterprise shall obtain an invoice from the supplier. The invoice should list the generic name, specifications, units, quantity, unit price, amount, etc. of the drug; if it cannot be specified in full, a "List of Goods Sold or Taxable Services Provided" should be attached, and the original seal of the supplier's special invoice seal should be affixed. , indicate the tax invoice number.

Article 67 The name of the purchasing and selling unit, the amount, and the name of the product on the invoice shall be consistent with the payment flow, amount, and product name, and shall correspond to the contents of the financial accounts. Invoices are kept in accordance with relevant regulations.

Article 68: Procurement records must be established when purchasing drugs. Procurement records should include the generic name, dosage form, specifications, manufacturer, supplier, quantity, price, purchase date, etc. of the drug. When purchasing Chinese herbal medicines and Chinese herbal medicine pieces, the place of origin should also be indicated.

Article 69: In the event of special circumstances such as disasters, epidemics, emergencies or clinical emergency treatment, and other situations that comply with relevant national regulations, enterprises may purchase and sell drugs through direct transfer, and the purchased drugs will not be placed in the enterprise's warehouse. Send directly from the supplier to the purchasing unit, and establish special purchasing records to ensure effective quality tracking and traceability.

Article 70: The procurement of drugs under special management shall be carried out in strict accordance with relevant national regulations.

Article 71: Enterprises shall regularly conduct comprehensive quality reviews on the overall situation of drug procurement, establish drug quality reviews and supplier quality files, and conduct dynamic tracking management.

Section 9 Receipt and Acceptance

Article 72: Enterprises shall receive and inspect the incoming drugs batch by batch in accordance with prescribed procedures and requirements to prevent substandard drugs from entering the warehouse.

Article 73 When medicines arrive, the receiving personnel should verify whether the transportation method meets the requirements, and check the medicines against the accompanying invoices (tickets) and purchase records to ensure that the invoices, accounts, and goods are consistent.

The accompanying slip (ticket) should include the supplier, manufacturer, generic name, dosage form, specification, batch number,

quantity, receiving unit, receiving address, delivery date, etc. of the drug, and should be stamped with the drug of the supplier The original seal dedicated to shipping out of warehouse.

Article 74 When refrigerated and frozen medicines arrive, key inspections and records shall be conducted on their transportation methods, temperature records during transportation, transportation time and other quality control conditions. Products that do not meet the temperature requirements shall be rejected.

Article 75: The receiving personnel shall place the drugs that meet the receiving requirements in the corresponding areas to be inspected according to the characteristics of the varieties, or set up status signs to notify acceptance. Refrigerated and frozen medicines should be kept in cold storage pending inspection.

Article 76 When accepting drugs, the inspection report of the same batch number shall be checked according to the drug batch number. If the supplier is a wholesale enterprise, the inspection report shall be stamped with its original quality management seal. The transmission and storage of the inspection report can be in the form of electronic data, but its legality and validity should be ensured.

Article 77: Enterprises shall, in accordance with the acceptance regulations, conduct batch-by-batch sampling inspection of each arriving drug, and the samples taken shall be representative:

(1) At least one minimum package of drugs with the same batch number should be inspected. However, if the manufacturer has special quality control requirements or opening the minimum package may affect the quality of the drug, the minimum package does not need to be opened;

(2) If there are packaging abnormalities such as damage, contamination, leakage, or damaged seals, as well as individual items or LCLs, the packaging should be unpacked and inspected to the minimum packaging;

(3) APIs with complete outer packaging and sealing, and biological products subject to batch release management do not need to be opened for inspection.

Article 78 The acceptance personnel shall inspect and verify the appearance, packaging, labels, instructions and relevant supporting documents of the sampled drugs one by one; after the acceptance inspection, the intact samples taken shall be returned to the original packaging box, sealed and labeled. .

Article 79: Drugs under special management shall be inspected and accepted in special warehouses or special areas in accordance with relevant regulations.

Article 80 Acceptance records shall be kept for drugs to be accepted, including the common name, dosage form, specifications, approval number, batch number, production date, validity period, manufacturer, supplier, arrival quantity, arrival date, and acceptance of the drug. Quantity, acceptance results, etc. The acceptance personnel shall sign their name and acceptance date on the acceptance record.

The acceptance record of Chinese medicinal materials shall include the name of the product, place of origin, supplier, quantity of arrival, quantity that has passed the acceptance inspection, etc. The acceptance record of traditional Chinese medicine prepared pieces should include product name, specifications, batch number, place of origin, production date, manufacturer, supplier, quantity of arrival, quantity that has passed the acceptance inspection, etc. Chinese medicine prepared pieces that are subject to approval number management should also record the approval number.

If the inspection fails, the unqualified matters and disposal measures should also be noted.

Article 81: Enterprises shall establish inventory records, and drugs that pass the acceptance inspection shall be put into the warehouse for registration in a timely manner; drugs that fail the acceptance inspection shall not be put into the warehouse and shall be handled by the quality management department.

Article 82: If an enterprise conducts direct transfer of drugs in accordance with Article 69 of these specifications, it may entrust the purchasing unit to conduct drug acceptance. Purchasing units shall strictly comply with the requirements of this specification to accept drugs and establish special acceptance records for directly adjusted drugs. On the day of acceptance, the relevant information of the acceptance record shall be transmitted to the direct adjustment enterprise.

Section 10 Storage and Maintenance

Article 83: Enterprises shall reasonably store drugs based on their quality characteristics and meet the following requirements:

(1) Store drugs according to the temperature requirements indicated on the packaging. If there is no specific temperature indicated on the packaging, they shall be stored in accordance with the storage requirements stipulated in the Pharmacopoeia of the People's Republic of China;

(2) The relative humidity of stored drugs is 35%-75%;

(3) Drugs are stored in manual warehouses, and color-coded management is implemented according to quality status. Qualified drugs are green, unqualified drugs are red, and drugs to be determined are yellow;

(4) When storing medicines, measures such as light protection, shading, ventilation, moisture-proof, insect-proof, and rodent-proof shall be adopted as required;

(5) The handling and stacking of medicines should be carried out in strict accordance with the requirements for labeling on the outer packaging, and the stacking height should comply with the requirements of the packaging illustrations to avoid damaging the medicine packaging;

(6) Drugs are stacked according to batch numbers. Drugs with different batch numbers are not allowed to be stacked. The distance between stacks is not less than 5 cm. The distance between the stacks is not less than 30 cm. centimeter;

(7) Drugs and non-drugs, external drugs and other drugs are stored separately, and Chinese medicinal materials and Chinese herbal pieces are stored in separate warehouses;

(8) Specially managed drugs should be stored in accordance with relevant national regulations;

(9) Retail medicines with their outer packaging removed should be stored in a centralized manner;

(10) Shelves, pallets and other facilities and equipment for storing medicines should be kept clean and free of damage and debris;

(11) Unauthorized personnel are not allowed to enter the storage operation area, and personnel in the storage operation area are not allowed to conduct behaviors that affect the quality and safety of drugs;

(12) Items unrelated to storage management shall not be stored in the drug storage operation area.

Article 84 Maintenance personnel shall maintain drugs according to warehouse conditions, external environment, drug quality

characteristics, etc. The main contents are:

(1) Guide and urge storage personnel to properly store and operate drugs.

(2) Check and improve storage conditions, protective measures, and sanitary environment.

(3) Effectively monitor and regulate the temperature and humidity of the warehouse.

(4) Inspect the appearance, packaging and other quality conditions of the drugs in stock according to the maintenance plan, and establish maintenance records; varieties with special requirements for storage conditions or short validity periods should be subject to key maintenance.

(5) Drugs with problems found should be locked and recorded in the computer system in a timely manner, and the quality management department should be notified for processing.

(6) Effective methods should be adopted to maintain and record Chinese medicinal materials and Chinese medicinal pieces according to their characteristics. The maintenance methods adopted should not cause contamination to the medicines.

(7) Regularly summarize and analyze maintenance information.

Article 85 Enterprises should use computer systems to automatically track and control the expiration dates of drugs in stock, and take measures such as early warnings about the expiration date and automatic locking after the expiration date to prevent the sale of expired drugs.

Article 86: When medicines are damaged and cause leakage of liquid, gas, or powder, safety measures should be taken quickly to prevent contamination of the storage environment and other medicines.

Article 87: Drugs of doubtful quality should be immediately suspended from sale, locked in the computer system, and reported to the quality management department for confirmation. The following measures should be taken for drugs with quality problems:

(1) Stored in a clearly marked special place and effectively isolated, and shall not be sold;

(2) If a drug is suspected to be counterfeit, report it to the food and drug supervision and administration department in a timely manner;

(3) Drugs under special management shall be handled in accordance with relevant national regulations;

(4) The handling process of substandard drugs should have complete procedures and records;

(5) The reasons for substandard drugs should be identified and analyzed, and preventive measures should be taken in a timely manner.

Article 88: Enterprises shall conduct regular inventory of medicines in stock to ensure that accounts and goods are consistent.

Section 11 Sales

Article 89: Enterprises shall sell drugs to legal purchasing units, and verify the purchasing unit's certification documents and the identity certificates of purchasing personnel and delivery personnel to ensure that the flow of drug sales is true and legal.

Article 90: Enterprises shall strictly review the production scope, business scope or diagnosis and treatment scope of the purchasing unit, and sell drugs according to the corresponding scope.

Article 91 When an enterprise sells medicines, it shall issue invoices truthfully so that the invoices, accounts, goods and payments are consistent.

Article 92: Enterprises shall keep good drug sales records. Sales records should include the generic name, specifications, dosage form, batch number, validity period, manufacturer, purchasing unit, sales quantity, unit price, amount, sales date, etc. of the drug. If direct drug transfer is carried out in accordance with the provisions of Article 69 of these specifications, special sales records shall be established.

The sales records of Chinese herbal medicines should include the product name, specifications, origin, purchasing unit, sales quantity, unit price, amount, sales date, etc.; the sales records of Chinese herbal medicine pieces should include the product name, specifications, batch number, origin, manufacturer, purchasing unit, sales date, etc. Quantity, unit price, amount, sales date, etc.

Article 93 The sale of drugs under special management and drugs with special management requirements by the state shall be strictly implemented in accordance with relevant state regulations.

Section 12 Departure from the warehouse

Article 94 When leaving the warehouse, a review shall be made against the sales record. If the following conditions are found, they shall not be shipped out of the warehouse and reported to the quality management department for processing:

(1) Problems such as damage, contamination, loose sealing, incorrect padding, damaged seals, etc. in pharmaceutical packaging;

(2) There is abnormal noise or liquid leakage in the package;

(3) The label has fallen off, the writing is unclear, or the content of the label does not match the actual object;

(4) The drug has expired;

(5) Drugs for other abnormal situations.

Article 95: Records shall be established for the review of drugs leaving the warehouse, including the purchasing unit, the generic name of the drug, dosage form, specification, quantity, batch number, expiration date, manufacturer, date of shipment, quality status and review personnel, etc.

Article 96: The shipment of drugs under special management from the warehouse shall be reviewed in accordance with relevant regulations.

Article 97 Substitute packaging boxes for LCL shipment of pharmaceuticals should have eye-catching LCL signs.

Article 98 When drugs are shipped out of the warehouse, an accompanying receipt (ticket) stamped with the original seal of the company's special drug shipping stamp shall be attached.

If an enterprise directly transfers drugs in accordance with the provisions of Article 69 of these specifications, when the directly transferred drugs leave the warehouse, the supplier will issue two accompanying orders (tickets) and send them to the direct transfer enterprise and the purchasing unit respectively. The content of the accompanying bill (ticket) shall comply with the requirements of paragraph 2 of Article 73 of these specifications, and shall also indicate the name of the direct transfer enterprise.

Article 99: Packing and loading of refrigerated and frozen medicines shall be carried out by dedicated personnel and shall meet the following requirements:

(1) Vehicle-mounted refrigerators or insulated boxes should meet the corresponding temperature requirements before use;

(2) Packing and sealing of refrigerated and frozen drugs should be completed in a refrigerated environment;

(3) The starting and operating status of the refrigerated vehicle should be checked before loading, and the vehicle can be loaded only after reaching the specified temperature;

(4) Transportation records should be kept at the time of departure, including the means of transportation and departure time.

Section 13 Transportation and Distribution

Article 100: Enterprises shall strictly implement transportation operating procedures in accordance with the requirements of the quality management system, and take effective measures to ensure the quality and safety of drugs during transportation.

Article 101: To transport medicines, appropriate means of transportation should be selected based on the packaging and quality characteristics of the medicines, as well as vehicle conditions, roads, weather and other factors, and corresponding measures should be taken to prevent damage, contamination and other problems.

Article 102: When shipping drugs, the means of transportation shall be inspected. If the transportation conditions are found not to meet the regulations, they shall not be shipped. During the transportation of drugs, the vehicle should be kept airtight.

Article 103: Enterprises shall handle, load and unload drugs in strict accordance with the requirements marked on the outer packaging.

Article 104: Enterprises shall take necessary heat preservation or refrigeration and freezing measures during transportation according to the temperature control requirements of drugs.

During transportation, drugs must not come into direct contact with cold storage agents such as ice packs and ice rows to prevent any impact on the quality of the drugs.

Article 105: During the transportation of refrigerated and frozen medicines, the temperature data in refrigerated trucks, refrigerated boxes or insulated boxes shall be monitored and recorded in real time.

Article 106: Enterprises shall formulate emergency plans for the transportation of refrigerated and frozen pharmaceuticals, and be able to take corresponding measures to deal with emergencies such as equipment failures, abnormal weather effects, traffic congestion, etc. that may occur during transportation.

Article 107: If an enterprise entrusts other units to transport drugs, it shall audit the quality assurance capabilities of the carrier

for transporting drugs and obtain relevant information on the transport vehicles. Only those that meet the conditions and requirements of transportation facilities and equipment in this specification can be entrusted.

Article 108: Enterprises entrusted to transport drugs shall sign a transportation agreement with the carrier to clarify drug quality responsibilities, comply with transportation operating procedures, and in-transit time limits, etc.

Article 109: Enterprises entrusting the transportation of drugs should have records to achieve quality traceability during the transportation process. The record shall at least include the delivery time, delivery address, receiving unit, delivery address, bill of lading number, number of medicines, mode of transportation, entrusted person, and carrier. If a vehicle is used for transportation, the license plate number shall also be stated and retained. A copy of the driver's driver's license. Records should be kept for at least 5 years.

Article 110: Medicines that have been loaded into trucks must be shipped promptly and delivered as soon as possible. If transportation is entrusted, the enterprise shall require and supervise the carrier to strictly implement the entrusted transportation agreement to prevent the quality of the drug from being affected by long transit time.

Article 111 Enterprises shall adopt transportation safety management measures to prevent accidents such as drug theft, loss, and replacement during transportation.

Article 112: The transportation of drugs under special management shall comply with relevant national regulations.

Section 14 After-sales Management

Article 113: Enterprises should strengthen the management of returns, ensure the quality and safety of drugs during the return process, and prevent the mixing of counterfeit drugs.

Article 114 : Enterprises shall, in accordance with the requirements of the quality management system, formulate complaint management operating procedures, including complaint channels and methods, file records, investigation and evaluation, handling measures, feedback and subsequent follow-up, etc.

Article 115 Enterprises should assign full-time or part-time personnel to be responsible for after-sales complaint management, identify the causes of quality problems complained of, take effective measures to handle and provide feedback in a timely manner, keep records, and notify the supplier and drug supplier when necessary. manufacturer.

Article 116: Enterprises shall record complaints and handling results and other information in files in a timely manner for inquiry and tracking.

Article 117: If an enterprise discovers that a sold drug has serious quality problems, it shall immediately notify the purchasing unit to stop selling, recover and keep records, and report to the food and drug supervision and administration department at the same time.

Article 118 Enterprises shall assist pharmaceutical manufacturers in fulfilling their recall obligations, promptly communicate and feedback drug recall information in accordance with the requirements of the recall plan, control and recall drugs with potential safety hazards, and establish drug recall records.

Article 119 The quality management department of an enterprise shall be equipped with full-time or part-time personnel to undertake the monitoring and reporting of adverse drug reactions in accordance with relevant national regulations.

Chapter 3 Quality Management of Pharmaceutical Retailing

Section 1 Quality Management and Responsibilities

Article 120 : Enterprises shall formulate quality management documents and carry out quality management activities in accordance with relevant laws, regulations and the requirements of these specifications to ensure drug quality.

Article 121: An enterprise shall have operating conditions commensurate with its business scope and scale, including organizational structure, personnel, facilities and equipment, and quality management documents, and shall set up computer systems in accordance with regulations.

Article 122: The person in charge of an enterprise is the main person responsible for drug quality and is responsible for the daily management of the enterprise. He is responsible for providing necessary

conditions to ensure that the quality management department and quality management personnel effectively perform their duties and ensure that the enterprise operates drugs in accordance with the requirements of this specification.

Article 123 An enterprise shall set up a quality management department or assign quality management personnel to perform the following duties:

(1) Supervise relevant departments and personnel to implement laws and regulations on drug management and these specifications;

(2) Organize the formulation of quality management documents, and guide and supervise the implementation of the documents;

(3) Responsible for the review of the qualification certificates of supplier units and their sales personnel;

(4) Responsible for reviewing the legality of purchased drugs;

(5) Responsible for the acceptance of drugs, guiding and supervising the quality management of drug procurement, storage, display, sales and other links;

(6) Responsible for drug quality inquiry and quality information management;

(7) Responsible for the investigation, handling and reporting of drug quality complaints and quality incidents;

(8) Responsible for the confirmation and handling of substandard drugs;

(9) Responsible for reporting on counterfeit and substandard drugs;

(10) Responsible for reporting adverse drug reactions;

(11) Carry out drug quality management education and training;

(12) Responsible for the review and control of computer system operation permissions and the maintenance of basic quality management data;

(13) Responsible for organizing the calibration and verification of measuring instruments;

(14) Guide and supervise pharmaceutical service work;

(15) Other duties that should be performed by the quality management department or quality management personnel.

Section 2 Personnel Management

Article 124: Personnel engaged in drug operation and quality management in an enterprise shall meet the qualification requirements

stipulated in relevant laws, regulations and these specifications, and shall not be prohibited from practicing by relevant laws and regulations.

Article 125: The legal representative of an enterprise or the person in charge of the enterprise shall have the qualification of a practicing pharmacist.

Enterprises should deploy licensed pharmacists in accordance with relevant national regulations to be responsible for reviewing prescriptions and guiding the rational use of drugs.

Article 126: Quality management, acceptance, and procurement personnel should have a degree in pharmacy or medicine, biology, chemistry, or other related majors or have a professional technical title in pharmacy. Personnel engaged in quality management, acceptance and procurement of traditional Chinese medicine pieces should have a technical secondary school degree or above in traditional Chinese medicine or a professional technical title above junior level in traditional Chinese medicine.

Salespersons should have a high school education or above or meet the conditions stipulated by the provincial food and drug supervision and administration department. Personnel dispensing traditional Chinese medicine pieces should have a technical secondary school degree or above in traditional Chinese medicine or have the qualification of a traditional Chinese medicine dispenser.

Article 127: Personnel in each position of the enterprise shall receive pre-job training and continuing training on relevant laws, regulations and pharmaceutical professional knowledge and skills to comply with the requirements of this specification.

Article 128: Enterprises shall formulate annual training plans and conduct training in accordance with the training management system so that relevant personnel can correctly understand and perform their duties. Training work should be well recorded and archived.

Article 129: Enterprises shall provide conditions for personnel who sell specially managed drugs, drugs with special national management requirements, and refrigerated drugs to receive corresponding training so that they can master relevant laws, regulations and professional knowledge.

Article 130: In business premises, enterprise staff shall wear clean and sanitary work clothes.

Article 131: Enterprises shall conduct pre-job and annual health examinations for personnel in direct contact with pharmaceuticals, and establish health files. Those suffering from infectious diseases or other diseases that may contaminate medicines are not allowed to engage in work with direct contact with medicines.

Article 132 Articles unrelated to business activities and personal belongings shall not be stored in areas such as drug storage and display, and no behavior may affect the quality and safety of drugs in the work area.

Section 3 Documents

Article 133: Enterprises shall, in accordance with relevant laws, regulations and these specifications, formulate quality management documents that are consistent with the actual conditions of the enterprise. Documents include quality management systems, job responsibilities, operating procedures, files, records and vouchers, etc. Quality management documents are reviewed regularly and revised in a timely manner.

Article 134: Enterprises shall take measures to ensure that personnel in each position correctly understand the contents of quality management documents and ensure that quality management documents are effectively implemented.

Article 135 The pharmaceutical retail quality management system shall include the following contents:

(1) The management of drug procurement, acceptance, display, sales and other links. If a warehouse is set up, it should also include the management of storage and maintenance;

(2) Review of supplier units and purchased varieties;

(3) Management of prescription drug sales;

(4) Management of drug dismantling;

(5) Management of drugs under special management and drugs with special management requirements by the state;

(6) Management of records and vouchers;

(7) Management of collecting and querying quality information;

(8) Management of quality accidents and quality complaints;

(9) Management of review, deployment and verification of prescriptions for traditional Chinese medicine pieces;

(10) Management of drug validity period;

(11) Management of substandard drugs and drug destruction;

(12) Regulations on environmental sanitation and personnel health;

(13) Provide management of pharmaceutical services such as medication consultation and guidance on rational medication use;

(14) Regulations on personnel training and assessment;

(15) Regulations on reporting adverse drug reactions;

(16) Management of computer systems;

(17) Regulations on drug traceability;

(18) Other contents that should be stipulated.

Article 136: Enterprises should clarify the responsibilities of the person in charge, quality management, procurement, acceptance, sales staff, prescription review, deployment and other positions. If a warehouse is set up, it should also include storage, maintenance and other job responsibilities.

Article 137: The responsibilities of quality management positions and prescription review positions shall not be performed by personnel in other positions.

Article 138 Pharmaceutical retail operating procedures shall include:

(1) Drug procurement, acceptance, and sales;

(2) Prescription review, deployment and verification;

(3) Review, preparation and verification of prescriptions for traditional Chinese medicine pieces;

(4) Dismantling and selling of medicines;

(5) Sales of drugs under special management and drugs with special management requirements by the state;

(6) Display and inspection of drugs in business premises;

(7) Storage of refrigerated medicines in business premises;

(8) Operation and management of computer systems;

(9) The establishment of a warehouse should also include operating procedures for storage and maintenance.

Article 139: Enterprises shall establish records related to drug procurement, acceptance, sales, display inspection, temperature and humidity monitoring, and disposal of unqualified drugs to ensure that they are true, complete, accurate, effective, and traceable.

Article 140: Records and relevant vouchers shall be kept for at least 5 years. Records and vouchers for specially managed drugs are kept in accordance with relevant regulations.

Article 141: When recording data through a computer system, relevant personnel shall log in to the computer system through authorization and password in accordance with operating procedures to enter data to ensure that the data is original, authentic, accurate, safe and traceable.

Article 142: Electronic record data shall be backed up regularly in a safe and reliable manner.

Section 4 Facilities and Equipment

Article 143: The business premises of an enterprise shall be compatible with its pharmaceutical business scope and business scale, and shall be separated from pharmaceutical storage, office, living assistance and other areas.

Article 144 The business premises shall have corresponding facilities or take other effective measures to prevent drugs from being affected by the outdoor environment, and shall be spacious, bright, clean and sanitary.

Article 145 A business place shall have the following business equipment:

(1) Shelves and counters;

(2) Equipment for monitoring and regulating temperature;

(3) Those who deal in traditional Chinese medicine pieces must have equipment for storing the pieces and preparing prescriptions;

(4) Those who deal in refrigerated medicines must have special refrigeration equipment;

(5) Those who deal in Class II psychotropic drugs, toxic traditional Chinese medicines and poppy shells must have special storage equipment that meets safety regulations;

(6) Preparation tools and packaging supplies required for dismantling and selling medicines.

Article 146: Enterprises shall establish a computer system that can meet the requirements for operation and quality management, and meet the requirements for drug traceability.

Article 147: When an enterprise sets up a warehouse, it shall ensure that the interior walls and roof of the warehouse are smooth and clean, the floor is flat, the doors and windows are tightly constructed, and reliable safety protection, anti-theft and other measures are in place.

Article 148 A warehouse shall have the following facilities and equipment:

(1) Equipment for effective isolation between medicines and the ground;

(2) Light protection, ventilation, moisture-proof, insect-proof, rodent-proof and other equipment;

(3) Equipment to effectively monitor and regulate temperature and humidity;

(4) Lighting equipment that meets the requirements for storage operations;

(5) Special place for acceptance;

(6) Special storage place for unqualified drugs;

(7) Those who deal in refrigerated medicines must have special equipment suitable for their business varieties and business scale.

Article 149: Drugs under special management must have storage facilities that comply with national regulations.

Article 150 Special warehouses should be set up to store traditional Chinese medicine pieces.

Article 151: Enterprises shall regularly calibrate or verify measuring instruments, temperature and humidity monitoring equipment, etc. in accordance with relevant national regulations.

Section 5 Procurement and Acceptance

Article 152: Enterprises purchasing drugs shall comply with the relevant provisions of Section 8 of Chapter 2 of these specifications.

Article 153 When the medicine arrives, the receiving personnel shall verify the physical substance of the medicine according to the purchase record and the accompanying receipt (invoice) of the supplier, so that the invoice, account and goods are consistent.

Article 154: Enterprises shall inspect and accept the incoming drugs batch by batch in accordance with prescribed procedures and requirements, and make acceptance records in accordance with Article 80 of these specifications.

The samples taken for acceptance should be representative.

Article 155 When refrigerated medicines arrive, they shall be inspected in accordance with the provisions of Article 74 of these specifications.

Article 156: Drug inspection reports shall be inspected in accordance with the provisions of Article 76 of these specifications when accepting drugs.

Article 157: Drugs under special management shall be inspected and accepted in accordance with relevant regulations.

Article 158: Drugs that pass the acceptance inspection shall be put into the warehouse or put on the shelves in a timely manner. Those that fail the acceptance inspection shall not be put into the warehouse or put on the shelves and shall be reported to the quality management personnel for handling.

Section 6 Display and Storage

Article 159: Enterprises shall monitor and regulate the temperature of business premises so that the temperature of the business premises meets normal temperature requirements.

Article 160: Enterprises shall conduct regular health inspections to keep the environment clean and tidy. Equipment for storing and displaying medicines should be kept clean and sanitary, and items unrelated to sales activities should not be placed. Insect-proof, rodent-proof and other measures should be taken to prevent contamination of medicines.

Article 161 The display of medicines shall meet the following requirements:

(1) Classify and display the dosage forms, uses and storage requirements, and set up eye-catching signs. The category labels are clearly written and placed accurately.

(2) Medicines should be placed on shelves (cabinets) in a neat and orderly manner and protected from direct sunlight.

(3) Prescription drugs and over-the-counter drugs are displayed in separate areas, and there are special signs for prescription drugs and over-the-counter drugs.

(4) Prescription drugs shall not be displayed or sold in an open-shelf manner.

(5) External medicines should be placed separately from other medicines.

(6) Drugs that are sold in parts are stored centrally in special counters or special areas for parts dismantling.

(7) Category II psychotropic drugs, toxic traditional Chinese medicine varieties and poppy shells shall not be displayed.

(8) Refrigerated medicines are placed in refrigeration equipment, the temperature is monitored and recorded according to regulations, and the storage temperature is ensured to meet the requirements.

(9) The names of the Chinese medicine pieces in the cabinet should be written correctly; they should be reviewed before loading into buckets to prevent mishandling and mixing; the buckets should be cleaned regularly to prevent the pieces from becoming wormy, moldy, and deteriorating; different batches of pieces should be cleaned before being packed into buckets. Fight and record.

(10) A special area should be set up for the operation of non-pharmaceuticals, which should be clearly separated from the pharmaceutical area and have eye-catching signs.

Article 162: Enterprises shall regularly inspect displayed and stored drugs, focusing on inspecting dismantled drugs, drugs that are perishable, have a near-validity period, and have been stored for a long time, as well as traditional Chinese medicine pieces. Drugs with quality doubts should be removed from the cabinets in a timely manner, stopped selling, and should be confirmed and processed by quality management personnel, and relevant records should be retained.

Article 163: Enterprises shall track and manage the validity period of drugs to prevent possible expired use of drugs with near-validity dates after they are sold.

Article 164: If an enterprise sets up a warehouse, the storage and maintenance management of drugs in the warehouse shall comply with the relevant provisions of Section 10 of Chapter 2 of these specifications.

Section 7 Sales Management

Article 165: Enterprises shall hang the "Pharmaceutical Business License", business license, practicing pharmacist registration certificate, etc. in a conspicuous place in the business premises.

Article 166: Business personnel shall wear work badges with photos, names, positions, etc., and if they are licensed pharmacists or pharmaceutical technicians, the work badges shall also indicate their professional qualifications or pharmaceutical professional and technical titles. Licensed pharmacists practicing on-the-job must clearly indicate their status.

Article 167 The sale of drugs shall meet the following requirements:

(1) Prescriptions can only be dispensed after being reviewed by a licensed pharmacist; the drugs listed in the prescription may not be changed or substituted without authorization. Prescriptions with incompatible or excessive dosages shall be refused to be dispensed. However, they may be dispensed if corrected or re-signed by the prescribing physician for confirmation. ; Only after the prescription is prepared and verified can it be sold.

(2) Prescription review, deployment, and verification personnel should sign or seal the prescription, and keep the prescription or its copy in accordance with relevant regulations.

(3) When selling drugs with a near-validity date, customers must be notified of the expiry date.

(4) When selling traditional Chinese medicine pieces, the measurements should be accurate, and the decoction method and precautions should be informed; providing the service of decoction of traditional Chinese medicine pieces should comply with relevant national regulations.

Article 168: Enterprises selling drugs shall issue sales vouchers, including the name of the drug, manufacturer, quantity, price, batch number, specifications, etc., and keep sales records.

Article 169: Dismantling and selling of drugs shall meet the following requirements:

(1) Personnel responsible for dismantling and selling have received special training;

(2) Keep the disassembled workbench and tools clean and hygienic to prevent cross-contamination;

(3) Keep records of dismantling and sales, including the start date of dismantling, generic name of the drug, specifications, batch number, manufacturer, validity period, sales quantity, sales date, dismantling and review personnel, etc.;

(4) Clean and hygienic packaging should be used for retail sales, with the name, specifications, quantity, usage, dosage, batch number, expiration date, pharmacy name, etc. of the drug indicated on the packaging;

(5) Provide the original or copy of the drug instructions;

(6) During the period of dismantling and selling, keep the original packaging and instructions.

Article 170: Relevant national regulations must be strictly implemented when selling drugs under special management and drugs with special management requirements by the state.

Article 171: Pharmaceutical advertisements shall strictly comply with national regulations on advertising management.

Article 172 Non-employees of the enterprise shall not engage in activities related to drug sales in the business premises.

Section 8 After-sales Management

Article 173: Except for drug quality reasons, once a drug is sold, it cannot be returned or exchanged.

Article 174: Enterprises shall publish the supervision telephone number of the food and drug supervision and administration department at the business premises, set up a customer opinion book, and handle customer complaints about drug quality in a timely manner.

Article 175: Enterprises shall collect and report adverse drug reaction information in accordance with national regulations on adverse drug reaction reporting systems.

Article 176: When an enterprise discovers that a sold drug has serious quality problems, it shall take timely measures to recover the drug, keep records, and report to the food and drug supervision and administration department.

Article 177: Enterprises shall assist pharmaceutical manufacturers in fulfilling recall obligations, control and recall drugs with potential safety hazards, and establish drug recall records.

Chapter 4 Supplementary Provisions

Article 178 The meanings of the following terms in this specification are:

(1) In-service: Registered personnel who have established a labor relationship with the enterprise.

(2) On-duty: Personnel in relevant positions perform their duties at specified positions during working hours.

(3) First operating enterprise: the pharmaceutical manufacturing or operating enterprise that has a supply and demand relationship with the enterprise for the first time when purchasing drugs.

(4) First-time products: drugs purchased by the enterprise for the first time.

(5) Original seal: The original seal of the enterprise, the special seal for invoices, the special seal for quality management, and the special seal for drug delivery that are stamped on relevant documents or vouchers to prove the identity of the enterprise during purchase and sale activities cannot be printed, Imprints of copies, photocopies, etc.

(6) Pending inspection: Use effective methods to isolate or distinguish drugs that have arrived or been returned after sales, and are waiting for quality inspection before entering the warehouse.

(7) Spare goods: Medicines used for transportation and storage packaging have been removed.

(8) LCL delivery: A method of consolidating retail medicines into the same packaging box for delivery.

(9) Dismantling and selling: the method of splitting and selling the smallest package.

(10) Drugs with special management requirements by the state: drugs for which the state implements special regulatory measures for anabolic preparations, peptide hormones, compound preparations containing special drugs, etc.

Article 179: The management of the headquarters of pharmaceutical retail chain enterprises shall comply with the relevant provisions of this specification for pharmaceutical wholesale enterprises, and the management of stores shall comply with the relevant regulations of this specification for pharmaceutical retail enterprises.

Article 180 : This specification is the basic requirement for quality management of pharmaceutical operations. Specific requirements for enterprise information management, automatic monitoring of temperature and humidity in drug storage and transportation, drug acceptance management, drug cold chain logistics management, retail chain management, etc. will be separately formulated by the State Food and Drug Administration in the form of an appendix.

Article 181 The traceability of narcotic drugs, psychotropic drugs, and pharmaceutical precursor chemicals shall comply with relevant national regulations.

Article 182: The quality management specifications for drug procurement, storage, and maintenance in pharmacies of medical institutions and family planning technical service institutions shall

be separately formulated by the State Food and Drug Administration in consultation with relevant competent authorities.

The quality management regulations for drugs sold on the Internet will be formulated separately by the State Food and Drug Administration.

Article 183 If a pharmaceutical trading enterprise violates these regulations, the food and drug regulatory department shall impose penalties in accordance with the provisions of Article 78 of the Drug Administration Law of the People's Republic of China.

Article 184 This specification shall come into effect on the date of promulgation, and the "Good Manufacturing Practice for Pharmaceutical Distribution" (Order No. 90 of the Ministry of Health of the People's Republic of China) implemented by the Ministry of Health on June 1, 2013 shall be abolished at the same time.