Notice of the Shanghai Municipal Medical Products Administration on Issuing the "Guiding Opinions on Modern Drug Logistics in Shanghai"[1]

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Guiding Opinions on Modern Pharmaceutical Logistics in Shanghai

Chapter I: General Provisions

Article 1- Purpose and Basis

In order to accelerate the development of modern pharmaceutical logistics in Shanghai, optimize resource allocation, promote the scale and standardization of pharmaceutical business enterprises, establish an efficient and professional modern pharmaceutical logistics system, and ensure drug supply security and quality throughout the circulation process, these Opinions are formulated in accordance with the Drug Administration Law of the People's Republic of China, the Vaccine Administration Law of the People's Republic of China, the Regulations on the Administration of Drugs and Medical Devices in Shanghai, the Measures for the Supervision and Administration of Drug Operation and Use Quality, the Good Supply Practice (GSP) for Pharmaceutical Products, and other relevant laws and regulations, taking into account the actual situation in Shanghai.

Article 2- Scope of Application

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

These Opinions apply to newly established pharmaceutical wholesale enterprises in Shanghai and to pharmaceutical wholesale enterprises engaged in entrusted storage and transportation of drugs.

Existing pharmaceutical wholesale enterprises in Shanghai shall gradually upgrade their modern pharmaceutical logistics capabilities. For those undertaking entrusted storage and transportation, the entrusted wholesale enterprises shall comply with the requirements set forth herein regarding entrusted storage and transportation of drugs.

Article 3- Encouragement of Modern Pharmaceutical Logistics Development

Pharmaceutical wholesale enterprises are encouraged to equip themselves with facilities and equipment suitable for drug storage and for performing drug receipt, inspection, conveyance, shelving, sorting, and outbound operations, as well as independent computerized logistics management systems. Such systems should cover the entire business management process, including procurement, storage, transportation, and sales, to ensure quality control and information traceability at all stages. By reducing pharmaceutical logistics operating costs and improving service capacity and quality, enterprises are expected to achieve logistics management and operations that are scaled, centralized, standardized, informatized, and intelligent.

Article 4- Responsibility for Drug Traceability

Pharmaceutical wholesale enterprises and those engaged in entrusted storage and transportation of drugs shall establish and implement a drug traceability system in accordance with the unified drug traceability standards and norms formulated by the National Medical Products Administration (NMPA). They shall cooperate with marketing authorization holders in fulfilling primary responsibility for drug traceability, ensuring that the source, distribution, and accountability of drugs under their management are fully traceable.

Chapter II: Organizations and Personnel

Article 5- General Requirements for Organizations and Personnel

Newly established pharmaceutical wholesale enterprises (hereinafter referred to as the "enterprise") shall establish a complete management system in compliance with the Good Supply Practice (GSP) for Pharmaceutical Products. The enterprise shall set up organizational

units or assign personnel appropriate to its business, including quality management, receipt and maintenance, logistics management, and information management. The person in charge of quality shall fully exercise quality management functions and possess decision-making authority over drug quality within the enterprise, ensuring that the entire drug operation process continuously complies with statutory requirements.

Article 6- Employment Requirements for Key Management Personnel

The legal representative and principal executives of the enterprise shall bear full responsibility for the enterprise's pharmaceutical operations. The legal representative, principal executives, and personnel engaged in drug operation and quality management shall meet the qualification requirements specified in the Good Supply Practice (GSP) for Pharmaceutical Products and shall not have circumstances that are prohibited from engaging in drug production or operation activities under the Drug Administration Law of the People's Republic of China or the Vaccine Administration Law of the People's Republic of China.

Article 7- Personnel Requirements

The enterprise's legal representative, principal executives, person in charge of drug quality, head of the quality department, and other personnel engaged in pharmaceutical management shall comply with the Good Supply Practice (GSP) for Pharmaceutical Products and the following requirements:

1-The principal executives shall possess at least a college degree or an intermediate or higher professional technical title, have received basic pharmaceutical knowledge training, and be familiar with relevant drug management laws, regulations, and these Opinions.

2-The person in charge of drug quality shall hold at least a bachelor's degree, possess a licensed pharmacist qualification, have no less than three years of experience in pharmaceutical quality management, and demonstrate the ability to make correct judgments and ensure implementation in quality management work.

3-The head of the quality department shall possess a licensed pharmacist qualification, have no less than three years of experience in pharmaceutical quality management, and be able to independently resolve quality issues arising during operations.

4-The enterprise shall provide pre-employment and continuing training to personnel for each position in accordance with their responsibilities and job content, ensuring familiarity with the Drug Administration Law, its Implementing Regulations, and other applicable laws and

regulations, mastery of pharmaceutical knowledge, and proficiency in relevant professional skills.

5-The enterprise shall organize pre-employment and annual health examinations for personnel in positions directly handling drugs, including quality management, receipt, maintenance, and storage, and shall establish and maintain health records.

Chapter III: Facilities and Equipment

Article 8- General Requirements for Facilities and Equipment

Enterprises shall possess business premises, warehouses, facilities, equipment, and transport vehicles that comply with the Good Supply Practice (GSP) for Pharmaceutical Products and are commensurate with the scope of operations and the scale of pharmaceutical logistics. Enterprises shall conduct validation and calibration as required and shall have the storage and distribution capabilities necessary to carry out modern pharmaceutical logistics operations.

Article 9- Functional Areas of Warehouses

Enterprise warehouses shall meet the needs of logistics scale and operational workflows, and shall be divided into functional areas in accordance with pharmaceutical quality management and logistics operation requirements. Specific requirements are as follows:

1-Enterprises shall have storage areas suitable for full-case and partial-case goods according to the scale of pharmaceutical logistics. The total warehouse building area shall be no less than 10,000 square meters or the total volume no less than 50,000 cubic meters, of which the automated warehouse volume shall be no less than 25,000 cubic meters. For enterprises specializing in biological products, the total warehouse building area shall be no less than 3,000 square meters or the volume no less than 10,000 cubic meters. For enterprises specializing in pharmaceutical in vitro diagnostic reagents, the warehouse building area shall be no less than 60 square meters.

2-Warehouses shall be divided according to drug storage requirements into ambient-temperature warehouses, cool warehouses, cold warehouses, and other warehouses with special temperature requirements. Enterprises conducting cold-chain drug logistics shall be equipped with at least two independent cold storage units, with a total volume of no less than 500 cubic meters. For enterprises specializing in biological products, the total cold storage volume shall be no less than 1,000 cubic meters. For enterprises specializing in pharmaceutical in vitro diagnostic reagents conducting cold-chain operations, the cold storage volume shall be no less than 20 cubic meters.

3-Enterprises shall have a computer-controlled room or area capable of remotely monitoring warehouse temperature and humidity, warehouse video surveillance, refrigerated vehicle temperature, and abnormal condition alarms.

Article 10- Warehouse Facilities and Equipment

Enterprises shall be equipped with facilities and equipment that meet the operational requirements of modern logistics, including receipt, inspection, conveyance, shelving, sorting, outbound, verification, and consolidation, ensuring smooth and continuous pharmaceutical logistics operations while preventing confusion and errors. Specific requirements include:

1-Inbound Management Equipment

Under the coordination of the warehouse management system, enterprises shall use suitable equipment to achieve automatic location allocation, identification, addressing, and handling functions based on factors such as area, storage method, and distance.

2-Storage Equipment

Enterprises may selectively use pallets, racks, and automated warehouses. Goods shall be effectively isolated from the floor, walls, and between storage locations. Barcodes shall be used for location management, one code per location, with centralized control, management, and scheduling through the warehouse management system.

3-In-Warehouse Conveyance Equipment

Facilities and equipment appropriate to the logistics scale shall cover storage areas, picking areas, outbound verification areas, and consolidation/distribution areas, ensuring precise and continuous logistics operations and preventing confusion or errors.

4-Information Identification and Management Equipment

Equipment such as barcode printers/scanners, RFID technology, and electronic label-assisted picking systems shall be adopted.

5-Temperature and Humidity Control Equipment

Enterprises shall be equipped with central air-conditioning systems or other equipment capable of controlling warehouse temperature and humidity and enabling air exchange between the interior and exterior of the warehouse, meeting relevant environmental standards.

Article 11- Transport Vehicles

Enterprises shall select closed pharmaceutical transport vehicles that are compatible with drug storage conditions and the scale of distribution. Enterprises distributing cold-chain drugs shall be equipped with their own refrigerated vehicles and shall comply with the following requirements:

1-The enterprise-owned refrigerated vehicles and on-board refrigeration equipment (refrigerated boxes, insulated boxes, etc.) shall be commensurate with the quality management requirements and scale of the distributed drugs.

2-The technical performance of refrigerated vehicles and on-board refrigeration equipment shall comply with the requirements of the Good Supply Practice (GSP) for Pharmaceutical Products.

3-Refrigerated vehicles shall be equipped with independent cooling (or heating) power, connected to a satellite positioning system, and installed with automatic on-board temperature and humidity monitoring devices as well as a remote data transmission system, enabling real-time monitoring of the vehicle's transport status.

Chapter IV: Information Management Systems

Article 12- General Requirements for Information Management

Enterprises shall possess an independent information management system. The system's database software, network and application security management software, operating system software, and other components shall be commensurate with the scale of pharmaceutical logistics, comply with the relevant requirements of the Good Supply Practice (GSP) for Pharmaceutical Products, and meet the operational needs of modern pharmaceutical logistics, drug quality management, and information security.

Article 13- Specific Requirements for Information Management Systems

The enterprise information management system shall include, but not be limited to, an enterprise resource planning (ERP) system, warehouse management system (WMS), equipment control system, transport management system, automatic temperature and humidity monitoring system, and drug traceability system. Enterprises shall use information technology to ensure real-time data interfacing, interaction, and traceability among these systems. Specific requirements are as follows:

1-The ERP system shall cover the entire process of pharmaceutical operations and logistics quality management.

2-The WMS shall interface in real time and accurately with the ERP system, equipment control system, transport management system, and other relevant systems to achieve quality

management and control of all warehouse and logistics processes, including drug receipt, storage, maintenance, inventory, outbound, returns, and transportation. The WMS shall also provide comprehensive goods inquiry and tracking functions.

3-The equipment control system shall enable automated and continuous logistics conveyance for all warehouse operations, with all facilities and equipment interfacing in real time with the WMS.

4-The transport management system shall enable tracking, recording, and scheduling of the entire drug transportation process.

5-The automatic temperature and humidity monitoring system shall perform real-time monitoring and recording of warehouse temperature and humidity, as well as temperatures during refrigerated and frozen drug transport.

6-The drug traceability system shall ensure traceability and verifiability of all levels of drug packaging units.

7-Data entry, collection, exchange, modification, and storage across all information management systems shall be true, accurate, complete, secure, and traceable.

Article 14- Computer Hardware and Network Conditions

Enterprises shall be equipped with computer hardware systems and network environments appropriate to the scale of pharmaceutical logistics and shall comply with the following requirements:

1-Enterprise computer information systems shall have the capacity for continuous operation and data integrity, effectively preventing service interruptions or data loss caused by a single server failure, and ensuring uninterrupted service provision.

2-Computer management systems shall have fixed internet access and a reliable information security platform. The enterprise's network bandwidth shall be commensurate with its business scale.

3-Data shall be backed up daily and stored securely and reliably (e.g., remote servers, multi-machine hot backup, or cloud storage) to ensure traceable management. Data records shall be maintained for at least five years and no less than one year after the expiration of the drug's shelf life.

Chapter V: Systems and Management

Article 15- Management System

Enterprises shall establish management system documents that comply with business management requirements and ensure the quality of pharmaceuticals. Such documents shall include the systems stipulated in the Good Supply Practice for Pharmaceutical Products, as well as management systems covering job responsibilities related to pharmaceutical quality for logistics and information departments or personnel, pharmaceutical logistics and distribution management, and standard operating procedures and maintenance management for facilities and equipment.

Article 16- Quality Management Records

Enterprises shall establish pharmaceutical quality management records in accordance with regulatory requirements. These records shall cover receipt and inspection of pharmaceuticals, return of pharmaceuticals, warehouse temperature and humidity monitoring, pharmaceutical maintenance inspections, verification prior to dispatch, transportation of pharmaceuticals, acceptance of returned pharmaceuticals from sales, control and destruction of nonconforming pharmaceuticals, and handling of pharmaceuticals with potential quality or safety risks. Quality management records shall be retained for no less than five years, and no less than one year after the expiration of the pharmaceuticals' shelf life.

Article 17- Destruction of Pharmaceuticals

Destruction of pharmaceuticals shall comply with applicable laws and regulations. Enterprises may supervise the destruction themselves or conduct it under the supervision of regulatory authorities. Destruction methods shall adopt environmentally harmless procedures, and all processes and steps of destruction shall be fully documented.

Chapter VI: Requirements for Contracted Storage and Transportation of Pharmaceuticals

Article 18- General Requirements for Contracted Storage and Transportation

Pharmaceutical wholesale enterprises that undertake contracted storage and transportation of pharmaceuticals shall conduct storage and transportation activities in accordance with the Good Supply Practice for Pharmaceutical Products, cooperate with the consignor in conducting quality assessments, perform obligations in accordance with the entrustment agreement, and assume corresponding legal and contractual liabilities. In addition to complying with the provisions set out in the preceding chapters of this Opinion, enterprises engaged in contracted storage and transportation of pharmaceuticals shall also comply with the requirements of Chapter 6 of this Opinion.

Article 19- Storage Facilities

Pharmaceutical wholesale enterprises engaged in contracted storage and transportation of pharmaceuticals shall have storage facilities with a total area of no less than 15,000 square meters or a total volume of no less than 75,000 cubic meters.

Article 20- Transportation Vehicles

Pharmaceutical wholesale enterprises undertaking contracted storage and transportation of pharmaceuticals shall be equipped with an adequate number of enclosed, self-owned transportation vehicles appropriate to the scale of pharmaceutical distribution, and in any case no fewer than eight vehicles. Enterprises engaged in cold-chain pharmaceutical logistics shall additionally be equipped with no fewer than three refrigerated vehicles that meet the requirements set out in Article 11.

Article 21- Information Exchange for Contracted Storage and Transportation

Pharmaceutical wholesale enterprises engaged in contracted storage and transportation shall be equipped with an electronic data exchange platform to support information exchange related to logistics operations and the contracted storage and distribution activities. The platform shall be capable of processing consignor instructions relating to receipt, acceptance, warehousing, storage, maintenance, dispatch, transportation, and returns of pharmaceuticals, ensuring quality management and control throughout the entire contracted storage process. It shall also provide full-process cargo inquiry and traceability functions to ensure effective traceability of pharmaceutical information.

Pharmaceutical wholesale enterprises engaged in contracted storage and transportation shall conduct functional testing, confirmation, and validation of the information exchange platform when undertaking new contracted services, during annual quality internal audits, and whenever significant functional changes to the platform occur, to ensure that the platform continuously facilitates effective communication and information exchange between the consignor and the consignee.

Article 22- Quality Management Systems and Records

Pharmaceutical wholesale enterprises engaged in contracted storage and transportation shall establish management systems for contracted pharmaceutical storage and distribution, systems governing the exchange of instructions and information with the consignor, and systems for the consignor's audits. Quality management records shall include, among others, the consignor's receiving instructions and shipping instruction records.

Article 23- Entrustment Agreement

Pharmaceutical wholesale enterprises engaged in contracted storage and transportation shall enter into an entrustment agreement with the consignor. The agreement shall specify the scope of the entrusted activities, requirements for records and data management, invoice and document management, quality responsibilities and liabilities for breach, reporting of significant issues, assessment requirements, and other relevant matters.

Chapter VII: Multi-Warehouse Coordination

Article 24- General Requirements for Multi-Warehouse Collaboration]

Several wholesale enterprises that share a unified quality management system may, in accordance with relevant regulations, designate a leading entity and utilise information technology to share personnel, information, warehousing, transportation and other resources with other wholesale enterprises (hereinafter referred to as "collaborating parties"). These enterprises may conduct cross-regional pharmaceutical logistics activities through multi-warehouse collaboration.

Article 25- Entrusted Storage and Transportation under Multi-Warehouse Collaboration

Marketing authorisation holders and pharmaceutical trading enterprises that entrust the storage and transportation of pharmaceuticals may make use of the multi-warehouse collaborative logistics resources of the entrusted party (the leading entity) to achieve cross-regional storage of pharmaceuticals.

Article 26- Requirements for the Multi-Warehouse Collaboration System

The leading entity and the collaborating parties shall establish and implement unified quality management system documents for multi-warehouse collaboration activities, applying uniform risk control mechanisms and audit standards.

Article 27- Requirements for Computerised Systems in Multi-Warehouse Collaboration

The leading entity and the collaborating parties shall, through information-based tools, achieve standardised management of logistics operations and complete real-time interfacing, exchange and storage of data relating to pharmaceutical distribution operations, logistics information and quality management information, ensuring that multi-warehouse collaborative logistics activities meet the requirements of Good Supply Practice for pharmaceutical operations.

Article 28- Quality Agreement for Multi-Warehouse Collaboration

The leading entity shall enter into a quality agreement with the collaborating parties, specifying the division of quality responsibilities for multi-warehouse collaboration, operational requirements, mechanisms for handling quality issues and emergency response arrangements.

Chapter VIII: Integrated Wholesale and Retail Pharmaceutical Operations

Article 29- General Requirements

The municipality supports pharmaceutical business enterprises under the same legal entity in integrating internal resources to conduct unified wholesale and retail chain operations (hereinafter referred to as "integrated wholesale-retail operations"). Enterprises conducting integrated wholesale-retail operations shall possess modern pharmaceutical logistics warehouses that meet the requirements of this document and concurrently satisfy the requirements applicable to pharmaceutical retail chain headquarters.

Article 30- System Requirements

Enterprises engaged in integrated wholesale-retail operations shall separately establish quality management systems that meet the requirements for pharmaceutical wholesale activities and retail chain operations. The quality management systems and related documentation shall effectively cover the quality management requirements for both wholesale activities and retail chain headquarters, implement effective measures to prevent product mix-ups or errors, and ensure that pharmaceutical quality and safety remain controllable.

Article 31- Organizational and Personnel Requirements

Enterprises conducting integrated wholesale-retail operations shall establish organizational structures or personnel arrangements appropriate to their business activities and quality management needs. Pharmaceuticals shall be procured centrally by the department responsible for wholesale operations. A single quality director may assume overall responsibility for pharmaceutical quality management, while the heads of the wholesale and retail chain quality management departments shall respectively carry out quality management responsibilities for their respective segments.

Article 32- Computerized System Requirements

Enterprises conducting integrated wholesale-retail operations shall use a unified computerized system appropriate to their business scope and shall, based on the principle that wholesale

and retail chain operational processes must be identifiable and distinguishable, achieve synchronized sharing of pharmaceutical quality master data and integrated management of pharmaceutical quality information.

Chapter IX: Supplementary Provisions

Article 33- Definitions

An automated warehouse refers to a system that uses automated and intelligent mechanical facilities (such as high-bay shelving, aisle stackers, unloading robots, automated sorting systems, intelligent single-item picking manipulators, and automated conveying systems for inbound and outbound operations, as well as related equipment) together with computerized management and control systems to achieve automated storage and retrieval of materials. Integrated pharmaceutical wholesale and retail chain operations refer to activities in which a single legal entity has obtained the pharmaceutical business licenses for both wholesale operations and retail chain headquarters and conducts such activities in accordance with the law.

Article 34- Storage and Transportation of Vaccines and Special Pharmaceuticals

The storage, transportation and data recording requirements for vaccines and pharmaceuticals subject to special control shall be implemented in accordance with relevant national regulations.

Article 35- Implementation Period

These provisions shall enter into force on 7 November 2025 and remain effective for five years until 6 November 2030. The former “Shanghai Guidance on Modern Pharmaceutical Logistics”) shall be repealed simultaneously.